BEYOND EUROPEAN PRODUCT LIABILITY:
ITS MIXED NATURE AND PERFORMANCE

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BEYOND EUROPEAN PRODUCT LIABILITY: ITS MIXED NATURE AND PERFORMANCE

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This thesis takes a global approach to analyzing, discussing and critiquing the effectiveness of product liability law in Europe. The thesis approaches the study of European product liability law beyond the main product liability instruments themselves. It first offers a purely legal analysis, based on the content, effects and judicial interpretation of the European product liability directive and on the procedural context in which it is framed. Second, it analyzes the directive's effects on accident deterrence, examining the interaction between Europe's ex post liability laws and ex ante safety regulations from theoretical as well as practical perspectives. Third, the thesis analyzes the effectiveness of ex post liability as a mechanism for compensating the victims of product-related accidents in Europe. This last issue of victim compensation reaches beyond tort law to include alternative sources of compensation, such as public and private insurance. Social insurance systems, in particular, arise as the major mechanism of compensation in Europe, and for this reason the compensation of product-related accident victims proves to be one of the issues that differentiates the role, development and effectiveness of product liability law in Europe from the U.S. experience.

Using the European product liability directive as the starting point and focus of analysis, this thesis contributes to the literature by shifting the analysis from the product liability directive itself to the more general question of product regulation in Europe.

BIOGRAPHICAL SKETCH

Mireia Artigot i Golobardes was born in Barcelona, Spain. She holds a B.A. in Economics and Business Administration (1997) and a J.D. (2001) from Universitat Pompeu Fabra in Barcelona, an LL.M. from Cornell Law School (2002) and a B.A. in Music, specialized in piano performance (2000) from the Superior Conservatory of Music in Barcelona. In 2006 she joined the Law School and the Economics Department of Universitat Pompeu Fabra as an associate professor. She has been admitted to practice law in New York since 2009.

Al meu pare i a la meva mare,

pel vostre exemple, amor incondicional i tendresa infinita

i per a tu, John, for making our life a wide, big, warm smile

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TABLE OF CONTENTS

INTRODUCTION 1

CHAPTER 1 11
EUROPEAN PRODUCT REGULATION: AN OVERVIEW 11

1.Historical developments of the European Union 11
2.Brief overview of European Union institutions 13
3.The European Community legislative instruments 15
4.The development of product regulation within the consumer protection goal of the European Union 19

CHAPTER 2 27
EUROPEAN PRODUCTS LIABILITY: 27
A LEGAL ANALYSIS OF DIRECTIVE 85/374 27

1 Introduction 27
2 Following Section 402a of the Restatement (Second)? The Directive's Strict Liability Regime 55
3 Products Covered by the Directive 62
4 Producers and other Actors Subject to the Strict Liability Regime 66
5 Plaintiffs Protected by the Directive 78
6 The Concept of Defect 95
7 Defenses 123

CHAPTER 3 146
PROCEDURAL RULES AS BARRIERS TO BRING 146
PRODUCT LIABILITY CLAIMS IN EUROPE 146

CHAPTER 4 166
ECHOES OF NEGLIGENCE IN EUROPEAN PRODUCTS LIABILITY 166

1.The legal costs of defining a legal regime: Negligence elements in the product liability directive 167
2 Strict product liability or a negligence regime with a reversal of the burden of proof? 177
3 Are the negligence-based elements of the product liability directive distortive enough of the liability regime? 181

CHAPTER 5 184
EX ANTE PRODUCT REGULATION: EUROPEAN PRODUCT SAFETY LAW 184

1.Structure of product safety law in Europe 184
2.The standardization process 187
3 New Approach Directives 195
4 Standard-Receptive Directives (General Product Safety Directive) 212
5 Challenges Presented by the GPSD 250

CHAPTER 6 258
INTERACTION BETWEEN SAFETY AND LIABILITY RULES: THE JOINT USE OF EX ANTE AND EX POST PRODUCT REGULATION 258

1 The functioning of ex ante regulation and ex post liability as risk-minimizing mechanisms 263
2. The joint use of ex ante regulation and ex post liability: from substitutes to complements 276
3 Toward a comprehensive approach to European product regulation: The interaction between ex ante safety regulation and ex post liability 299
4 Ex ante and ex post liability: finding the adequate role for each mechanism 312
5 Working together: a proposal for enhancing the joint performance of European product safety and product liability 317

CHAPTER 7 327
COMPENSATION OF PRODUCT-RELATED ACCIDENT VICTIMS IN EUROPE: SOURCES, INTERACTION AND EFFECTS 327

1 Tort law -- product liability -- as a victim's compensation system 330
2 Private insurance as an instrument to compensate injured victims 336
3 Mixing tort law and insurance: Finding the adequate role for each instrument 345
4 Product liability insurance coverage in Europe: the importance of the phenomenon 351
5 Public insurance in Europe: a safety net 358
6 Tort law and social insurance: finding the adequate role of each instrument 367
7 The interaction between social insurance compensation and product liability claims in Europe: Visible and invisible effects 374
8 The difficult balance between ex ante incentives, compensation and low administrative costs of the different coordination systems 393
9 The variability of the coordination systems implemented in the different European member states 398

10 .....The collision of alternative compensation systems in Europe: reaching an equilibrium between product liability and struggling social insurance systems 404

CHAPTER 8 433
CONCLUSIONS 433

REFERENCES 440

LIST OF FIGURES

Chapter 5 - Ex Ante Product Regulation: European Product Safety Law

Figure 5.1 - The European Standardization Process

Figure 5.2 - Number of RAPEX Notifications Circulated 2001-2009

Figure 5.3 - RAPEX Notifications and Notifications by Spain

Figure 5.4 - Measures Adopted by Number of Notifications 2006-2009

Chapter 6 - Interaction between Safety and Liability Rules: The Joint Use of Ex Ante and Ex Post Product Regulation

Figure 6.1 - Total number of RAPEX notifications circulated 2001-2009

Figure 6.2 - Product liability judgments in Spain

Figure 6.3 - Scope of Application of Pre-Market and Post-Market Controls

Figure 6.4 - Interaction between European Product Safety and Product Liability Regulations

LIST OF TABLES

Chapter 1 - European Product Regulation: An Overview

Table 1.1 - The European Commission's Jurisdiction on Product Regulation: From Ensuring a Proper Functioning of the Internal Market to Achieving a High Level of Consumer Protection

Chapter 2 - European Products Liability: A Legal Analysis of Directive 85/374

Table 2.1 - Transposition Laws of the European Member States

Table 2.2 - Optional Provisions

Table 2.3 - Optional Provisions in the EFTA States

Chapter 5 - Ex Ante Product Regulation: European Product Safety Law

Table 5.1 - General Structure of European Product Safety Regulation

Table 5.2 - Categories of Product Notified Under RAPEX

Table 5.3 - Nature of the Danger under Article 12 of the GPSD

Table 5.4 - Total Number of RAPEX Notifications Circulated 2001-2009

Table 5.5 - Total RAPEX Notifications and Notifications by Spain 2001-2009

Table 5.6 - Type of Measure by Number of Notifications 2006-2009

Chapter 6 - Interaction between Safety and Liability Rules: The Joint Use of Ex Ante and Ex Post Product Regulation

Table 6.1 - Product Liability Judgments In Spain Over Time

Chapter 7 - Compensation of Product-Related Accident Victims in Europe: Sources, Interaction and Effects.

Table 7.1 - Performance of the Coordination Systems of Alternative Compensation Schemes with respect to three dimensions

Table 7.2 - European Social Insurance Systems

INTRODUCTION

This dissertation is a journey through European product liability law. Starting with the European law and the U.S. sources on which it has drawn, it analyzes and discusses the historical, legal, and economic contexts that have conditioned the effects and performance of product liability in Europe. The dissertation then examines the interaction of ex post product liability laws with ex ante product safety laws and with alternative mechanisms for compensating victims of product-related accidents, and it uses this global perspective to suggest ways in which the effectiveness and performance of European product liability law could be improved.

In 1985 European authorities adopted a product liability directive[1] with the goal of harmonizing product liability law in Europe. Following the product liability regime in force at the time in the United States, the product liability directive introduced for the first time in Europe a strict liability regime for products.[2] Despite the remarkable formal similarities between the product liability directive and U.S. product liability law in force at the time,[3] the development, effects, and impact of the European and U.S. regimes have been significantly different from the perspective of accident deterrence and victim's compensation.[4] Compared to the experience of the United States, the strict liability rule for products has had much less of an impact in Europe.[5] While data on European product

[1] Council Directive 85/374/EEC of 25 July 1985 On The Approximation of The Laws, Regulations and Administrative Provisions Of The Member States Concerning Liability for Defective Products O. J. L 210, 07/08/1985 P. 0029 – 0033.

[2] Alfred E. Mottur, The European Product Liability Directive: A Comparison With U.S. Law, An Analysis Of Its Impact On Trade, And A Recommendation For Reform So As To Accomplish Harmonization And Consumer Protection, 25 Law & Pol'y Int'l Bus. 983, 1004 (1994) noting that the introduction of strict product liability in Europe and in the United States was the result of a similar evolution. See also Jane Stapleton, Bugs in Anglo-American products liability, 53 S. C. L. Rev. 1225, 1230 (2002) noting that the adoption of the product liability directive was the result of social and political considerations.

[3] During the 1990s, U.S. product liability moved from strict liability to negligence-based liability. This evolution culminated with the 1998 the Restatement (Third) of Torts: Products Liability, § 2.

[4] Andrew C. Spacone, Strict Liability in the European Union - Not a United States Analog, 5 Roger Williams U. L. Rev. 341, 346 (2000).

[5] See Joan T. Schmit, Factors Likely to Influence Tort Litigation in the European Union, The Geneva Papers 31, 304–313, 305 (2006): Silva, F. & Cavaliere, Alberto, The Economic Impact of Product Liability:

litigation is limited,[6] over twenty years after the adoption of the product liability directive, it appears that Europe has not experienced the type of significant increase in product liability cases and judgments that the United States experienced[7] and that damage awards remain significantly lower in Europe than in the United States.[8] Moreover, litigation seems to continue to play different roles in U.S. and European society, and fears that the product liability directive would import a "litigation culture"[9] into Europe do not appear to have been borne out.[10]

Lessons from the US and the EU Experience, in G. Galli and J. Pelkmans (Eds.), REGULATORY REFORM AND COMPETITIVENESS IN EUROPE, Cheltenham, UK: Edward Elgar, 299-305 (2000) discussing the often-called 'product laibility crisis' in the U.S. during the 80s. See also Mark A. Geistfeld, Products liability, New York University School Of Law, Law & Economics Research Paper Series Working Paper NO. 09-19 (2009).

[6] Joan T. Schmit, Factors Likely to Influence Tort Litigation in the European Union, The Geneva Papers 31, 304–313, 305 (2006) including an approximation to the number of product liability cases in the different member states.

[7] The level of product liability litigation in the United States has been significantly different and higher than in Europe. See also Alfred E. Mottur, The European Product Liability Directive: A Comparison With U.S. Law, An Analysis Of Its Impact On Trade, And A Recommendation For Reform So As To Accomplish Harmonization And Consumer Protection, 25 Law & Pol'y Int'l Bus. 983, 1003-1004 (1994) noting the role of litigation in European product liability..

[8] See Jane Stapleton, Bugs in Anglo-American Products Liability, in PRODUCT LIABILITY IN COMPARATIVE PERSPECTIVE, edited by Duncan Fairgrieve, Cambridge, 295 (2005) noting that the level of product liability litigation remains significantly low because injured victims in Europe do not generally pursue their product claims. See also Robert W. McGee, Who Really Benefits from Liability Litigation?, num. 24, Dumont Institute Policy Analysis (1996) noting that liability costs in the United States are 15 times higher than in Japan and twenty times higher than in Europe; Paul Burrows, Consumer Safety under Products Liability and Duty to Disclose, International Review of Law and Economics 12, 457-478, 462 (1992); Eleonora Rajneri, Interaction between the European Directive on Product Liability and the former liability regime in Italy, in Product Liability in Comparative Perspective, Duncan Fairgrave (ed.) 67 - 84, Cambridge University Press (2005) for an analysis of the impact of the adoption of the product liability directive in Italy. From the perspective of an insurance company see Susan Narita, Product Liability Claims in Europe, Swiss Reinsurance Company, Zurich, 38 (1996) noting that in many European countries less than 5% of product liability claims and insurance coverage disputes actually reach the courts. In the same line, see also Hein Kotz, Civil Justice Systems In Europe And The United States, 13 Duke J. Comp. & Int'l L. 61, 73 (2003).

[9] Mark Mildred, Litigation Rules and Culture: The European Perspective, 23 N.Y.U. Rev. L. & Soc. Change 433, 441 (1997). See also Susan Narita, Product Liability Claims in Europe, Swiss Reinsurance Company, Zurich, 35 (1996).

[10] See Michael J. Moore and W. Kip Viscusi, Product liability entering the twenty-first century, AEI Brookings joint center for regulatory studies (2001) noting that during the 1980s the litigiousness of U.S. society increased around 33 percent annually – from 2.393 in 1975 to 13.408 in 1989 - while product liability lawsuits increased from 2 to 5.7 percent during that same period. See also Geraint G. Howells, The relationship between product liability and product safety – understanding a necessary element in the European Product Liability through a comparison with the U.S. position, 39 Washburn L. J. 305, 306 (2000).

This is not to say that the introduction of the European product liability directive was entirely without effect. The Lovells Report,[11] issued in 2003, represented a first attempt to asses the impact of the directive with respect to the level of product-related accidents, litigation, and victim compensation. While this report does not include sufficient detail on specific product liability cases to permit independent analysis, it concludes that there was a slight increase in product liability claims in Europe during the 1990s.[12]

At the member state level there is no systematic data collection of product-related accidents or lawsuits. Despite the efforts to seek this information in different authorities of the member states, the only information available has been for Spain. The source of information on European product litigation in Spain comes from the collection of Spanish product liability judgments maintained by the civil law department at Universitat Pompeu Fabra.[13] I draw on this collection to analyze the amount and evolution of product liability litigation in Spain as an example of the effects of the product liability directive in the different European member states. The number of judgments is clearly not equivalent to the number of accidents or claims, as some victims do not file suits and many of the suits that are filed result in settlements.[14] Even with these caveats in mind, however, the

[11] Lovells, PRODUCT LIABILITY IN THE EUROPEAN UNION: A REPORT FOR THE EUROPEAN COMMISSION (2003) available at http://ec.europa.eu/enterprise/policies/single-market-goods/files/goods/docs/liability/studies/lovells-study_en.pdf. Between 2001 and 2003 Lovells did a survey between European companies regarding product safety and their view on product liability. The results of this survey are the core of the report.

[12] See Lovells, PRODUCT LIABILITY IN THE EUROPEAN UNION: A REPORT FOR THE EUROPEAN COMMISSION, 31,37 (2003) noting that 22% of the companies taking part in the survey noticed an increase in the number of product liability claims in the EU during the 10 year previous to issuing the report and qualifying the slight increase in product liability litigation as normal. See also Susan Narita, Product Liability Claims in Europe, Swiss Reinsurance Company, Zurich, 8 (1996) also noting that the number of claims in most European countries has raised slightly in the past years.

[13] See Guía InDret de jurisprudencia sobre responsabilidad de producto, available at www.InDret.com and Fernando Gómez and Pablo Salvador, APÉNDICE 2009 AL TRATADO DE RESPONSABILIDAD CIVIL DEL FABRICANTE, Civitas, Madrid (2010) for a complete collection of product liability judgments in Spain.

[14] See Susan Narita, Product Liability Claims in Europe, Swiss Reinsurance Company, Zurich, 38 (1996) noting that over 90% of the product liability disputes in Europe do not reach the courts. See also John Meltzer Reform of Product Liability in the EU: New Report Finds General Satisfaction, 71 Def. Counsl. J. 42, 47 (2004).

Spanish judgment collection suggests, like the Lovells report, that the introduction of the strict liability in the European products directive resulted in only a slight increase in product liability claims during the 1990s.[15]

There are multiple explanations for this small increase in European product liability lawsuits. The Lovells report suggests that, in addition to the introduction of the product liability directive, three major factors might explain the increase in the litigation: consumers' awareness of their rights, their access to information, and their access to legal assistance.[16] The report also suggests that the combination of the directive with greater access to legal assistance and a change in judicial attitudes toward consumer rights[17] may have made product litigation plaintiffs more successfull, and that this success, in turn, may have contributed to the increase.[18] Overall, however, the report attributes a small part of the increase in litigation to the directive itself.

In any event, the small increase in litigation that appears to have occurred in Europe[19] is nowhere near the increase in litigation reported in the United States following the adoption of strict liability in product suits there. It could be argued that product

[15] See Lovells, PRODUCT LIABILITY IN THE EUROPEAN UNION: A REPORT FOR THE EUROPEAN COMMISSION, 31, 37 (2003) and Susan Narita, Product Liability Claims in Europe, Swiss Reinsurance Company, Zurich, 8 (1996).

[16] The adoption and implementation of the product liability Directive has been an important, but not major factor to explain the increase in product liability claims. See Lovells, PRODUCT LIABILITY IN THE EUROPEAN UNION: A REPORT FOR THE EUROPEAN COMMISSION, 32-34 (2003) suggesting that a main factor explaining the slight increase in product liability claims might have been the increase in the awareness of consumers' rights.

[17] Communication From The Commission "Action Plan on consumer access to justice and the settlement of consumer disputes in the internal market," Brussels, 14.2.1996, COM(96) 13 final available at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:1996:0013:FIN:EN:PDF. See also the European Commission Green Paper: Access of consumers to justice and the settlement of consumer disputes in the Single market, COM/93/576FINAL,, Noivember 16, 1993, 56 (1993) Available at http://europa.eu/legislation_summaries/other/l32023_en.htm

[18] See Lovells, PRODUCT LIABILITY IN THE EUROPEAN UNION: A REPORT FOR THE EUROPEAN COMMISSION, 34-37 (2003). U.S. product liability cases seem to have followed a similar pattern. See Theodore Eisenberg et al., Litigation Outcomes in State and Federal Court: A Statistical Portrait, 19 Seattle U. L. Rev. 433, 437 (1996). See also John Meltzer Reform Of Product Liability In The EU: New Report Finds General Satisfaction, 71 Def. Counsl. J. 42, 47 (2004) noting an increase in the number of settlements since the adoption of the Directive.

[19] See Table 6.1 in Chapter 6 compiling product liability judgments in Spain since the product liability directive was transposed and incorporated into Spanish law.

liability has been used less in Europe than in the United States because products are safer in Europe. However, there is no evidence of this.

The role, effects and development of product liability in Europe have been remarkably different than in the United States. The drafters and the industry[20] had very strong expectations about how the Directive would change the European product liability reality, including an expected increase in the level of product liability litigation, the rate of insurance premiums, and the contracted insurance coverage.[21] It does not appear, however, that these expectations have been borne out.[22]

This thesis aims at approaching the different factors that could explain the nature, impact and effects of product liability law in Europe since the adoption of the product liability directive with its introduction of a strict product liability regime. Through its different chapters, this thesis presents the broad scope of factors that can explain the nature and performance of product liability in Europe, its effects on other institutions interacting with tort law and further includes regulatory proposals in each of the issues discussed.

Given that this thesis focuses on European law, institutions and legal structure, Chapter 1 presents a brief historical description of the European Union and a brief general overview of the main European institutions, their roles and the most important legal instruments in European law. This is of special importance given that the main object of this thesis is a piece of European Union legislation, the product liability directive.

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[20] Andrew C. Spacone, Strict Liability in the European Union - Not a United States Analog, 5 Roger Williams U. L. Rev. 341, 346 (2000).

[21] Mark Mildred, Litigation Rules and Culture: The European Perspective, 23 N.Y.U. Rev. L. & Soc. Change 433, 441 (1997).

[22] See Alfred E. Mottur, The European Product Liability Directive: A Comparison With U.S. Law, An Analysis Of Its Impact On Trade, And A Recommendation For Reform So As To Accomplish Harmonization And Consumer Protection, 25 Law & Pol'y Int'l Bus. 983 (1994). See also Lucille M. Ponte, Guilt By Association In United States Products Liability Cases: Are The European Community And Japan Likely To Develop Similar Cause-In-Fact Approaches To Defendant Identification?, 15 Loy. L.A. Int'l & Comp. L.J. 629, 657 (1993).

Chapter 2 extensively presents and discusses the main parameters defining product liability in Europe since the harmonization of this body of law under the product liability directive. It examines the scope of the classes of tortfeasors and victims covered by the directive, the content of the strict liability regime it introduced, and the contours of its defectiveness test – the consumer expectations test. This chapter also focuses on some of the problems encountered by Spanish courts in applying the directive.

After presenting the European product liability regime and discussing its main challenges, the thesis turns to discuss a variety of issues that may influence its effectiveness. The first such issue is procedure, and Chapter 3 focuses on the procedural context in which the product liability directive is applied.[23] The civil procedure rules in force in most European member states are remarkably different from those of the United States and present important obstacles for injured plaintiffs. These obstacles may reduce the likelihood of product victims prevailing in their claims and this may reduce their incentives to bring claims to begin with.[24]

Rules of procedure, however, are not the most important factor conditioning victims' incentives to bring their product liability claims. Chapter 4 of the thesis argues that the directive itself generated uncertainty among injured victims by including optional -- and significant -- provisions such as the development risk defense, and by opting for the the consumer expectations test as the test for defectiveness, which have been difficult for member state courts to apply uniformly. This problem of application has been particularly acute because member states tend to rely on negligence-based liability in their tort systems. The interaction of the directive's strict liability regime with these

[23] See Alfred E. Mottur, The European Product Liability Directive: A Comparison With U.S. Law, An Analysis Of Its Impact On Trade, And A Recommendation For Reform So As To Accomplish Harmonization And Consumer Protection, 25 Law & Pol'y Int'l Bus. 983 (1994) emphasizing the importance of procedural and contextual factors that significantly differ from the U.S. context and affect the implementation of the product liability directive in Europe.

[24] See Michael G. Faure, Ton Hartlief and Niels J. Philipsen, Funding of personal injury litigation and claims culture, Evidence from the Netherlands, Utrecht Law Review, Volume 2, issue 2 (2006) claiming that the litigation culture is different in the U.S. and in Europe because of the different procedural rules and of the different evolution of substantive law.

negligence-based domestic systems has led to confusion in both legislative transposition and court interpretation of the directive's provisions. Compounding this problem is the remarkably vague and sometimes abstract language used in the directive, the product of long and difficult negotiations among the European member states and of the European Commission's desire to reach consensus after making adoption of the directive a priority.[25]

Chapters 5 and 6 focus on the relationship between European product liability law, an ex post tort remedy, and other product-related laws such as the ex ante product safety rules manufacturers must comply with in order to be able to market their products. As the chapters make clear, the product liability directive is not the only regulation product manufacturers must take into account when deciding their level of investment in care. European product regulation, when considered beyond the directive itself, includes a broad product safety regime that directly conditions product manufacturers' decisions in care combined with a liability regime that aims to create incentives for care by forcing manufacturers to internalize the costs of accidents caused by their defective products. Both regulations, when jointly analyzed, influence manufacturers' ex ante decisions on care and more generally, on accident deterrence.

Not only are product manufacturers subject to ex ante product safety regulation and ex post product liability, but the two regimes also overlap in terms of scope of application, tests for defectiveness, and product safety requirements. However, their interaction takes place through a very restricted compliance defense and no further coordination mechanism is in place. Chapter 6 analyzes the implications of the interaction between ex ante safety regulation and ex post liability, discusses the impact of this interaction on the effectiveness of each of them, and suggests potential mechanisms and

[25] See Jane Stapleton, Bugs in Anglo-American Products Liability in Product liability in comparative perspective, edited by Duncan Fairgrieve, Cambridge, 295 (2005); Susan Narita, Product Liability Claims in Europe, Swiss Reinsurance Company, Zurich, 35 (1996) and Lovells, PRODUCT LIABILITY IN THE EUROPEAN UNION: A REPORT FOR THE EUROPEAN COMMISSION (2003).

parameters that could and should be taken into account in order to enhance their joint performance.

Finally, Chapter 7 addresses the compensation of victims of product-related accidents. One of the goals of the European consumer protection regime as well as of the product liability directive is ensuring and facilitating victim compensation. However, compensation under tort interacts with alternative compensation mechanisms such as private insurance and, most importantly in Europe, (public) social insurance mechanisms. Victims' incentives to pursue their claims under tort are directly affected by the availability and functioning of these alterantive mechanisms. Evidence suggests that the introduction of the product liability directive has not had a significant effect on private insurance premiums. At the same time, social insurance provides incomplete but immediate compensation that dilutes victims' incentives to pursue product liability claims under the directive and, thus, conditions the directive's impact as an effective legal instrument.[26] The product liability practice in Europe suggests that the major costs of product-related accidents are born by social insurance systems. The dislocation of the costs of product-related accidents from tortfeasors to social insurance systems affects not only victims' compensation (generally leaving victims under-compensed), but also torfeasors' incentives for care and the social insurance systems themselves, which are currently going through a period of financial struggle. Chapter 7 examines the different compensation mechanisms available to victims of product-related accidents in Europe, the coordination mechanisms between them that have been implemented in the different member states, and their effects and implications.

Chapter 8 concludes.

[26] Alfred E. Mottur, The European Product Liability Directive: A Comparison With U.S. Law, An Analysis Of Its Impact On Trade, And A Recommendation For Reform So As To Accomplish Harmonization And Consumer Protection, 25 Law & Pol'y Int'l Bus. 983, 1006-1007 (1994) noting that the existence and availability of mandatory health care coverage results in victims being compensated - even if under-compensated - by the public insurance system and hence unlikely to subsequently file a claim under tort.

Methodology of the thesis

The methodology used in this thesis is a combination of purely legal analysis and a law and economics approach to discuss the effects and consequences of the interaction of product liability law with other regulatory regimes and institutions. This choice of methodology is based on a number of considerations: First, product liability can be described as regulation framed in the market context. The market economy in place both in Europe and in the United States implies that when products are placed in the market and are purchased by consumers, some of them might be defective and some of those might cause damage to their consumer or users. Product liability, together with product safety regulation aims at minimizing the amount of product-related accidents and the magnitude of these accidents while providing instruments to consumers or more generally, product users, to claim compensation when they have been injured by consumer products. The nature of the law and the issues addressed in this thesis have a clear economic component.

The language used by the European legislature when stating the goals of the European product liability directive is framed in law and economics terms. The European Commission, in the directive's preamble, clearly states that its goal is to apportion risks among parties. Additionally, one of the major goals of European consumer protection regulation is to facilitate compensation of victims of product-related accidents.[27] Further, the law and economics approach is often used in the U.S. literature and jurisprudence on tort law generally, and product liability in particular. In contrast, the law and economics approach is not especially popular in the European legal literature. This thesis focuses on European product liability law but with constant references to the regulatory framework,

[27] The product liability directive, in its Preamble, paragraph 2 states the apportionment of risks as one of its major goals. Facilitating victim's compensation is one of the major goals of the overall consumer protection system in the European Union. See Andrew C. Spacone, Strict Liability in the European Union - Not a United States Analog, 5 Roger Williams U. L. Rev. 341, 350 (2000).

its evolution and the practical experience of product liability litigation in the United States. In this context, the economic analysis is also well suited. Finally, the law and economics approach allows me to draw on my training and interests in both of these disciplins when analyzing legal rules.

At the same time, there are reasons to be hesitant in relying too heavily on law and economics given the inherent limitations of this approach and the sometimes questionable results and conclusions to which it leads.[28] Law and economics aims to identify the potential effects of legal rules on the behavior and decisions of individuals and firms and to discuss their economic consequences and efficiency in order to determine policy preferences. Considerations of economic efficiency are undoubtedly important but also leave aside other important aspects of law and policy that deserve consideration. As a general matter, law and economics imposes strong assumptions on how individuals decide and behave based on the understanding that they are rational and selfish. Such assumptions are unquestionably useful but at the same time neglect many parameters that individuals also take into account when taking decisions. With respect to product liability, the accident-minimizing goal seems to be desirable but the instrument to achieve it, incentive-creation through litigation, is more questionable.

Despite the inherent limitations of the economic analysis of the law, this dissertation relies on it because it still seems the best available approach to product liability, its nature, performance and its relationship with other product regimes and with alternative compensation mechanisms.

[28] See, for example, A. Mitchell Polinsky, Economic Analysis as a potentially defective product: a buyer's guide to Posner's economic analysis of law, 37 Harv. L. Rev. 1655 (1974) arguing that a certain conclusion provided by the economic analysis, in the article, a market-type solution offered, did not take into account the existence of transaction costs and of income redistribution and hence resulted in creating inequality and inefficiencies.

CHAPTER 1

EUROPEAN PRODUCT REGULATION: AN OVERVIEW

1. Historical developments of the European Union

The origins of today's European Union lie in the 1957 Treaties of Rome,[29] which established the European Economic Community and the European Atomic Energy Community. These two entities added to the already existing European Coal and Steel Community,[30] forming what came to be known first as the European Communities[31] and later, with the 1992 Treaty of Maastricht, as the European Union.[32]

One of the major goals of the European Economic Community was the creation of a common market with free movement of goods, services, capital and individuals between the member states.[33] In order to achieve this goal, certain policies of the member states were harmonized,[34] and intra-European barriers to trade were replaced with

[29] See Treaty Establishing the European Economic Community, Mar. 25, 1957, art. 189, 298 U.N.T.S. 11 (hereinafter, Treaty of Rome). See http://eur-lex.europa.eu/en/treaties/index.htm for the text of the founding Treaties.

[30] The Treaty establishing the European Coal and Steel Community was signed in 18.04.1951, entered into force in 24.07.1952 and expired on 23.07.2002. This Treaty was not published in the Official Journal of the European Community. See http://europa.eu/legislation_summaries/institutional_affairs/treaties/treaties_ecsc_en.htm

[31] With the creation of the European Communities, a Council and a single Commission governing the three areas were instituted. See the Treaty Instituting a Single Council and a Single Commission of the European Community, Apr. 8, 1965, art. 9, 10 O.J. Eur. Comm. (No. C 152) 2 (1967).

[32] The Maastricht Treaty, called Treaty on European Union O. J. C 191 (1992). Under the Maastricht Treaty the European Economic Community Treaty was officially renamed the European Community Treaty. For the full text of the Maastricth Treaty see http://europa.eu/eur-lex/en/treaties/dat/EU_treaty.html.

[33] Article 9-37 of the Treaty of Rome establishing the free movement of goods and articles 48-73 for the movement of persons, services and capital. See also Norbert Reich, CHRISTOPHER GODDARD AND KSENIJA VASILJEVA, UNDERSTANDING EU LAW, OBJECTIVES, PRINCIPLES AND METHODS OF COMMUNITY LAW, 54, 89-130 (Interscentia 2003).

[34] The approximation of the laws of the member states to the extent required for the proper functioning of the common market is one of the goals laid down in article 3(h) and article 100 of the Treaty of Rome. Article 100 of the Treaty of Rome reads as follows:

> *"The Council shall, acting unanimously on a proposal from the Commission and after consulting the European Parliament and the Economic and Social Committee, issue directives for the*

common customs tariffs on imports from third countries. These trade developments needed to be coordinated with a series of economic measures that would ensure the proper functioning of the common market. For example, market competition had to be protected and domestic and monetary policies were harmonized so that the member states' macro-economic and micro-economic evolutions would take place in a coordinated way and would eventually converge.

After the first step taken in Rome, the completion of the internal market[35] was made possible through the Maastricht Treaty on European Union, which entered into force in 1993.[36] Among other things, this treaty established the economic convergence requirements for adopting the Euro as the common currency of participating member states.[37] The Treaty of Amsterdam followed in 1999, and included provisions aimed at

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> *approximation of such laws, regulations or administrative provisions of the Member States as directly affect the establishment or functioning of the common market."*

These provisions provide for three major elements: First, allowing European authorities to approximate the laws of the member states but not to unify them. Second, establishing that the legal approximation must be done to the extent required, that is, only whenever it would serve the general interest. Third, stating that the approximation must be framed within the goal of ensuring the proper functioning of the internal market – and the proper exercise of the free circulation of goods, persons, services and capital. The Treaty of Maastricht also included the protection of consumers' interests and the environment as fields subject to regulatory approximation. See Hans Claudius Taschner, Harmonization of product liability in the European Community, 34 Tex. Int'l L. J. 21, 23 (1999) analyzing the harmonization of product liability regulation in Europe.

[35] The internal market was completed pursuant to the Single European Act (OJ L 169 of 29.6.1987), signed on 28 February 1986 and entered into force on 1st July 1987.

[36] For the full text of the Maastricht Treaty see http://europa.eu/eur-lex/en/treaties/dat/EU_treaty.html. For information regarding the European internal market see http://europa.eu/pol/singl/index_en.htm. See Günter Verheugen, Exchange of views of Vice-President Verheugen with the Internal Market and Consumer protection Committee (IMCO) European Parliament Internal Market and Consumer Protection Committee European Parliament, Brussels, 14 September 2006 for an assessment of the performance of the European internal market. This speech can be found at http://europa.eu/rapid/pressReleasesAction.do?reference=SPEECH/06/500&format=HTML&aged=1&language=EN&guiLanguage=en

[37] Article 1 of the Treaty on European Union states the convergence criterion:

> *"The criterion on price stability referred to in the first indent of Article 109j(1) of this Treaty shall mean that a Member State has a price performance that is sustainable and an average rate of inflation, observed over a period of one year before the examination, that does not exceed by more than 11/2 percentage points that of, at most, the three best performing Member States in terms of price stability. Inflation shall be measured by means of the consumer price index on a comparable basis, taking into account differences in national definitions."*

The creation of the internal market implied the creation of a new, possibly unintended, legal system. See Jan M. Smits, The Harmonisation of Private law in Europe: some insights from evolutionary theory, special volume in Honor of Alan Watson, Georgia Journal of international and Comparative Law 31, 79-99, 94 (2002).

transferring greater authority from member state governments to European Union bodies.[38] Further institutional reform was mandated by the Treaty of Nice,[39] which came into force in 2003 largely for the purpose of regulating and organizing the ongoing process of European Union enlargement. The most recent step in the project of European integration has been the attempt to create some form of constitution or similar treaty to streamline institutional decision-making and unify foreign policy. The member states, however, have so far been unable to reach a consensus on such a document (with the so-called European Constitution[40] being rejected by referenda in France and the Netherlands in 2007), and instead the Treaty of Lisbon,[41] created as an alternative to the constitutional treaty, entered into force on December 1, 2009.[42] At the time of writing, it remains to be seen what will come of these constitutional efforts.

2. Brief overview of European Union institutions

[38] Treaty of Amsterdam was signed on October 2, 1997 and entered into force on May 1st, 1999. It amended and renumbered the Treaty on the European Union, the Treaties establishing the European Communities and certain related acts, October 2 1997, OJ C 340. The text of this Treaty can be found at http://europa.eu/eur-lex/en/treaties/selected/livre546.html

[39] The Treaty of Nice changed the weight of the votes of the different member states in the Council of Ministers, introduced qualified majority requirements for the adoption of certain decisions and reduced the legislative areas that required unanimity. See http://ec.europa.eu/comm/nice_treaty/index_en.htm for additional information on this Treaty.

[40] The Governments of the member states agreed in 2004 that the Treaty establishing a European Constitution would enter into force following its ratification by all member states. Even though some member states such as Spain ratified it, the text was rejected by France and the Netherlands during 2005. It was then agreed that developments in the implementation of the Treaty would be postponed. The partially ratified text of the European Constitution can be found at http://europa.eu/scadplus/constitution/index_en.htm

[41] Treaty of Lisbon amending the Treaty on European Union and the Treaty establishing the European Community, C 306/01, signed at Lisbon on 13 December 2007. The text of the Treaty is available at http://eur-lex.europa.eu/JOHtml.do?uri=OJ:C:2007:306:SOM:EN:HTML

[42] Additional information about the Treaty of Lisbon is available at http://europa.eu/lisbon_treaty/index_en.htm

The principal institutions of the European Union are the Commission, the Parliament and the Council.[43]

The European Commission is the governmental body of the Community and represents the interests of the European Union as a whole, independent of national governments.[44] It has four main roles with a hybrid administrative and political nature. First, it has the "right of initiative," meaning that it proposes legislation to the Parliament and the Council. Second, it manages and implements European Union policies, ensures that they are properly applied in all member states, and elaborates the budget. Third, it enforces European law. Fourth, it represents the European Union on the international stage and negotiates international agreements on behalf of the European Union.

The European Parliament is directly elected by the citizens of the European Union to represent their interests.[45] The Parliament has three main roles: (1) adopting European legislation together with the Council, (2) providing democratic supervision over the European institutions, and (3) controling and influencing the European Union budget together with the Council.[46]

Finally, the Council of the European Union[47] is the main decision-making body of the European Union and represents the member states through a minister of the member

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[43] The three institutions were established in 1950. See, P.S.R.F. Mathijsen, A GUIDE TO EUROPEAN UNION LAW 12-55, Sweet & Maxwell (7th ed. 1999) and John Fairhurst & Chrsitopher Vincenzi, LAW OF THE EUROPEAN COMMUNITY, 3-71 (Pearson Education Limited) (4th ed. 2003).

[44] John Peterson and Michael Shackleton, THE INSTITUTIONS OF THE EUROPEAN UNION, 81-103, Oxford University Press, 2nd ed. (2006) and UNDERSTANDING EUROPEAN UNION INSTITUTIONS, Alex Warleigh ed., 52-58, Routledge (2002).

[45] UNDERSTANDING EUROPEAN UNION INSTITUTIONS, Alex Warleigh ed., 62-78, Routledge (2002) and John Peterson and Michael Shackleton, THE INSTITUTIONS OF THE EUROPEAN UNION, 104-124, Oxford University Press, 2nd ed. (2006).

[46] The European Parliament has "advisory and supervisory powers" and further has some power over the European budget. P.S.R.F. MATHIJSEN, A GUIDE TO EUROPEAN UNION LAW 12-55 (7th ed. 1999) and JOHN FAIRHURST & CHRSITOPHER VINCENZI, LAW OF THE EUROPEAN COMMUNITY 3-71 (Pearson Education Limited) (4th ed. 2003).

[47] Also called the Council of Ministers. Note that the Council of the European Union is different from the European Council, which is formed by the heads of state of the different member states. See http://ec.europa.eu/archives/european-council/index_en.htm

state's government.[48] The Council has six major responsibilities: (1) proposing European laws at the request of the Commission, (2) broadly coordinating the economic policies of the member states, (3) concluding international agreements between the European Union and other countries or international organizations, (4) approving the European Union's budget, (5) developing the European Union Common Foreign and Security Policy (CFSP),[49] and (6) facilitating cooperation between member states' national courts and police forces in criminal matters.

3. The European Community legislative instruments

European legislative instruments are structured in two major bodies: primary legislation and secondary legislation. Primary legislation consists of the treaties discussed above and the annexes and protocols attached to them, as well as the additions and amendments that some of the texts have undergone.[50] Additionally, primary legislation includes the accession treaties of the different member states.[51] All of this legislation spells out the objectives, organization and functioning of the European Union and its predecessors.

Secondary legislation consists of the instruments promulgated by European Union institutions through the powers given to these institutions in the primary legislation. The

[48] John Peterson and Michael Shackleton, THE INSTITUTIONS OF THE EUROPEAN UNION, 68-80, Oxford University Press, 2nd ed. (2006) and UNDERSTANDING EUROPEAN UNION INSTITUTIONS, Alex Warleigh ed., 26-29, Routledge (2002).
[49] Information on the European Common Foreign and Security Policy (CFSP) can be found in http://ec.europa.eu/external_relations/cfsp/index_en.htm
[50] T.C. Hartley, THE FOUNDATIONS OF EUROPEAN COMMUNITY LAW, 99-106, Oxford, Clarendon Law Series (1994).
[51] The United Kingdom, Denmark and Ireland signed their treaty of Accession in 1973, Greece in 1981, Spain and Portugal in 1986 and ten years later Finland, Austria and Sweden in 1995. In 2003 the enlargement of the European Union included the accession of the Czech Republic, Estonia, Cyprus, Latvia, Lithuania, Hungary, Malta, Poland, Slovenia and Slovakia. More recently, the Accession Treaties for Bulgaria and Romania were signed on 2005 to take place in 2007. See http://europa.eu/abc/index_en.htm

different kinds of secondary legislation are spelled out in article 249 of the Treaty of Rome, which states that:

> In order to carry out their task and in accordance with the provisions of this Treaty, the European Parliament acting jointly with the Council, the Council and the Commission shall make regulations and issue directives, take decisions, make recommendations or deliver opinions.
>
> A regulation shall have general application. It shall be binding in its entirety and directly applicable in all Member States.
>
> A directive shall be binding, as to the result to be achieved, upon each Member State to which it is addressed, but shall leave to the national authorities the choice of form and methods.
>
> A decision shall be binding in its entirety upon those to whom it is addressed. Recommendations and opinions shall have no binding force.

As can be seen, article 249 lays out five different kinds of secondary legislation: regulations, directives, decisions, recommendations and opinions.[52]

Regulations are instruments of general application that are directly binding on all member states and take effect regardless their transposition into domestic law. Member states are prohibited from modifying or transposing incompletely or incorrectly the text of a regulation; to the extent that they do so, citizens can simply bypass the offending national legislation and assert directly their rights under the regulation.[53] Examples of product-related regulations are the Council Regulation on the protection of geographical indications and designations of origin for agricultural products and foodstuffs[54] and the Council Regulation on organic production and labeling of organic products.[55]

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[52] T.C. Hartley, THE FOUNDATIONS OF EUROPEAN COMMUNITY LAW, 107-136, Oxford, Clarendon Law Series (1994).
[53] T.C. Hartley, THE FOUNDATIONS OF EUROPEAN COMMUNITY LAW, 107, Oxford, Clarendon Law Series, (1994).
[54] Council Regulation (EC) No 510/2006 of 20 March 2006 on the protection of geographical indications and designations of origin for agricultural products and foodstuff. OJ L93 p. 12, 31.3.2006. The regulation is available at http://www.tpe.gov.tr/dosyalar/ABcografi/510_2006_Sayili_AB_Tuzugu.pdf
[55] Council Regulation (EC) No. 834/2007 of 28 June 2007 on organic production and labeling of organic products, that repealed the Council Regulation (EEC) No. 2092/91. OJ L189, p1, 20.07.2007. The

Directives are the instruments used most frequently in European Union law. Directives aim to reconcile the need for Union-wide uniformity with the different political structures and administrative procedures of the member states.[56] Directives are binding on member states with respect to their intended results and the deadlines they lay down for implementation, but they allow member states to choose the form and method of implementation.[57]

In order to take effect, directives generally must be transposed by the member states into their domestic law.[58] The transposition process, however, often has been used by member states to delay or otherwise obstruct the implementation of directives, either by transposing them slowly or incorrectly or by simply failing to transpose them at all. This hinders citizens from achieving their rights and otherwise undermines the purposes of the directives in question, as well as the goal of Union-wide harmonization. This has led the Commission to order certain member state governments to carry out the transposition process and to bring member states before the European Court of Justice. That court, in turn, has held that even in cases where directives have not been transposed, individuals may possess certain rights under them.[59] Further it has also held that member states may be liable for damages caused by their non-implementation.[60]

Regulation is available at http://eur lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:189:0001:0023:EN:PDF

[56] Sacha Prechal, DIRECTIVES IN EC LAW, Oxford Law Library, 13 and following (2nd Ed. 2005).

[57] Sacha Prechal, DIRECTIVES IN EC LAW, Oxford Law Library, 73-91 (2nd Ed. 2005).

[58] Sacha Prechal, DIRECTIVES IN EC LAW, Oxford Law Library, 55-72 (2nd Ed. 2005).

[59] Even though the directive's direct effect is not mentioned in any of the EC Treaties, it was established by the European Court of Justice in the case *Van Gend en Loos v. Nederlandse Administratie der Belastingen* Case 26/62; [1963] ECR 1; [1970] C.M.L.R. 1 where the European Court of Justice held that the rights conferred to individuals under European Community legislation should be enforceable by those individuals in national courts. In that case, the court stated that

> *"3. The European Economic Community constitutes a new legal order of international law for the benefit of which the states have limited their sovereign rights, albeit within limited fields, and the subjects of which comprise not only the member states but also their nationals.*
>
> *Independently of the legislation of member states, community law not only imposes obligations on individuals but is also intended to confer upon them rights which become part of their legal heritage. These rights arise not only where they are expressly granted by the treaty but also by reason of obligations which the treaty imposes in a clearly defined way upon individuals as well as upon the member states and upon the institutions of the community.*

The European Union generally takes two approaches to maximize the impact and effect of directives. The first approach is to adopt sector-specific directives, which address specific issues needing certain regulation. The second approach is to adopt what are often called "horizontal framework directives." Directives of this latter type establish broad frameworks of principles that apply to a wide range of areas.[61] Examples of both of types of directives will be seen in the subsequent chapters of this thesis.

After regulations and directives, decisions form the third type of European secondary legislation. These instruments do not have general application but instead apply only to specific enumerated parties.[62] Decisions do not need to be transposed or implemented by member states; they are directly binding as issued. The Treaty of Rome limits the areas in which decisions may be employed, and as a result decisions tend to be issued less frequently than other types of secondary legislation. Examples of decisions are the Council Decision on a common framework for the marketing of products[63] or the Council Decision regarding the functioning of a system for the exchange of information in respect of certain products which may jeopardize consumers' health or safety.[64]

> *4. The fact that articles 169 and 170 of the EEC Treaty enable the commission and the member states to bring before the court a state which has not fulfilled its obligations does not deprive individuals of the right to plead the same obligations, should the occasion arise, before a national court."*

[60] European Court of Justice joined cases C-6/90 and C-9/90, Andrea Francovich and Danila Bonifaci and others v Italian Republic. Failure to implement a directive - Liability of the Member State (1991) and stated that

> *"a principle of Community law that the Member States are obliged to make good loss and damage caused to individuals by breaches of Community law for which they can be held responsibl*e." [36].

[61] Horizontal directives, as opposed to vertical directives, include rights that can be invoked and enforced by an individual vis-à-vis other individuals. There is a significant amount of literature discussing what is the most adequate and effective legislative technique. See Sacha Prechal, Directives in EC law, Oxford Law Library, 255 (2nd Ed. 2005).

[62] T.C. Hartley, THE FOUNDATIONS OF EUROPEAN COMMUNITY LAW, 107, Oxford, Clarendon Law Series, (1994).

[63] Council Decision 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, OJ L 218, 13.8.2008, 82-128, repealing Council Decision 93/465/EEC. This Council Decision is available at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32008D0768:EN:NOT

[64] Council Decision 93/580/EEC of 25 October 1993 concerning the institution of a Community system for the exchange of information in respect of certain products which may jeopardise consumers' health or

The last types of secondary legislation are recommendations and opinions. These are non-binding instruments with no direct effect.[65] They mostly have persuasive value and are used where the Commission believes them is necessary. Examples of such texts are the Commission Recommendation on the prevention of smoking and on improving tobacco control[66] and the Opinion of the Scientific Committee on emerging and newly identified health risks on potential health risks of exposure to noise from personal music players and mobile phones[67] requested by the European Commission.[68]

4. The development of product regulation within the consumer protection goal of the European Union

Product regulation is part of the European consumer protection regime that originated together with the creation of the European common market through the Treaty of Rome.[69] In order to ensure a successful functioning of the internal market and its subsequent expansion with the European economic and monetary union, it was necessary to ensure an effective consumer protection regime and hence a shared product regulation throughout the European market.

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safety, O.J. L 278, 11.11.1993, p. 64–69. This Council Decision is available at http://eur-lex.europa.eu/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Decision&an_doc=1993&nu_doc=580

[65] Direct effect refers to the possibility for an individual to invoke provisions of community law in order to protect his interests. See Sacha Prechal, Directives in EC law, Oxford Law Library, 100 (2nd Ed. 2005).

[66] Council Recommendation 2003/54/EC of 2 December 2002 on the prevention of smoking and on initiatives to improve tobacco control (O.J. L 22 of 25.01.2003). The Council Recommendation can be found at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:022:0031:0034:EN:PDF

[67] Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) on the Potential health risks of exposure to noise from personal music players and mobile phones including a music playing function. This http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_018.pdf

[68] The European Commission's request of the opinion can be found at http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_q_011.pdf

[69] See article 100 of the Treaty of Rome.

Subsequently,[70] the Treaty of Maastricht established consumer protection as one of its major goals.[71] Most of consumer protection legislation is based on article 100 of the Treaty of Rome (today Article 95)[72], which allows measures to be adopted for the approximation of the provisions laid down by law, regulation or administrative action in member states which have as their object the establishment and functioning of the internal market.[73] This "high level of protection" has been interpreted not as being binding, but as an inspirational principle that should be the basis of European legislation dealing with consumers. The principle has often been included in the recitals of the different European regulations dealing with safety, health and consumer protection.[74]

Soon after this principle was laid out, however, concerns arose over the danger that the existing domestic rules on product specifications, product testing and product liability -- whether based on contract law or torts -- could be used by member states to

[70] Article 3 of the Treaty of Rome does not mention consumer protection as one of the principles of the European Community. It is not until the adoption of the Treaty of Maastricht, on February 7th, 1992 – and entered into force on November 1st 1993 – when article 3 was amended and its new text included, in its article 3(s) consumer protection as one of the principles of the European Community. There is a surprising lack of literature discussing, justifying or defending the desirability of the adoption of this "high level of protection" in the regulation and discussing its implementation and effectiveness in the subsequent European Directives that develop and implement this policy. See Christopher Hodges, EUROPEAN REGULATION OF CONSUMER PROTECTION SAFETY, 31, Oxford University Press (2005) for one of the few existing analysis of European consumer protection regulation.

[71] This requirement is included in article 95.3 of the Maastricth Treaty (formerly article 100a of the Treaty of Rome), which requires that for all measures based on this article regarding health, safety, environmental protection, and consumer protection, the Commission "*will take as a base level of high level of protection*" of health and safety, taking account in particular any new development based on scientific facts.

[72] Today article 100 of the Treaty of Rome is Article 95 of the consolidated version of the Treaty of Rome, C 325, O.J., 24 December 2002. The consolidated version can be found at http://eur-lex.europa.eu/en/treaties/dat/12002E/htm/C_2002325EN.003301.html

[73] Consumer protection was introduced as a goal of the European Community in the Treaty of Maastricht in articles 3 and 129a that were maintained in the later Treaty of Amsterdam - that amended and consolidated the Treaties of Rome and Maastricht - in its articles 3 and 153. It should be noted that the diversity of private law regulation within the European Union is not by itself a reason that would justify harmonization because the European Commission does not have a general competence to harmonize the European private law. There needs to be a general interest and such harmonization must be necessary for the proper functioning of the internal common market. See Jacobien W. Rutgers, The Rule of Reason and Private Law or the Limits to Harmonization, in RULE OF REASON; RETHINKING ANOTHER CLASSIC OF EC LEGAL DOCTRINE, Annette Schrauwen, ed. The Hogendorp Papers (4), Groningen: Europa Law Publishers (2005). See also Hans Claudius Taschner, Harmonization of product liability in the European Community, 34 Tex. Int'l L. J. 21, 23 (1999) discussing the former legal bases of articles 3(h), 100 and 100a of the Treaty of Rome.

[74] Jacques Pelkmans, The new approach to technical harmonization and standardization, 25 J. Comm. Mkt. Studies 249, 252-253 (1987).

create trade barriers and thus jeopardize the success of one of the major goals of the common market as well as the goal of achieving a high level of consumer protection. These concerns needed to be addressed from a Europe-wide perspective because a state-by-state approach could not adequately ensure the proper functioning of the common market and the removal of protectionist regulations of the member states.[75] The Treaty of Amsterdam addressed such concerns and in its article 153 reflected the already existing Community's goal of creating a high level of consumer protection without allowing member states to adopt barriers to free trade.[76]

European consumer protection laws, including product regulation, aim to regulate all phases of a product's life, from pre-marketing to post-marketing. The European Commission through its Directorate General of Health and Consumers emphasizes

[75] The Community created a consumer protection program covering a wide range of matters. These issues were regulated in the amendments of the Maastricht Treaty. See arts 3f ad 129a of the Maastricht Treaty. Geraint Howells and Stephen Weatherill, CONSUMER PROTECTION LAW, 62, Ashgate Publishing Company (2005).

[76] Article 153 (former Art. 129A) of the Treaty of Amsterdam (signed on 1997 and entered into force in 1999) states:

1. *In order to promote the interests of consumers and to ensure a high level of consumer protection, the Community shall contribute to protecting the health, safety and economic interests of consumers as well as to promoting their right to information, education and to organize themselves to safeguard their interests.*
2. *Consumer protection requirements shall be taken into account in defining and implementing other Community policies and actions.*
3. *The Community shall contribute to the attainment of the objectives referred to in paragraph 1 by:*
   a)measures adopted pursuant to Article 95 in the context of the completion of the internal market;
   b)measures which support, supplement and monitor the policy pursued by the Member States.
4. *The Council, acting in accordance with the procedure referred to in Article 251 and after consulting the Economic and Social Committee, shall adopt the measures referred to in paragraph 3(b).*
5. *Measures adopted pursuant to paragraph 4 shall not prevent any Member State from maintaining or introducing more stringent protective measures. Such measures must be compatible with this Treaty. The Commission shall be notified of them."*

As it can be seen, member states are allowed to adopt measures more protective with consumers than the ones established by European authorities. However, such measures should be "compatible with the Treaty" and could not amount to a restriction of competition or become a barrier of trade within the European common market.

product safety as the major focus of consumer protection law.[77] European product safety law aims to influence the safety decisions made by manufacturers before their products are marketed while also imposing obligations on these manufacturers during the post-marketing phase. This law thus impacts the entire life a product.

To understand and evaluate European product regulation, one must remember that product safety provisions are complemented by product liability provisions, that allow consumers to seek compensation for the harm caused by defective products.[78] This body of law is considered by the European Commission to be part of Europe's internal market regulation.[79]

Despite the division between product safety -- considered part of consumer protection regulation -- and product liability -- considered part of the internal market regulation, there is obviously overlap between these two bodies of law -- overlap that affects on one side the economic decisions of product manufacturers and, on the other, the rights of the consumers and users of products. Although the overlap is not complete, the common scope of application and the importance of both bodies of law to producers and consumers warrant a comprehensive analysis of product regulation as a whole. This type of analysis, however, has been lacking thus far, and the present study is intended to fill the gap.

From a theoretical view and, more particularly, from a law and economics perspective, the analysis of product liability within the context of product regulation arises as very attractive because of the diversity of approaches of different regulations

[77] See http://ec.europa.eu/consumers/safety/prod_legis/index_en.htm for an overview of regulation on consumer product safety. See also Stephen Weatherill, EC CONSUMER LAW AND POLICY, John A. Usher ed. (1997) describing the evolution of the EC consumer policy.

[78] Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products, O. J. L 210**,** 07/08/1985 P. 0029 – 0033.

[79] See the regulation of Enterprise and Industry of the European Commission's web site. http://ec.europa.eu/enterprise/regulation/goods/liability/index_en.htm. It should be noted that product liability is not considered part of the regulation dealing with consumer affairs. See the product legislation on consumer affairs of the Directorate General of Health and Consumers of the European Commission http://ec.europa.eu/consumers/safety/prod_legis/index_en.htm

when addressing product risks. Product regulation as a whole aims at creating incentives to achieve optimal levels of safety and, thus, to minimize accidents.[80] There are two different models for achieving such an objective, both of which are used in European product regulation laws.[81] The first model uses the tort system as an instrument to create optimal incentives for safety. The threat of potential tort liability leads agents to adopt optimal safety levels in order to avoid subsequent liability.[82] Law and economics analysis predicts that rational agents, when subject to the threat of tort liability, internalize the expected consequences of potential accidents and adopt an efficient level of care.[83] This is the model used in European product liability laws.[84] The second model is to determine the desired level of care through legislation. This is essentially the model employed in European product safety law: Safety standards, New Approach Directives, and the General Product Safety Directive -- all of which are discussed further below -- are the essential instruments used to ensure that product manufacturers adopt the level of safety determined by the law.

From the perspective of the consumer who is exposed to a product's risks, these models are also different. Under the product liability model, victims may seek compensation from the manufacturer for the harm caused by the defective product. It is

[80] From a law and economics perspective, it would not be efficient, assuming it was possible, to reduce accidents so to achieve a zero level of accidents, because some risks would be too expensive to eliminate. For that reason, law and economics suggests to reduce accidents up to the point where the cost of preventing them is lower or equal to the cost resulting from the accidents prevented. This was also announced by Judge Hand in United States v. Carroll Towing Co., 159 F2d 169 (2d Cir. 1947). See also Thomas J. Miceli, ECONOMICS OF THE LAW, 15, Oxford University Press (1997).

[81] Geraint G. Howells, The relationship between product liability and product safety – understanding a necessary element in the European Product Liability through a comparison with the U.S. position, 39 Washburn L. J. 305, 308 (2000).

[82] Richard Posner, ECONOMIC ANALYSIS OF LAW, Aspen Law & Business, 192-197, 615-616, 5th Ed. (1998) and Thomas J. Miceli, ECONOMICS OF THE LAW, 57-70, Oxford University Press (1997). See in general A. Mitchell Polinsky, AN INTRODUCTION TO LAW AND ECONOMICS, 3rd ed., Gaithersburg, Md.: Aspen Publishers (2003).

[83] Thomas J. Miceli, ECONOMICS OF THE LAW, 57-70, Oxford University Press (1997). See also Richard Posner, ECONOMIC ANALYSIS OF LAW, Aspen Law & Business, 192-197, 615-616, 5th ed. (1998).

[84] The market-type solution suggested by law and economics literature has been sometimes challenged given that such solution will not achieve equity and efficiency because of the existence of transaction costs and the costs of redistributing income. See A. Mitchell Polinsky, Economic Analysis as a potentially defective product: a buyer's guide to Posner's economic analysis of law, 37 Harv. L. Rev. 1655 (1974).

through this potential for compensation that manufacturers internalize the costs of the harm their products may cause, and thereby end up with incentives to adopt optimal levels of care. In contrast, under the product safety model, a consumer may report the product's risks to the appropriate authorities, who may in turn impose a penalty on the manufacturer or require the manufacturer to withdraw the product. To the extent the consumer has been injured, however, he or she has no recourse to compensation from the manufacturer under this model.

Consumer protection, and hence product regulation, is one of the major concerns not just of the European Commission but also of European consumers generally. While public opinion polls indicate that a majority of European consumers think that the adoption of internal market rules at the European level has increased consumer protection within the European Union,[85] there is wide geographical variance in the perception of European consumers as to whether manufacturers and sellers are complying with the rules.[86] European consumers do not feel equally and uniformly protected. [87]

Hence, an analysis of the practical functioning of product legislation seems pertinent.

[85] European Commission, Consumer protection in the Internal Market, Special Eurobarometer, 29 (2006) where the results indicated that 53 % of European consumers thought that internal market rules increased consumer `protection within the European Union. This document is available at: http://ec.europa.eu/consumers/topics/eurobarometer_09-2006sum_en.pdf

[86] The general assessment of compliance is quite high, 62%. However, there is also variance in this perception: North-West European consumers perceive that their consumer rights are respected -- 65% -- in others this perception dropts to 48%. See European Commission, Consumer protection in the Internal Market, Special Eurobarometer, 30 (2006). document is available at: http://ec.europa.eu/consumers/topics/eurobarometer_09-2006sum_en.pdf

[87] Northern European consumers consider that they are adequately protected but Mediterranean and Eastern European consumers are significantly less satisfied. European Commission, Consumer protection in the Internal Market, Special Eurobarometer, 29-30 (2006). This document is available at: http://ec.europa.eu/consumers/topics/eurobarometer_09-2006sum_en.pdf

TABLE 1.1 – THE EUROPEAN COMMISSION'S JURISDICTION ON PRODUCT REGULATION: FROM ENSURING A PROPER FUNCTIONING OF THE INTERNAL MARKET TO ACHIEVING A HIGH LEVEL OF CONSUMER PROTECTION

TREATY OF ROME (1957)[88]	TREATY OF MAASTRICHT (1992)[89]	TREATY OF AMSTERDAM (1997)[90]
Article 3 For the purposes set out in Article 2, the activities of the Community shall include, as provided in this Treaty and in accordance with the timetable set out therein … (h) the approximation of the laws of Member States to the extent required for the proper functioning of the common market;	**Article 3** For the purposes set out in Article 2, the activities of the Community shall include, as provided in this Treaty and in accordance with the timetable set out therein: … (h) the approximation of the laws of Member States to the extent required for the functioning of the common market; … (s) a contribution to the strengthening of consumer protection;	**Article 3** For the purposes set out in Article 2, the activities of the Community shall include, as provided in this Treaty and in accordance with the timetable set out therein … (h) the approximation of the laws of Member States to the extent required for the proper functioning of the common market; … (s) a contribution to the strengthening of consumer protection;
CHAPTER 3 - APPROXIMATION OF LAWS **Article 100** The Council shall. acting unanimously on a proposal from the Commission, issue directives for the approximation of such provisions laid down by law, regulation or administrative action in Member States as directly affect the establishment or functioning of the common market. The Assembly [European Parliament] and the Economic and Social Committee shall be consulted in the case of directives whose implementation would, in one or more Member States, involve the amendment of legislation. …	**ARTICLE 100 OF THE TREATY OF ROME CURRENTLY CORRESPONDS TO ARTICLE 95 OF ITS CONSOLIDATED VERSION[91]** **Article 95** 1. By way of derogation from Article 94 and save where otherwise provided in this Treaty, the following provisions shall apply for the achievement of the objectives set out in Article 14. The Council shall, acting in accordance with the procedure referred to in Article 251 and after consulting the Economic and Social Committee, adopt the measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market. … 3. The Commission, in its proposals envisaged in paragraph 1 concerning health, safety, environmental protection and consumer protection, will take as a base a high level of protection, taking account in particular of any new development based on scientific facts. Within their respective powers, the European Parliament and the Council will also seek to achieve this objective. …	

[88] The text of the Treaty of Rome can be found at http://ec.europa.eu/economy_finance/emu_history/documents/treaties/rometreaty2.pdf
[89] The text of the Treaty of Maastricht can be found at http://eur-lex.europa.eu/en/treaties/dat/11992M/htm/11992M.html
[90] The text of the Treaty of Amsterdam can be found at http://eur-lex.europa.eu/en/treaties/dat/11997D/htm/11997D.html
[91] Article 100 is currently article 95 in the consolidated version of Treaty of Rome, C 325, O.J., 24 December 2002. The consolidated version can be found at http://eur-lex.europa.eu/en/treaties/dat/12002E/htm/C_2002325EN.003301.html

	TITLE XI - CONSUMER PROTECTION **Article 129a** 1. The Community shall contribute to the attainment of a high level of consumer protection through: (a) measures adopted pursuant to Article 100a in the context of the completion of the internal market; (b) specific action which supports and supplements the policy pursued by the Member States to protect the health, safety and economic interests of consumers and to provide adequate information to consumers. 2. The Council, acting in accordance with the procedure referred to in Article 189b and after consulting the Economic and Social Committee, shall adopt the specific action referred to in paragraph 1(b). 3. Action adopted pursuant to paragraph 2 shall not prevent any Member State from maintaining or introducing more stringent protective measures. Such measures must be compatible with this Treaty. The Commission shall be notified of them.	**TITLE XIV (ex Title XI) - CONSUMER PROTECTION** **Article 153 (ex Article 129a of the Maastricht Treaty)** 1. In order to promote the interests of consumers and to ensure a high level of consumer protection, the Community shall contribute to protecting the health, safety and economic interests of consumers, as well as to promoting their right to information, education and to organise themselves in order to safeguard their interests. 2. Consumer protection requirements shall be taken into account in defining and implementing other Community policies and activities. 3. The Community shall contribute to the attainment of the objectives referred to in paragraph 1 through: (a) measures adopted pursuant to Article 95 in the context of the completion of the internal market; (b) measures which support, supplement and monitor the policy pursued by the Member States. 4. The Council, acting in accordance with the procedure referred to in Article 251 and after consulting the Economic and Social Committee, shall adopt the measures referred to in paragraph 3(b). 5. Measures adopted pursuant to paragraph 4 shall not prevent any Member State from maintaining or introducing more stringent protective measures. Such measures must be compatible with this Treaty. The Commission shall be notified of them.

This table includes the evolution of European product regulation. In a first phase, under the Treaty of Rome, product regulation was part of the common internal market regulation that intended to ensure that domestic regulation did not become a barrier to the free circulation of goods between the member states. Article 3 of the Treaty of Rome provided for the Commission's authority to adopt regulation for the purpose of ensuring the proper functioning of the common market and article 100 laid down the legislative process necessary to adopt regulation with the object of ensuring the proper functioning of the common market. The consolidated version of the Treaty of Rome includes the provision of former article 100 in its article 95, in force today. The product regulation derived from the Treaty of Rome is what the table represents in light blue.

A second phase started with the Treaty of Maastricht under which consumer protection become on of the goals of the European Union – and for that reason was clearly stated in article 3 (s) -- and established n its article 129a the measures that should be adopted in order to achieve this "high level of consumer protection". The area in green represents the relevant provisions regarding consumer protection included in the Treaty of Maastricht.

Finally, the Treaty of Amsterdam has maintained the provisions in force of former article 3 and has slightly amended article 129a of the Maastricht Treaty in its article 153 that today is in force. The orange area represents the relevant provisions on consumer protection included in the Treaty of Amsterdam.

It should be noted that in addition to the provisions included in article 3 as well as article 153 of the Treaty of Amsterdam currently in force, article 95 of the consolidated version of the Treaty of Rome regarding the approximation of laws necessary to ensure the proper functioning of the common market, is still in force today.

CHAPTER 2

EUROPEAN PRODUCTS LIABILITY:

A LEGAL ANALYSIS OF DIRECTIVE 85/374

1. Introduction

1.1 Drafting of the Directive

The origins of European product liability law go back to the European consumer movement of the late 1960s and 1970s. That movement ultimately culminated in the adoption of Council Directive 85/374/EEC of 25 July 1985 on the Approximation of the Laws, Regulations and Administrative Provisions of the Member States Concerning Liability for Defective Products (hereinafter the products liability directive).[92]

Before the adoption of this directive, product liability law was undeveloped in most European member states.[93] Product liability was simply not one of the main priorities of the European legislative agenda at that time. It was not that injured parties were without recourse to seek compensation: most member states had general negligence-based tort systems that provided a basis for victims' recovery even before the Europe-wide product liability system was put in place. However, there was no product liability

[92] Council Directive 85/374/EEC of 25 July 1985 On The Approximation of The Laws, Regulations and Administrative Provisions Of The Member States Concerning Liability for Defective Products O. J. L 210 , 07/08/1985 P. 0029 - 0033. Hereinafter the "product liability directive." See also Anita Bernstein, L'Harmonie Dissonante: Strict Products Liability Attempted in the European Community, 31 Va. J Int'l L. 673, 677-79 (1991). For a description of the consumer movement outside the United States see Warren Freedman, PRODUCTS LIABILITY: AN INTERNATIONAL MANUAL OF PRACTICE, 56 - 103, London; New York: Oceana Publications (1987).

[93] See Jane Stapleton, Bugs in Anglo-American products liability, 53 S. C. L. Rev. 1225, 1230 (2002). See also Andrew C. Spacone, Strict Liability in the European Union - Not a United States Analog, 5 Roger Williams U. L. Rev. 341, 347- 348 (2000).

regulation as such. It was not until the 1960's, with an increase in trade and commercial relations between the different member states and the mass production of consumer goods that it became increasingly apparent that the traditional rules found in European legal systems were inadequate to deal with the modern phenomenon of product accidents.[94]

The change came with the Thalidomide crisis in the 1960s.[95] Thalidomide was a drug developed by a German company in 1956 and used largely by pregnant women to alleviate morning sickness and induce sleep. One of this drug's side effects turned out to be that it could cause birth defects, the first warnings of which were sounded publicly in 1961.[96] Immediately, German authorities recalled the drug and banned its sale. Germany then adopted a pharmaceutical law in 1976, which introduced a strict liability regime for defective medicines.[97] The episode led consumers all over Europe to put pressure on authorities to adopt consumer protection measures -- from both the product safety and product liability perspectives -- and to make the issue a priority for the European Commission.[98]

Given this level of public concern, the European Commission took action drafting a proposal in 1976 of a European Convention on Product Liability in Regard to Personal Injury and Death.[99] The Strasbourg Convention, as this came to be known, was adopted but never implemented because it was signed only by France, Belgium and Luxembourg

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[94] See J.H.H. Weiler, The Transformation of Europe, 100 Yale L. J. 2403, 2456 (1991); Mark Mitchell, A Manufacturer's Duty to Warn in a Modern Day Tower of Babel, 29 Ga. J. Int'l & Comp. L. 573, 579-580 (2001).

[95] In 1962 Thalidomide, a medicine used to prevent miscarriage caused the birth of several thousand deformed babies in Europe. See generally PHILLIP KNIGHTLEY ET AL., SUFFER THE CHILDREN: THE STORY OF THALIDOMIDE, London: Andre Deutsch (1979).

[96] See generally PHILLIP KNIGHTLEY ET AL., SUFFER THE CHILDREN: THE STORY OF THALIDOMIDE, London: Andre Deutsch (1979).

[97] The German Pharmaceutical law, called the *Arzneimittelgesetz,* was adopted on August 24, 1976.

[98]. See Jane Stapleton, Bugs in Anglo-American products liability, 53 S. C. L. Rev. 1225, 1231 (2002) arguing that the product liability directive was a result of the Thalidomide crisis Takahashi Fumitoshi, Japan's Product Liability Law: Issues and Implications, 22 Journal of Japanese Studies, 1, 107 (1996).

[99] This was a Commission Proposal for a Council Directive Relating to the Approximation of the Laws, Regulations, and Administrastive Provisions of the M?ember States Concerning Liability for Defective Products, 19 O.J. Eur. Comm. (No. C 241) 9 (1976).

(then Member States of the EEC) and Austria (then a non-Member) and because it was upstaged by the subsequent product liability directive, a draft of which was presented two weeks prior to the presentation of the final draft of the Strasbourg Convention.[100] The reluctance that many states had to signing the Strasbourg Convention may have resulted from a decision to focus legislative efforts on the product liability directive instead.

The European Commission believed that the Directive could represent a first step in harmonizing product liability laws in Europe.[101] The Commission viewed such harmonization as a necessity and a priority in order to avoid a patchwork of different laws that would leave consumers with varying degrees of protection depending on the state in which they lived,[102] while allowing risks to flow through the internal European market along with the free movement of goods.[103] Considering that the European Community was at the time increasing its membership from six to nine countries,[104] and that the Treaty of Rome, signed twenty years earlier,[105] was only slowly developing, the

[100] See Mark Mitchell, A Manufacturer's Duty to Warn in a Modern Day Tower of Babel, 29 Ga. J. Int'l & Comp. L. 573, 580-581 (2001) for a description of the drafting process of the product liability directive.

[101] See Sandra N. Hurd and Frances E. Zollers, Statutes Of The European Community Member States Passed In Response To The Product Liability Directive, 32 I.L.M. 1347 (1993) and Sandra N. Hurd & Frances E. Zollers, Desperately Seeking Harmony: The European Community's Search for Uniformity in Product Liability Law, 30 AM. BUS. L.J. 35, 47-65 (1992) noting that the product liability directive represented another step towards the integration of the markets of the different member states. See also Commission of the European Communities, Green paper Liability for defective products presented by the Commission on July 28, 1999 COM (1999)396, at 11, final. Available at http://europa.eu/documents/comm/green_papers/pdf/com1999-396_en.pdf; Product liability directive, at preamble. See also Andrew C. Spacone, Strict Liability in the European Union - Not a United States Analog, 5 Roger Williams U. L. Rev. 341, 350 (2000).

[102] See the Preamble of the Commission Proposal for a Council Directive Relating to the Approximation of the Laws Regulations and Administrative Provisions of the Member States Concerning Liability for Defective Products, 1976 Directive. 19 O.J. Eur. Comm. (No. C 241) 9 (1976) which declared that "[w]hereas the approximation of the laws of the Member States concerning the liability of the producer for damage caused by the defectiveness of his products is necessary, because the divergences may distort competition in common market; . . . " See also Anita Bernstein, L'harmonie Dissonante: Strict Products Liability Attempted In The European Community, 31 Va. J. Int'l L. 673, 677-678 (1991).

[103] The European Commission was keen to promote consumer protection measures to show, after the Thalidomide crisis, that the common market was not just for businesses. See Jane Stapleton, Bugs in Anglo-American products liability, 53 S. C. L. Rev. 1225, 1231 (2002).

[104] Denmark, Ireland and the United Kingdom became new members of the European Community in 1973 and joined the founding members Germany, France, Italy, the Netherlands, Belgium and Luxembourg. See http://europa.eu/abc/history/index_en.htm.

[105] Article 3 of the Treaty of Rome provides for the European Commission to devote its efforts to the "*approximation of the laws of the Member States to the extent required for the proper functioning of the common market*."

Commission's rush to propose and to adopt this legislative text at the time may seem somewhat surprising. Two reasons appear particularly relevant for explaining this: First, the undeniable impact of the Thalidomide crisis, which led to public demands throughout Europe for better supervision of drugs and, more generally, a higher degree of consumer protection. In light of the difficulties in drafting the product liability directive, however, this crisis does not appear to fully explain the new shift in the European Commission's regulatory policy. Instead, it may be best viewed in combination with a second possible reason for the Commission's push, which is economics. As the Commission stated in the Directive itself, the existing divergences in member states' consumer protection laws risked distorting competition and affecting the movement of goods within the common market, imposing different economic burdens on their competing industries[106] and entailing a differing degree of protection of the consumer against damage to health and property caused by defective products.[107] Harmonized law, such as product liability, was considered as a way to promote economic and political integration of the member states.[108]

Ensuring a proper functioning of the European common market thus seems to have been a driving force behind this difficult legislative project.[109] The Commission

[106] See Sandra N. Hurd and Frances E. Zollers, Product Liability in the European Community: Implications for United States Business, 31 American Business Law Journal 245, 246-247 (1993).
[107] See the Preamble of the product liabiltiy directive. See also Hans Claudius Taschner, Harmonization of product liability in the European Community, 34 Tex. Int'l L. J. 21, 22 (1999). See also Patrick Thieffry, Philip Van Doorn and Simon Lowe, Strict Product Liability in the EEC: Implementation, Practice and Impact on U.S. Manufacturers of Directive 85/374, 25 Tort & Insurance Law Journal 65, 90 (1989-1990).
[108] Hans Claudius Taschner, Harmonization of product liability in the European Community, 34 Tex. Int'l L. J. 21, 23 (1999).
[109] This was explained to me by Pr. Dr. Ivo Schwartz, one of the drafters of the Directive, when I had the opportunity to meeting him at the Zeup meeting that was held in Barcelona in October 2003 and had the chance to have a long and profitable conversation where he shared his experiences in the Directive's drafting process with me. Despite the Commission's interest in the proper functioning of the internal market, there is no empirical evidence showing that divergent rules of products liability law represented a significant obstacle to the free movement of goods within the European member states. See Schwartz, Ivo E.and Will, Michael R., Wie geht es weiter mit der produkthaftung?, ZEUS 5 (Zeitschrigt fur Europearechtliche studien), 14 (2002). See also Lawrence C. Mann and Peter R. Rodrigues, The European Directive on PL: the promise or progress ?, 18 Ga. J. Int'l & Comp. L. 391, 403-404 (1988) arguing that in light of the lack of evidence for the need of a uniform product liability directive for the proper functioning of the internal market, consumer protection might have been the main goal of the Directive.

feared that given the free movement of goods, services and people within the European Community area, member states would be tempted to protect their own industries through product liability laws, and to thus compete with each other in a "race to the bottom" in terms of minimizing the risk of liability.[110] The result would be a low level of protection for European consumers.[111]

Given the historical context in which the Directive was drafted with the Thalidomide crisis as a background, the European Commission's fears regarding the potential failure in the European internal market, and the reluctance of the different member states to commit to a product liability regulation at the European level, it is not surprising that drafting and agreeing on the legal text was a difficult and slow process.

The draft of the Directive proposed by the Commission was repeatedly revised because of pressure from the governments of the different member states, which were reluctant to transfer regulatory power to the institutions of the European Community and feared that the Directive would adversely impact their domestic industries. Industry also feared the draft Directive's strict liability regime, particularly given perceptions of the history of strict product liability in the United States, which many blamed for causing an increase in U.S. litigation and, consequently, an increase in insurance-related costs.[112] At

[110] If member states would complete in lowering product liability in order to protect their manufacturers, states with low levels of consumer protection would provide fewer incentives to make high quality products given that they would have lower incentives for avoiding liability. By contrast, in states where liability laws were more demanding and hence expected liability was higher, manufacturers would have incentives to invest in higher product safety. If that discrepancy existed, differences in liability laws would condition the decisions of the manufacturers of the different member states and hence affect free movement of goods within the European market. For that reason, the European Commission believed that rules affecting the functioning of the internal market should be harmonized. See Geraint G. Howells, The rise of European Consumer Law - Whither National Consumer Law?, 28 Sydney Law Review 63-88, 70 (2006). See also Robert C. Weber, E.C. Directive Follows U.S. No-Fault Approach, But Litigation Is Rare, NAT'L L.J., 30 (1991) defending the need of for harmonized product liability regulation in Europe because a unique product liability regulation would encourage producers to produce products whose quality correspond to the expected liability they are exposed to regardless of the liability laws of the different member states so that cross-border trade was not affected.

[111] See Schwarts, Ivo E.and Will, Michael R., Wie geht es weiter mit der produkthaftung?, ZEUS 5 (Zeitschrigt fur Europearechtliche studien), 14 (2002).

[112] See Gorege L Priest The Current Insurance Crisis and Modern Tort Law, 96 Yale L. J. 1521 (1987) noting the relationship between product liability regimes and insurance premiums. However, the development of the strict product liability regime established by the Directive has not had the same effects

the same time, individuals, consumer associations, and other groups that were affected by the Directive and allowed to participate in the drafting process, also manifested their skepticism about the text.[113]

Consensus among the parties involved was difficult to reach in two respects. First, the European institutions responsible for drafting the Directive -- namely, the Commission and the Parliament -- were in disagreement over the strict liability standard. While the Commission thought its goal of consumer protection was best achieved through strict liability, the Parliament questioned the need of the industry or consumers for greater protection[114] and stated that the proposal lacked a jurisdictional basis under the Treaty of Rome.[115] In 1976, the European Economic and Social Committee[116] supported the proposed Directive. But member states feared the economic consequences of a strict liability regime on their domestic industries and on the competitiveness of European industry as a whole.[117]

This complicated process, which had a direct impact on the design of the Directive and the structure of its regime, continued with a second draft of the Directive

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as the former U.S. strict product liability. Alfred E. Mottur, The European Product Liability Directive: A Comparison With U.S. Law, An Analysis Of Its Impact On Trade, And A Recommendation For Reform So As To Accomplish Harmonization And Consumer Protection, 25 Law & Pol'y Int'l Bus. 983, 1004 (1994).

[113] This process contrasts with the evolution experienced in the U.S. that at the time did not involve a public debate as the European.

[114] See Kathleen M. Nilles, Note, Defining the Limits of liability: A legal and political analysis of the European Community Products Liability Directive, 25 Va. J. Int'l L., 729, 757-58 (1985).

[115] The European Parliament, through the Legal Affairs Committee and the Committee on the Environment, Public Health, and Consumer Protection, commented this issue in this opinion. Eur. Parl. Doc. (COM 71) 1979.

[116] See Economic and Social Committee (ECOSOC) Report on Proposal for a Council Directive on Liability for Defective Products, COM(76)372 final at 41-45. See, later, the Opinion on the Proposal for a Council Directive Relating to the Approximation of the Laws, Regulations and Administrative Provisions of the Member States Concerning Liability for Defective Products, 1979, O.J. (C 114) 15 (1979).

[117] During that decade there was a big impulse on increasing the size of the European common market. The number of member states doubled so that in addition to the six initial member states (Belgium, West Germany, Luxembourg, France, Italy and the Netherlands); Britain, Ireland, and Denmark became members and then later Greece, Spain, and Portugal joined the European Community as well. J.H.H. Weiler, The Transformation of Europe, 100 Yale L. J. 2403, 2456 (1991). See also Europe at a glance http://europa.eu/abc/history/index_en.htm

presented by the European Commission in 1979[118] and the final adoption of the Directive in 1985.[119] Some consider that the long nine-year process from the first initiative in 1976 until its final adoption in 1985 was due to the Europeans' fixation on the U.S. experience as well as to general nervousness over introducing a strict product liability regime.[120] It is difficult to know the extent to which European authorities were learning from the U.S. experience during those long nine years. However, what seems likely is that the fears and skepticism involved in this process led to the significantly different wording used in the Directive ultimately adopted, as compared to the text initially proposed by the Commission.[121]

The Commission was so committed to its pro-consumer argument that in its first draft it even went beyond strict liability and suggested a form of absolute liability under which the producer would not be permitted to present any evidence to prove its lack of knowledge of a product's risk at the time the product was put into circulation.[122] This included evidence that the state of scientific and technical knowledge at the time when the product went into circulation was not such as to enable the existence of the risk to the

[118] Amendment of the Proposal for a Council Directive Relating to the Approximation of the Laws, Regulations and Administrative Provisions of the member States Concerning Liability for Defective Products, O.J. Eur. Comm. C 271, 3 (1979).

[119] The product liability directive came nine years after the first draft of the Directive was proposed. See Sandra N. Hurd and Frances E. Zollers, Statutes Of The European Community Member States Passed In Response To The Product Liability Directive, 32 I.L.M. 1347, 1348 (1993). See also Jane Stapleton, Bugs in Anglo-American products liability, 53 S. C. L. Rev. 1225, 1231 (2002) stating that the result of such a difficult negotiating process is a "directive (…) of the high water marks of Euro fudge and textual vagueness." In the same line see Geraint Howells, Europe's Solution to the Product liability phenomenon, 20 Anglo-Am. L. Rev. 204, 206 (1991) noting that many of the criticisms that can be made to the directive arise from the need to compromise between the different member states.

[120] Mark Mitchell, A Manufacturer's Duty to Warn in a Modern Day Tower of Babel, 29 Ga. J. Int'l & Comp. L. 573 (2001).

[121] See the Opinion of Mr. Advocate General Tesauro delivered on 23 January 1997 in the case of the Commission of the European Communities v United Kingdom of Great Britain and Northern Ireland; Case C-300/95; 1997 ECJ CELEX LEXIS 13458, p. 16-17.

[122] Article 1 of the Proposal for a Council Directive relating to the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products. COM (76) 372 final, 23 July 1976. Bulletin of the European Communities, Supplement 11/76 stated that the producer of an article would be held liable for damage caused by a defect in the article, whether or not he knew or could have known of the defect in the light of the scientific and technological development at the time when he put the article into circulation. Such liability system was equivalent to the imposition of absolute liability on producers.

discovered -- the so-called "development risks" defense. Under this proposal, liability would have been imposed regardless of the producer's knowledge of the risk; producers would have been held liable for product risks that appeared even after the product was put into circulation and that made the product defective, irrespective of whether those risks were known before the product was marketed.[123] The European Parliament, though, strongly opposed the Commissions' position on the development risks defense.[124]

The final draft of the product liability directive balanced both positions by introducing strict product liability in Europe while allowing member states to decide whether to introduce the development risks defense when transposing the Directive into their domestic laws. Strict liability was justified as a harmonized regime because it was believed not to threaten the comparative advantage of any domestic industry with respect to its neighbors[125] while preserving the principle of fair apportionment of risks between producers and potential victims[126] through the introduction of the development risks defense and by facilitating injured victims to pursue their product claims and seek compensation.[127]

However, despite its intentions, all of the problems in reaching consensus during the Directive's drafting process led to a text that goes only half way toward its goal of

[123] See Proposal for a Council Directive relating to the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products, COM (76) 372 final, 23 July 1976.
[124] See Josephine Liu, Two roads diverged in a yellow wood: the European Community stays on the path to strict liability, 27 Fordham Int'l L J. 1940, 1953-1954 (2004) explaining the European Parliament's position on the proposal.
[125] See Sandra N. Hurd & Frances E. Zollers, Desperately Seeking Harmony: The European Community's search for Uniformity in Product Liability Law, 30 Am. Bus. L. J. 35 (1992) and Geraint G. Howells & Mark Mildred, Is European Products Liability More Protective Than The Restatement (Third) Of Torts: Products Liability?, 65 Tenn. L. Rev. 985, 993 (1998).
[126] See Calabresi & Hirschoff, Toward a Test for Strict Liability in Torts, 81 Yale L. J. 1055, 1075-76 (1972) stating that the move towards strict liability responded to a goal of minimizing accident costs and hence minimize accidents as well as providing injured victims with an easier and more predictable liability instrument compared to liability based on fault.
[127] Andrew C. Spacone, Strict Liability in the European Union - Not a United States Analog, 5 Roger Williams U. L. Rev. 341, 350 (2000).

harmonizing the product liability regime in Europe and introducing strict liability for the first time.

From a harmonization perspective, the Directive was intended to establish a common product liability regime for all member states that would ensure that European manufacturers where exposed to the same potential liability anywhere in Europe. However, this goal did not fully materialize in that the final version ultimately allowed some variation between member states in their transposition. As already noted, member states could choose whether or not to allow for development risk defenses. In addition, they could choose whether or not to place caps on damages.[128] In practice, this has led to a variation in the product liability laws adopted in each member state.[129]

In terms of substance, the Directive was intended to introduce strict product liability in Europe.[130] For the first time, producers would be liable for the harm caused by defective products they put into circulation regardless of their level of care when producing them. The economic effect of a strict liability regime is such that producers become the victims' insurers for the harm caused by their defective products because they bear the risks of this harm regardless of care.[131] This is generally considered an

[128] See below. The issues left for the member states to decide whether to include them or not in their domestic transposition regulation were the inclusion of the "development risk" defense, the existence of a cap on damages awarded for death and personal injury resulting from the defective product and the possibility of including agricultural products. However, in 1997 the mad cow crisis lead the European Commission to propose the modification of the Directive 85/374/EEC and to include agricultural products and hold producers accountable. Therefore, the Directive was amended in the year 1999 by the Directive 99/34/EC, OJ L 141 and primary agricultural products such as meat, cereals; fruit, vegetables and game were included within the scope of application of the Directive.

[129] See infra a table on the adoption of these provisions by the different member status.

[130] The adoption of a strict product liability regime is not unanimously shared in the literature. See, for example, William Powers, Jr., A modest proposal to abandon strict products liability, 1991 U. Ill. L. Rev. 639, 640 (1991), claiming that strict liability rests on two premises -- that product cases are significantly different from other types of personal injury cases and that product cases are substantially homogeneous among themselves -- and arguing that such assumptions are flawed because strict products liability is neither a general approach to personal injury law nor a system of strict liability at all. For a defense of strict product liability see Guido Calabresi & Jon T. Hirshoff, Toward a Test for Strict Liability in Torts, 81 Yale L. J. 1055 (1972).

[131] This is what in economic terms is called the residual bearer. In this situation, producers would be the residual bearers of the injured victim's losses not worth preventing. See Shavell, Steven, ECONOMIC ANALYSIS OF ACCIDENT LAW, Cambridge, Mass.: Harvard University Press, 47 (1987). See also Sheila L.

economically efficient liability system in light of the asymmetric information of producers and consumers regarding product risks (producers generally have a comparative advantage over the knowledge of product risks) and of the producers' better access to insurance against such risks.[132]

However, the ultimate text of the Directive betrays a fear that a strict liability regime would be too burdensome, and while it speaks of strict liability, it also includes a number of care considerations,[133] which significantly distort the nature and impact of its attempt at strict liability.

Because of the low confidence member states had during the Directive's drafting process, the final text included a revision clause under which, every five years, the Commission would issue a report about the Directive's implementation and impact, and about potential improvements that could be made to it.[134] The first report was issued in 1995,[135] the second in 2001,[136] and the third in 2006.[137] Thus far, the reports have suggested removing or increasing member states' damage caps, including pain and

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Birnbaum, Legislative reform or retreat? A response to the product liability crisis, 14 Forum 251, 253 (1978-1979).

[132] Richard Epstein, Product liability as an insurance market, 14 Journal of Legal Studies 645 (1985).

[133] See Preamble and article 7(e) of the product liability directive.

[134] Article 21 of the Directive. These revisions are preceded by consultations open to all interested parties and the reports adopt the form of Green Papers. These consultations give public authorities, consumer organizations and all interested parties an opportunity to participate actively in the debate on liability for defective products.

[135] Report on the application of council directive on the approximation of laws, regulations and administrative provisions of the member states concerning liability for defective products, COM (95) 617 final, 13.12.1995. The document can be found in http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:1996:0013:FIN:EN:PDF

[136] Report from the Commission on the Application of Directive 85/374 on Liability for Defective Products, COM(2000) 893 final, Brussels, 31.1.2001. The document can be found in http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2000:0893:FIN:EN:PDF

[137] Report on the application of Council Directive on the approximation of laws, regulations and administrative provisions of the Member States concerning liability for defective products (85/374/EEC of 25 July 1985, amended by Council Directive 1999/34/EC of the European Parliament and of the Council of 10 May 1999), COM(2006) 496 final, Brussels, 14.9.2006. This document can be found in http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2006:0496:FIN:EN:PDF

suffering in damage calculations, and excluding the so-called "development risks defense." These proposals, however, have led to very few changes in the law.[138]

1.2 Member states' domestic product liability laws prior to the Directive

Before the adoption of the product liability directive with its strict liability (or quasi-strict liability) rules, injured victims seeking compensation needed to look to domestic tort law, and this was not uniform across Europe. No European member state had a formal rule comparable to the wording of the Directive or to §402A of the U.S. Restatement (Second).[139] There were however, laws applicable to harm caused by products. The introduction of the Directive did not eliminate these pre-existing laws that remained applicable to products or types of harm not covered by the Directive.[140] Additionally, even though the Directive was intended to be a mandatory text, member states could still apply domestic laws that were stricter than those required under the Directive.[141] Hence, injured victims today often have a choice of suing under the product liability directive (as transposed domestically) or suing under pre-Directive legal instruments of redress, such as tort, contract or various special liability systems to the extent that states have opted to keep these instruments in force.

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[138] See Andrew C. Spacone, Strict Liability in the European Union - Not a United States Analog, 5 Roger Williams U. L. Rev. 341, 374 (2000) referring to the problems in writing the first report due to the lack of available data.

[139] Restatement (Second) of Torts (1965).

[140] See articles 8, 10 and 13 of the Directive 85/374 referring to domestic regulation. Article 13 is of special importance because it preserves the rights and injured person may have under contractual or non-contractual liability regulation in force in the member states before the Directive was adopted. See also the John Meltzer, Reform of Product Liability in the EU: New Report Finds General Satisfaction, 71 Defense Counsel Journal 42, 49 (2004).

[141] This duality has often been considered a serious handicap of the European regulatory structure in terms of determining which the applicable law is. See Thomas M.J. Mollers, The Role of Law in European Integration, 48 Am. J. Comp. L. 679, 683-684 (2000).

The structure of the European Union (and its predecessors) allows each member state to interpret its domestic law and determine the changes necessary to bring this law in line with European legislation.[142] This has led most, if not all, member states to switch from fault-based or contract-based product liability systems to product liability systems based on strict liability.[143]

Before the European Directive, the product liability laws of the individual member states varied greatly. There were, however, some features that the laws shared in common:[144]

(1) Member states had specific product liability statutes in force.[145]

(2) Liability was available under breach of contract rules.

(3) Liability in tort was available after proving fault. Presumption of fault and reversal of the burden of proof were available in some jurisdictions, but there was no such thing as a strict product liability regime.[146]

(4) The rules of each jurisdiction were detailed and full of exceptions.

Although the legal systems of most of the European member states share a similar heritage, the product liability regimes of the nine member states that formed the European

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[142] Even though the Directive's transposition into domestic legal systems is performed by legislators of the member states the Commission is the one able to determine whether this transposition has been conducted properly or not and in requesting the necessary changes to be adopted. Failure of a member state in complying with the Commission's requests could result in a judicial proceeding against such member state before the European Court of Justice.

[143] For a broad description of the different European member states before the implementation of the Directive and other product liability regimes such as the Australian or the U.S. regimes see generally Dennis Campbell, INTERNATIONAL PRODUCT LIABILITY, general editor, Christian T. Campbell editor; London; New York: Lloyd's of London Press (1993). See also William C. Hoffman and Susanne Hill-Arning, GUIDE TO PRODUCT LIABILITY IN EUROPE: THE NEW STRICT PRODUCT LIABILITY LAWS, PRE-EXISTING REMEDIES, PROCEDURE AND COSTS IN THE EUROPEAN UNION AND THE EUROPEAN FREE TRADE ASSOCIATION, Deventer; Boston: Kluwer Law and Taxation Publishers (1994) and see also Patrick Kelly, Rebecca Attree, EUROPEAN PRODUCT LIABILITY, London: Butterworths (1992).

[144] See Christopher J.S. Hodges, PRODUCT LIABILITY: EUROPEAN LAWS AND PRACTICE, 5, Sweet & Maxwell (1993) noting the specifics of individual member states.

[145] Christopher Hodges ed., PRODUCT LIABILITY: EUROPEAN LAWS AND PRACTICE, 328, Sweet & Maxwell (1993).

[146] Christopher Hodges ed., PRODUCT LIABILITY: EUROPEAN LAWS AND PRACTICE, 452, Sweet & Maxwell (1993) discussing treatment of burden of proof in Italy, at 391 discussing treatment of burden of proof in Greece, and at 589 discussing treatment of burden of proof in Spain.

Community when the first draft of the product liability Directive was presented in 1976[147] could be divided into three major groups:[148] A first group was composed of three civil law countries, France, Belgium, and Luxembourg, in which courts had developed an extensive product liability law based on contractual liability and on commercial warranty law.[149] These countries considered warranties to last for the entire life of a product and, therefore, imposed de facto strict product liability.[150]

A second group of countries was formed by Italy and the three countries that joined the European Community during or after the Council deliberations on the product liability directive: Greece in 1981, and Spain and Portugal in 1986. This group was characterized by fault-based product liability regimes with the burden of proof on the injured victim. Thus, plaintiffs had to produce evidence of the tortfeasors' fault and breach of warranty based on such fault was not presumed.[151]

The last group was formed by United Kingdom and Ireland, both common law countries, along with Germany, the Netherlands, and Denmark. The courts of these states had developed an intermediate solution between protecting industry and consumer interests by requiring plaintiffs to show evidence of breach of warranty or fault while

[147] The nine member states in 1977 were France, Belgium, Luxembourg, Italy, United Kingdom, Ireland, Germany, The Netherlands, and Denmark. During the negotiation process of the Directive Greece, Spain and Portugal joined the European Community. See generally CULTURE AND EUROPEAN UNION LAW, Rachael Craufurd Smith (ed.). Oxford University Press (2004).

[148] See Sandra N. Hurd & Frances E. Zollers, Desperately Seeking Harmony: The European Community's Search for Uniformity in Product Liability Law, 30 Am. Bus. L.J. 35, 47-65 (1992) presenting the different negligence and warranty claims in force in the different member states prior to the adoption of the Product Liability Directive.

[149] See William C. Hoffman and Susanne Hill-Arning, GUIDE TO PRODUCT LIABILITY IN EUROPE: THE NEW STRICT PRODUCT LIABILITY LAWS, PRE-EXISTING REMEDIES, PROCEDURE AND COSTS IN THE EUROPEAN UNION AND THE EUROPEAN FREE TRADE ASSOCIATION, 14, Deventer; Boston: Kluwer Law and Taxation Publishers (1994).

[150] See Anita Bernstein, L'Harmonie Dissonante: Strict Products Liability Attempted in the European Community, 31 Va. J Int'l L. 673, 697-700 (1991).

[151] William C. Hoffman and Susanne Hill-Arning, GUIDE TO PRODUCT LIABILITY IN EUROPE: THE NEW STRICT PRODUCT LIABILITY LAWS, PRE-EXISTING REMEDIES, PROCEDURE AND COSTS IN THE EUROPEAN UNION AND THE EUROPEAN FREE TRADE ASSOCIATION, 40, 72 Deventer; Boston: Kluwer Law and Taxation Publishers (1994).

placing the burden of proof on producers to prove that they were not negligent when they manufactured the product.[152]

It was not until 1985, with the adoption of the European product liability directive, that strict products liability, at least in the formal sense, became part of the European legal scene.[153]

1.2.1 Spanish product liability before and after the transposition of Directive 85/374

Spanish law, both before and after the adoption of the product liability directive, has had different sources of regulation under which injured victims can seek compensation for the harm suffered: contracts and tort law.[154]

Contracts are regulated in the Spanish Civil Code of 1889.[155] The civil code establishes the general principle of the effects of contracts between parties or their heirs[156] and establishes that a seller is liable to the buyer for breach of contract or for

[152] See William C. Hoffman and Susanne Hill-Arning, GUIDE TO PRODUCT LIABILITY IN EUROPE: THE NEW STRICT PRODUCT LIABILITY LAWS, PRE-EXISTING REMEDIES, PROCEDURE AND COSTS IN THE EUROPEAN UNION AND THE EUROPEAN FREE TRADE ASSOCIATION, 22, 30, 66, Deventer; Boston: Kluwer Law and Taxation Publishers (1994). See also Rebecca Korzec, Dashing Consumer Hopes: Strict Products Liability and the Demise of the Consumer Expectations Test, 20 B.C. Int'l & Comp. L. Rev. 227, 223 (1997).

[153] S. Mark Mitchell, A Manufacturer's Duty to Warn in a Modern Day Tower of Babel, 29 Ga. J. Int'l & Comp. L. 573 (2001).

[154] For an explanation on the distinctive characteristics of Spanish contractual and tort law see Luis Díez-Picazo, DERECHO DE DAÑOS, 246, Cívitas, Madrid (1999).

[155] Spanish Civil Code of 1889, Royal Decree of July 24 of 1889, published in the Gaceta of Madrid the reformed edition of the Civil Code.

[156] Article 1257 CC states that

> "*Los contratos sólo producen efecto entre las partes que los otorgan y sus herederos; salvo, en cuanto a éstos, el caso en que los derechos y obligaciones que proceden del contrato no sean transmisibles, o por su naturaleza, o por pacto, o por disposición de la ley.*
> *Si el contrato contuviere alguna estipulación en favor de un tercero, éste podrá exigir su cumplimiento, siempre que hubiese hecho saber su aceptación al obligado antes de que haya sido aquélla revocada*."

hidden defects that the object of the contract might have.[157] The responsibility of the seller is also established by Law 23/2003 of July 10 on Warranties in the Sale of Consumer Goods.[158] However, under contract law -- both under the Civil Code and under Law 23/2003 on Warranties in the Sale of Consumer Goods -- privity of contract is a requirement for liability. Consequently sellers are not liable to third parties who are not in privity of contract.

The civil code also regulates liability for intentional and non-intentional torts.[159] Injured victims of intentional torts or torts caused by negligence may seek compensation under article 1101 CC.[160]

"*Contracts will take effects between parties that enter into them and their heirs; except, regarding these, in the case in which the rights and obligations deriving from the contract would not be transferable or for its nature, or because of an agreement or for the provision of the law.*
If the contract contained any right in favor of a third party, such party would be allowed to request its performance, as long as such third party would have communicated its acceptance to the obligor before the provision in favor of the third party was revoked."

[157] Article 1484 CC provides that

"*El vendedor estará obligado al saneamiento por los defectos ocultos que tuviere la cosa vendida, si la hacen impropia para el uso a que se la destina, o si disminuyen de tal modo este uso que, de haberlos conocido el comprador, no la habría adquirido o habría dado menos precio por ella; pero no será responsable de los defectos manifiestos o que estuvieren a la vista, ni tampoco de los que no lo estén, si el comprador es un perito que, por razón de su oficio o profesión, debía fácilmente conocerlos.*"

"*The seller will have to remedy any hidden defects of the object sold whenever such defects would render the object inadequate for the purpose for which it was intended, or they would decrease its intended used in a way that had the buyer known of them he would not have acquired it or would have paid a lower price for it; but the seller will not be liable for obvious defects or defects in plain view, and defects not in plain view in cases where the buyer was an expert that because of its profession, should have easily known them."*

This principle is also established by article 335 of the commercial code of 1885.

[158] Ley 23/2003, de 10 de julio, de Garantías en la Venta de Bienes de Consumo (BOE núm. 165, de 11-07-2003, pp. 27160-27164). This law has been repealed by the Royal Decree 1/2007 of November 16, for which approved the merged text of the General Law for the Defense of Consumers and users and other complementary laws (BOE num. 287, de 30-11-2007, pp. 49181-49215).

[159] In fact, while there was no specific standard regarding liability for damages caused by defective products, injured victims find a remedy applying contract law based on the relationship between the tortfeasor and the injured victim. If there was no contract between both parties, extra contractual rules would apply. See Antonio J. Vela Sanchez, Products liability in Spain, 32 Tex. Tech. L. Rev. 979 (2001).

[160] Article 1101 of the Spanish civil code provides that

"*Quedan sujetos a la indemnización de los daños y perjuicios causados los que en el cumplimiento de sus obligaciones incurrieren en dolo, negligencia o morosidad, y los que de cualquier modo contravinieren al tenor de aquéllas*."

"*Compensation should be provided for harm caused intentionally, negligently or deliquently and the ones derived from such conducts*"

Tort liability is also regulated by the Spanish civil code but consumer protection relies on a number of additional laws as well. The general principle in Spain of liability for non-intentional harm outside of contract law was long based on negligence. The Civil Code provides that anyone whose negligent actions or omissions -- or the actions or omissions of others -- cause harm to others must repair this harm.[161] But the civil code is not the only source of consumer protection law in Spain.[162] In fact, Spain was one of the few countries to adopt strict liability laws prior to the promulgation of the product

[161] Article 1902 CC establishes that

"*El que por acción u omisión causa daño a otro, interviniendo culpa o negligencia, está obligado a reparar el daño causado*."

"Whoever caused damage to another by act or omission, because of fault or negligence, is obliged to repair the damage caused."

Article 1903 CC provides respondent superior liability and establishes liability for harm caused by others.

"La obligación que impone el artículo anterior es exigible, no sólo por los actos u omisiones propios, sino por los de aquellas personas de quienes se debe responder.
Los padres son responsables de los daños causados por los hijos que se encuentren bajo su guarda.
Los tutores lo son de los perjuicios causados por los menores o incapacitados que están bajo su autoridad y habitan en su compañía.
Lo son igualmente los dueños o directores de un establecimiento o empresa respecto de los perjuicios causados por sus dependientes en el servicio de los ramos en que los tuvieran empleados, o con ocasión de sus funciones.
Las personas o entidades que sean titulares de un centro docente de enseñanza no superior responderán por los daños y perjuicios que causen sus alumnos menores de edad durante los períodos de tiempo en que los mismos se hallen bajo el control o vigilancia del profesorado del centro, desarrollando actividades escolares o extraescolares y complementarias.
La responsabilidad de que trata este artículo cesará cuando las personas en él mencionadas prueben que emplearon toda la diligencia de un buen padre de familia para prevenir el daño."

"The obligation imposed in the precedent article is due, not only for the acts or omissions of their own, but also for the acts of other individuals for whom one must respond.
Parents are responsible for the damage caused for the children that are under their care.
Tutors are responsible for the damages caused by minors or disabled individuals that are under their authority and live in their company.
Similarly the owners or manager of a shop or of a company for the damage caused by its employees in the exercise of their duties or of their professional functions.
The individuals or entities who are holders of an elementary school will be liable for the harm caused by the minor-aged students during the periods of time in which they were under the control or supervision of teachers in the school, developing activities in the school or extracurricular and complementary activities.
The liability established in this article shall cease when the individuals mentioned herein prove that they employed the diligence of a good head of a family in order to prevent harm."

[162] See Antonio J. Vela Sanchez, Products liability in Spain, 32 Tex. Tech. L. Rev. 979, 985 (2001) describing the different sources oif regulation that would result in liability for the harm caused by products to users or consumers.

liability directive. Strict liability was first introduced in Spain in Law 26/1984 of July 19 on Defense of Consumers and Users,[163] which made manufacturers strictly liable for harm caused by their products, albeit in very restricted and specific circumstances.[164]

In the same way that the Thalidomide crisis led the European Commission to consider consumer protection as a priority and to introduce strict product liability in Europe, Spain's introduction of strict product liability was also based on a catastrophe: In 1981, industrial oil that contained toxic elements was sold to consumers and caused more than 300 deaths and thousands of injuries.[165] In light of this disaster the Spanish legislature responded with the imposition of strict liability on producers of certain products through Law 26/1984, for the defense of consumers and users (LGDCU).[166] In the early 1990s, when the case reached the Spanish Supreme Court, the Court held criminally liable the perpetrators of the contamination[167] and imposed liability on the state for the negligent activity of the public servants who authorized the faulty oil manipulation without properly ensuring the oil's quality and safety for consumers.

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[163] Law 26/1984, of July 19, General for the defense of consumers and users (BOE num. 175 and 176, of 24-07-1984) (hereinafter LGDCU).

[164] See article 28.1 of law 26/1984 establishing that

> *"No obstante lo dispuesto en los artículos anteriores, se responderá de los daños originados en el correcto uso y consumo de bienes y servicios, cuando por su propia naturaleza o estar así reglamentariamente establecido, incluyan necesariamente la garantía de niveles determinados de pureza, eficacia o seguridad, en condiciones objetivas de determinación y supongan controles técnicos, profesionales o sistemáticos de calidad, hasta llegar en debidas condiciones al consumidor o usuario."*
>
> *"Notwithstanding the established in the preceding articles, liability will be imposed for the harm caused by the correct use and consumption of goods and services, when for its nature or for the regulation applicable to it, include guarantees of certain levels of purity, effectiveness or safety, that can be determined in objective conditions and would represent technical controls, professional or systematic controls of quality, so that it would reach the consumer or user in the adequate conditions."*

[165] This is the case known as the Colza oil case. See Emilio Jimenez Aparicio "La ejecución de la Colza I" in Indret 1/2003 and "La ejecución de la Colza II" in Indret 3/2003. These documents can be found in www.indret.com

[166] R. Bercovitz: LA RESPONSABILIDAD POR LOS DAÑOS Y PERJUICIOS DERIVADOS DEL CONSUMO DE BIENES Y SERVICIOS, ed. Tecnos, Madrid, 224 (1987).

[167] Spanish Supreme Court, Section 2, Caso de la Colza, RJ 1992/6783, 23.4.1992 (Decision by Hon. Enrique Bacigalupo Zapater).

A year later, in 1985, the strict liability rules of the product liability directive were adopted by the European Commission and Spain entered the European Community in 1986. However, Spain did not transpose this Directive until 1994.[168] That transposition provided for a uniform liability claim for any harm caused by a defective product regardless of the relationship between the manufacturer and the injured victim – either user or consumer.

The diversity of legislation bearing on product liability in Spain has led the Spanish legislature to systematize and organize its laws in this area in order to avoid confusion as well as eliminate contradictory provisions. In 2007, it passed Royal Decree 1/2007 under which all product liability laws have been consolidated into a single law.[169] While it remains to be seen how this law will be applied by Spanish courts (which have not yet addressed it),[170] Royal Decree 1/2007 does not purport to make any substantial modifications to Spanish product liability law but instead largely systematizes the different acts into a single law. The only remarkable novelty introduced by this Royal Decree is its treatment of defective services -- an area not covered by the European product liability directive.[171]

1.2.2 The product liability directive's complete harmonization goal and its transposition by member states

[168] Law 22/1994 of July 6, of Liability for harm caused by defective products (BOE núm. 161, of 07-07-1994).
[169] Royal Decree 1/2007 of November 16, for which approved the merged text of the General Law for the Defense of Consumers and users and other complementary laws (BOE núm. 287, de 30-11-2007, pp. 49181- 49215) (hereinafter RDL 1/2007).
[170] For this reason all the cases cited and references to the Spanish product liability law transposing the Directive will cite law 22/1994.
[171] Articles 147-149 of RDL 1/2007 deal with liability for defective services.

Consumer protection was a legislative competence transferred to the European Commission in 1993 through article 129a of the Maastricht Treaty.[172] This competence was transferred to ensure a high level of consumer protection, through information and education, in such areas as health, safety and economic concerns.

The Maastricht Treaty identified two types of legislative measures the European Community could adopt regarding consumer protection: (1) measures to complete the internal market and facilitate economic integration through the harmonization of member states' domestic laws,[173] and (2) measures to support, supplement and monitor the policies pursued by the member states.

The harmonization goal in consumer protection regulation meant establishing common rules to ensure the proper functioning of the European internal market, but these common rules were to be flexible enough to give members states a choice of the instruments and standards to be used in implementing them.[174] Hence, harmonization did and still does imply not so much a simple uniformity of regulation but more a common approach with the determination of specific content left to member states. It is easy to understand, then, that the compromise achieved between member states and the European Commission was such that the European authorities would establish harmonized regulation regarding the competences given to them by the Maastricht Treaty but member states would still have some room to adopt secondary or complementary regulation to enhance or increase the consumer protection levels established by the European harmonized regulation.

[172] Treaty of the European Union (Maastricht Treaty), O. J. C 191, 29 July 1992. The Amsterdam Treaty, O. J. C 340, 10 November 1997 amended the Maastricht Treaty in 1999 and this article became article 153.
[173] These measures would be adopted pursuant article 95 (ex 100a) of the Traty of the European Union.
[174] European Consumer Law Group, Legal bases for EC consumer policy ECLG/036/05 (2005). This document can be found at
http://212.3.246.142/Common/GetFile.asp?ID=16576&mfd=off&LogonName=GuestEN

One of the major goals of the product liability directive was to harmonize product liability regulation across the European member states.[175] This goal has been repeatedly supported by the European Court of Justice in procedings against different member states. In such cases, the Court has considered both technical issues[176] and important policy questions such as whether strict liability extends to product suppliers in addition to product manufacturers.

The Directive seeks maximum harmonization[177] given that consumer protection is still today a high priority regulation area for the European Commission[178] and hence considered necessary to minimize domestic variation in consumer protection rules that could create fragmentation of the internal market to the detriment of consumers and business.

Therefore, member states had to properly transpose the Directive and amend their existing domestic legislation to avoid contradicting or overlapping with the Directive.[179]

The European Court of Justice has held that article 13 of the Directive means that a member state may not maintain a general system of product liability different from that provided by it.[180] But at the same time the Court has held that the Directive allows the co-

[175] See Stephen Weatherill, EU CONSUMER LAW AND POLICY, Edward Elgar, Cheltenham-Northampton 144 (2005).
[176] See Commission v. France C-52/00 (2002) ECR I-3827 where France extended the Directive's product liability regime for harm under 500 euros, which was the minimum threshold the Directive required in article 9 b in order to be able to file a product liability prima facie case.
[177] Simon Whittaker, LIABILITY FOR PRODUCTS: ENGLISH LAW, FRENCH LAW AND EUROPEAN HARMONIZATION, Oxford: Oxford University Press 436-444 (2005). See also Geraint G. Howells, The rise of European Consumer Law – Whither National Consumer Law?, 28 Sydney Law Review 63-88, 77 (2006).
[178] See the Commission's Consumer Policy Programme for 2002-2006 (COM 2002) 208). This document can be found at http://eur-lex.europa.eu/pri/en/oj/dat/2002/c_137/c_13720020608en00020023.pdf
[179] See ECJ C-177/04, Commission v. France (2006) where France extended the Directive's product liability regime for harm under 500 euros, which was the minimum threshold the Directive required in article 9 b in order to be able to file a product liability prima facie case. See also ECJ C-52/00, Commission v. France (2002); C-154/00, Commission v. Greece (2002); Skov AEG c. Bilka Lavprisvarehus A/S (2006); regarding the liability of the provider and finally, C-177/04, Comission v. France (2006).
[180] See ECJ C- 183/00 María Victoria González Sánchez v Medicina Asturiana where the European Court of Justice was asked for a preliminary ruling on the question whether Article 13 of the Directive should be interpreted as precluding, limiting or restricting rights granted to consumers under the legislation of the Member State. In this case the ECJ understood that the purpose of the Directive was to establish a harmonized product liability regime as

existence of product liability systems of a different type "based on other grounds such as fault, or warranty in respect of latent defects"[181] or based on special liability rules for specific types of products.

Thus, despite the maximum harmonization[182] sought by the product liability directive,[183] member states are not prevented from passing or keeping in force their domestic regulation complementing or covering the legislative gaps left by it or from establishing liability regimes based on principles different from defect, which is the basis of the Directive.[184] Such domestic regulation, though, may not contradict the Directive.[185]

In sum, when an individual is injured by a defective product and has a prima facie case under the product liability directive, the individual may claim compensation under the Directive and, in addition, under any relevant domestic regulation so long as it does not contradict the Directive.

Transposition of the Directive

"*to ensure undistorted competition between traders, to facilitate the free movement of goods and to avoid differences in levels of consumer protection'*.

Therefore, harmonization was to be interpreted as complete and therefore article 13 did not allow member states to maintain a general system of product liability different from that provided for in the Directive.

[181] See Commission v. France, C-52/00 (2002) ECR I-3827, at [15] and [24].

[182] Maximum harmonization is an essential element of the supremacy doctrine in European law. See Case C-52/00, Commission v. France, 2002 E.C.R. I-3827; Case C-183/00, Maria Victoria Gonzalez Sanchez v. Medicina Asturiana SA, 2002 E.C.R. I-3901; Case C-154/00, Commission v. Greece, 2002 E.C.R. I-3879.

[183] Harmonization was a priority for the first twenty years of the existence of the Economic Community. However, in recent years minimum harmonization has been increasingly emphasized. See Thomas M.J. Mollers, The Role of Law in European Integration, 48 Am. J. Comp. L. 679, 682 (2000). The need for complete harmonization has been more and more questioned.

[184] For example, Spain has a liability regime based on fault established in article 1902 of the Civil Code and contractual liability for hidden defects of articles 1484 of he Civil code and article 336 of the commercial code. See ECJ, C-183/00, María Victoria González Sánchez c. Medicina Asturiana (2002).

[185] This is one of the crucial elements of the supremacy doctrine that implies that domestic law cannot adopt provisions deviating from primary European law (the content of European Treaties) or from secondary law (acts adopted in the Community legislative process). See Geraint G. Howells, The relationship between product liability and product safety – understanding a necessary element in the European Product Liability through a comparison with the U.S. position, 39 Washburn L. J. 305, 312 (2000).

Once the Directive was adopted, all member states were required to transpose its provisions in their domestic legislation by July 30, 1988.[186] However, this transposition process ended up lasting many years, with most member states failing to comply with the 1988 deadline.[187] Only the United Kingdom, Italy,[188] and Greece actually complied with it. Today, however, all EU members have finally transposed the Directive. Among the last to do so were Spain,[189] which finally transposed it in 1994, and France, which did so in 1998.[190] The Directive has also inspired legislation in non-EU countries such as Australia, Japan, Norway and Switzerland.[191]

In addition to being slow, the implementation process has been problematic in other ways, with some states failing to carry out the transposition properly.[192] The European Commission brought the United Kingdom, Ireland, Italy, France, Greece and Denmark before the European Court of Justice on the grounds that their domestic laws transposing the Directive were not actually in line with it. At the same time, the

[186] Article 19 of the product liability directive. See also Christopher J. S. Hodges, Product Liability in Europe: Politics, Reform and Reality, 27 Wm. Mitchell L. Rev. 121, 122 (2000) and Sandra N. Hurd and Frances E. Zollers, Product Liability in the European Community: Implications for United States Business, 31 American Business Law Journal 245, 256-247 (1993).

[187] See Anita Bernstein, L'Harmonie Dissonante: Strict Products Liability Attempted in the European Community, 31 Va. J. Int'l L. 673, 675-76 (1991) (describing chronically the member states' adoption of the Directive).

[188] For the Italian product liability regulation, see Richard H. Dreyfuss, The Italian law on strict products liability, 17 N.Y.L. Sch. J. Int'. & Comp. L. 37 (1997).

[189] For an analysis on the Spanish product liability law see Antonio J. Vela Sanchez, Products Liability in Spain, 32 Tex. Tech. L. Rev. 979 (2001).

[190] S. Mark Mitchell, A Manufacturer's Duty to Warn in a Modern Day Tower of Babel, 29 Ga. J. Int'l & Comp. L. 573, 581-582 (2001).

[191] Mathias Reinmann, Product Liability in a Global Context: The Hollow Victory of the European Model, European Review of Product Liability, 128, 134 (2003).

[192] Article 189 of the EEC Treaty states that Directives have binding force in relation to the result to be achieved but leaves the member states free to choose the form and method to implement them as long as the implementing regulation gives effect to the relevant aspects of the Directive an its principles, which are set out in the Directives' recitals. See Andreas P. Reindl, Consumer Protection and the Uniform Commercial Code: Consumer Contracts and European Community Law, 75 Wash. U.L.Q. 627, 642-43(1997) noting that the European Commission has exclusive right to propose Community legislation and John G. Culhane, The Limits of Product Liability Reform Within a Consumer Expectation Model: A Comparison of Approaches Taken by the United States and the European Union, 19 Hastings Int'l & Comp. L. Rev. 1, 29 (1995) explaining that European directives establish community policy but its leave implementation to member states.

Commission also started proceedings against France,[193] Ireland and the Netherlands for failure to comply with the deadline.[194]

The earliest case, which is the one against the United Kingdom,[195] involved the transposition of article 7 e) of the Directive, which deals with the development risks defense. The European Commission argued that the British law transposing this provision violated article 7 e) by allowing certain considerations that were not included in that article. The European Court of Justice agreed and ordered the UK government to amend its law.

Two cases can be highlighted regarding the transposition of article 9 b) of the Directive, which contains the 500 euro damages threshold above which injured victims may seek compensation. The European Commission brought actions against France[196] and Greece,[197] arguing that the each country's transposition of the Directive failed to include this limitation and requested the French legislature to amend its civil code to change the provision. The European Court of Justice agreed with the Commission's arguments and requested France and Greece to amend their transposition law to comply with the Directive. Both countries amended their laws and complied with the requirements of the European Court of Justice.

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[193] Court of Justice of the European Communities; Judgment of the Court of 13 January 1993; Commission of the European Communities v French Republic. Case C-293/91. 1993 ECJ CELEX LEXIS 7268 where the court stated that by failing to communicate the laws, regulations and administrative provisions by which it considers itself to have fulfilled its obligations under the Council Directive 85/374/EEC or by failing to adopt the measures necessary to comply therewith, the French Republic failed to fulfill its obligations under the directive and under the Treaty. The French Government acknowledged in the judicial proceding that by the termination of the period laid down in the court opinion, it had not yet implemented the Directive.

[194] See table below. See also Sandra N. Hurd & Frances E. Zollers, European Community: Council Directive on the Approximation of the Laws, Regulations and Administrative Provisions of the Member States Concerning Liability for Defective Products, 32 Int'l Legal Materials 1347, 1350 (1993) discussing the timing of member states' passage of laws and also Anita Bernstein, L'Harmonie Dissonante: Strict Products Liability Attempted in the European Community, 31 Va. J. Int'l L. 673, 674-75 (1991) listing the member states' non-compliance by the established deadline.

[195] ECJ C-300/95, Commission v. United Kingdon and Northern Ireland. Opinion written by Melchior Wathelet.

[196] ECJ C-52/00 Commission v. Republic of France. Opinion written by Peter Jann.

[197] ECJ C-154/00, Commission v. Greece. Opinion written by Peter Jann.

The European Commission's action against Denmark also concluded with an amendment of the Danish transposition law, which the European Court of Justice considered improperly exposed manufacturers and distributors to the same liability standard, violating the Directive's approach of imposing strict liability on manufacturers in the first instance, and on distributors only when manufacturers cannot be identified.[198] This same issue was also raised by the European Commission in its case against France.[199] As of today, the various judgments of the European Court of Justice and orders of the European Commission for the different countries have resulted in amendments of the different domestic laws in order to adapt them to the product liability directive's text.

[198] See ECJ C-327/05 Commission v Denmark (2005/C 257/12) filed by the European Commission on August 30, 2005. The European Commission's claim is based on a wrongful transposition of article 3.3 of the product liability directive. This case is available at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2005:257:0007:0007:EN:PDF

[199] ECJ C-52/00 Commission v. Republic of France. Opinion written by Peter Jann. The ECJ understood that article 1386.7 of the French civil code subjected to the same liability standard product manufacturers and distributors and therefore, did not correctly transpose article 3.3 of the Directive.

TABLE 2.1 – TRANSPOSITION LAWS OF THE EUROPEAN MEMBER STATES[200]

MEMBER STATE	TRANSPOSITION LAW	PUBLISHED	ENTRY INTO FORCE	AMENDED
AUSTRIA	Austrian Product Liability Act, Bundesgesetz über die Haftung für ein fehlerhaftes Produkt (Produkthaftungsgesetz, ProdHG) of January 21, 1988	Federal Gazette 99		Law of February 11, 1993 and Law No. 510/1994
BELGIUM	Loi relative à la responsabilité du fait des produits defectueux, of February 25, 1991 (Belgium's Product Liability Act)	Belgisch Staatsblad of 22.23.91, p. 5884		
DENMARK	Lov om Produktansvar No. 371 of June 7, 1989	Lovtidende A n [degrees] 371, p.1260		
FINLAND (took Directive as a model)	Tuotevastuulaki/Prodcuktansvarslag (Product Liability Act of 1990) of August 17, 1990			Act n [degrees] 99/1993 of 8.1.1993 Act No 879 of 22.10.1993
FRANCE	Law No. 389-98 of May 19, 1998, JO May 21, 1998 and a modification of articles 1386 subs. 1 et seq CC on defective products			
GERMANY	Product Liability Act. Gesetz über die Haftung für fehlerhafte Produckte. Produkthaftung, §1 ProdHaftG of December 15, 1989	Bundesgesetzblatt 1989 I 2198		
GREECE	Law 2251/1994 (replacing law of 1988)			July 1 1988
ITALY	Decreto del Presidente della Republica No.244 of May 24, 1988	Gazzetta Ufficiale n [degrees] 146 of 23.6.88	June 24, 1988	April, 1., 1991
IRELAND	Liability for Defective Products Act 1991, (no 28 of 1991) and S.I.N [degrees] 316 of 1991		December 16, 1991	June 10. 1989
LUXEMBOURG	Loi du 21 Avril 1989 relative à la responsabilité du fait des produits défectueux of April 21, 1989	Memorial of 28.4.89	May 2, 1991	September 1, 1991
THE NETHERLANDS	Wet Productktenaansprakelijkeid 1990 (Netherlands Product Liability Act), contained in Book 6, Title 3, Chapter 3 §§ 185-193 of the Netherlands Civil Code of 1991 of September 13, 1990	Staatsblad 1990 no.487	November 1, 1990	
PORTUGAL	Decreto-Lei No. 383/89 of November 6, 1989	Diario da Republica n [degrees] 255, p. 4880	21.11.89	May 23, 1998

[200] Information from the Commission Green Paper on Liability for Defective Products, COM (1999) 396 of July 28, 1999 at 35 and from the European Centre of Tort and Insurance Law, Unification of Tort Law: Strict Liability (B.A. Koch and H. Kaziol eds.) Kluwer Law International (2002).

SPAIN	Law No. 22/1994 of 6 July 1994 de Responsabilidad Civil por los Danos Causados por Productos Defectuosos	Boletin Oficial del Estado of 7.7.1994, pg 217575	8.7.1994	January 1, 1990 and Royal Decree 1/2007 of November 16, 2007
SWEDEN	Produkansvarlag (1992:18) of January 23, 1992		January 1, 1993	Law 1993: 647 of June 10, 1993
UNITED KINGDOM	Consumer Protection Act 1987, Part 1 and Consumer Protection (Northern Ireland) Order 1987 of May 15, 1987		March 1, 1988	
ICELAND	Product Liability Act of March 27, 1991		January 1, 1992	Took Directive as a model for its domestic regulation.
NORWAY	Lov om produktansvar of December 23, 1988		Amended extensively in November 1991 effective January 1, 1993.	
FINLAND	Law 698 of 17-8-1990 (Tuotevastuulaki)		Law 8.1.1993/99; 22.10.1993/879 and 27.11.1998/880.	
LIECHTENSTEIN	Gesetz über die Produktehaftpflicht of November 12, 1992 (Liechtenstein Product Liability Act)			
SWITZERLAND	Bundesgesetz über die Produktehaftpflicht of June 18, 1993		January 1, 1994	

TABLE 2.2 - OPTIONAL PROVISIONS[201]

	INTRODUCTION OF THE DEVELOPMENT RISKS DEFENSE Art. 7(e)	**FINANCIAL CEILING Art. 16(1)(b)**
Austria	YES	NO
Belgium	YES	NO
Denmark	YES	NO
France	YES[202]	NO
Germany	YES	YES
Greece	YES	NO
Ireland	YES	NO
Italy	YES	NO
Luxembourg	NO	NO
The Netherlands	YES	NO
Portugal	YES	YES
Spain	YES	YES
Sweden	YES	NO
United Kingdom	YES	NO

[201] See Commission Green Paper on Liability for Defective Products, COM (1999) 396 of July 28, 1999 at 35 and William C. Hoffman and Susanne Hill-Arning, GUIDE TO PRODUCT LIABILITY IN EUROPE: THE NEW STRICT PRODUCT LIABILITY LAWS, PRE-EXISTING REMEDIES, PROCEDURE AND COSTS IN THE EUROPEAN UNION AND THE EUROPEAN FREE TRADE ASSOCIATION, 9, Deventer; Boston: Kluwer Law and Taxation Publishers (1994).

[202] The French regulation of the development risk defense is ambiguous. On one hand, Article 12 of the French Act provides for the exclusion of "development liability" under tort law but on the other hand, the Sales law provides for an irrebuttable presumption of bad faith of the professional seller which seems to be equivalent to a "development risk liability."

TABLE 2.3 – OPTIONAL PROVISIONS IN THE EFTA STATES[203]

	DEVELOPMENT RISKS DEFENSE Art. 7(e)	**FINANCIAL CEILING Art. 16(1)(b)**
Finland	NO	NO
Iceland	YES	YES
Liechtenstein	YES	NO
Norway	NO	NO
Sweden	YES	NO
Switzerland	YES	NO

[203] For the extraterritorial effect –especially among the EFTA states- of the community's products liability rules see Rudolph Hulsenbek, Dennis Campbell, PRODUCT LIABILITY: PREVENTION, PRACTICE, AND PROCESS IN EUROPE AND THE UNITED STATES, Deventer; Boston: Kluwer Law and Taxation Publishers, 71, (1989).

2 Following Section 402a of the Restatement (Second)? The Directive's Strict Liability Regime

Product liability systems -- and tort systems more generally -- can be divided into three basic categories: (1) negligence-based models, which are currently employed in most U.S. jurisdictions[204] for product liability cases, and particularly design defect cases; (2) strict liability models, which are laid out in section 402A of the U.S. Restatement (Second) of Torts, and which used to be employed in many U.S. jurisdictions for product liability cases; and (3) no-fault systems in which injured parties are compensated by the state -- the approach adopted in New Zealand.[205] Under negligence liability, the plaintiff has to show that the product was negligently made and created a foreseeable risk of injury and that the use or contact by the product user or consumer could be foreseen by the product manufacturer.[206] Under strict product liability, a manufacturer is held liable when a product it places into the stream of commerce causes injury to property or persons due to a defect that renders the product unreasonably dangerous. Strict liability is thought to be better able to allocate the loss that the product causes to the product user or consumer since the manufacturer may be able to insure against the risk of harm to person or

[204] Restatement (Third) of Torts: Products Liability (1998). See infra for an analysis of the impact and consequences of the strict liability regime established by the Directive. See Aaron D. Twerski & James A. Henderson, Jr, Manufacturers' Liability for Defective Product Designs: The Triumph of Risk-Utility, 74 Brook. L. Rev. 1061, 1063 (2008-2009) noting that the Restatement Second of Torts did not differentiate between product defects but the Restatement (Third) differentiated between three sub-categories of product defect.

[205] Under the New Zealand no-fault system, neither the victim nor the producer, but society at large absorbs the cost of damages. The necessary funds to compensate the victim are raised from contributions to the social security budget or by taxes. However, such scheme is unlikely to be established elsewhere and is even presently being scaled back in New Zealand. Private law rules are therefore the only feasible means of ensuing that product victims receive compensation. See, TODD, THE LAW OF TORTS IN NEW ZEALAND, 53-57 (3rd ed. 2001). See also GERAINT HOWELLS, CONSUMER PRODUCT SAFETY, 5 (1998).

[206] Hartwin Bungert, Compensating harm to the defective product itself -- A comparative analysis of American and German products liability law, 66 Tul. L. Rev. 1179, 1192 (1992).

property[207] and hence internalize and transfer the costs to the public through higher prices.[208]

The product liability directive introduced, for the first time in Europe, a strict liability system for personal injury, death, or damage to personal property resulting from products (but not services, which do not fall within the scope of the Directive).[209] The choice of such a system was made largely based on two reasons. First, such a regime was seen as the best way to protect the product user against any threat to life, health and property[210] because it imposed a lower burden of proof on injured victims and provided a relatively easy mechanism to such victims for pursuing their product liability claims and seeking compensation.[211] Second, strict liability was thought to be a better way of

[207] Insurance of victims of product-related accidents is one of the policy goals of strict liability, the idea being that firms should act as insurers of product losses by incorporating the cost of insurance in the product price and by spreading these costs among all consumers. W. Kip Viscusi, Product Liability and Regulation: Establishing the Appropriate Institutional Division of Labor, The American Economic Review, Vol. 78, No. 2, pp. 300-304 (1988) for a general discussion on the issue. See also Hans Claudius Taschner, Harmonization of product liability in the European Community, 34 Tex. Int'l L. J. 21, 28-29 (1999) regarding the goal of the product liability directive as insuring product victims and transferring such cost to the final product price.

[208] Prices are often thought as an efficient mechanism for transferring information regarding product risks in the sense that they can reflect the expected liability of the manufacturer and hence provide information to consumers regarding the probability of harm and the magnitude of damages. Whenever consumers were perfectly informed regarding the probability and magnitude of harm, the Coase Theorem would hold and the same equilibrium would be reached regardless of the liability rule in force. For early discussions on this issue See J. P. Brown, Toward and Economic Theory of Liability, Journal Legal Stud. 2, 323-349 (1973), W. Y. Oi, The Economic Analysis of Product Safety, Bell J. Econ., 4, 3-28 (1974), P. A. Diamond, Single Activity Accidents, J. Legal Stud., 3. 107-64 (1974); Koichi Hamada, Liability Rules and Income Distribution in Product Liability, The American Economic Review, Vol. 66, No. 1, 228-234 (1976) and R. H. Coase, The Problem of Social Costs, Journal Law Econ., 3, 1-44.(1960). For the application of this reasoning in the product liability discussion in Europe see Hans Claudius Taschner, Harmonization of product liability in the European Community, 34 Tex. Int'l L. J. 21, 28-29 (1999).

[209] Christopher J S Hodges, Product Liability In Europe: Politics, Reform And Reality, 27 Wm. Mitchell L. Rev. 121, 122 (2000).

[210] However, empirical studies on the effects of strict product liability on product safety are not concluding. See Thomas Lundmark The Restatement Of Torts (Third) And The European Product Liability Directive, 5 D.C.L. J. Int'l L. & Prac. 239 (1996). For a different perspective, see Jorg Finsinger & Jurgen Simon, An Economic Assessment of the EC Product Liability Directive and the Product Liability Law of the Federal Republic of Germany, in ESSAYS IN LAW AND ECONOMICS: CORPORATIONS, ACCIDENT PREVENTION AND COMPENSATION FOR LOSSES 185, 202-05 (Michael Faure & Roger van den Bergh eds., 1989). These authors develop an "informational product defect" concept that stresses the "sovereignty of the informed consumer," and his or her ability to choose risks that have been communicated to him.

[211] Victims' compensation through law, and more specifically using tort law as an insurance system has been widely criticized. See James A. Henderson, Revising Section 402 A: the limits of tort as social insurance, 10 Touro L. Rev. 107, 119 (1993-1994).

spreading risk, given that strict liability allows, at least in theory, transferring the cost of the victim's harm to the producer.[212]

The European model borrowed heavily from the then-existing U.S.[213] product liability system, with the product liability directive clearly taking as a reference the strict liability standard of the U.S. Restatement (Second) of Torts,[214] which was developed in 1965 and was adopted by most American states.[215] The U.S. model was perceived as workable, acceptable and broadly beneficial.[216] However, while the European Commission and the Directive's other drafters were looking to the U.S. model, they did not seem to take into account the changes that were then occurring in U.S. product liability law. The Second Restatement itself was a response to the early phases of product

[212] Under strict liability the producer, that is the residual risk bearer, is generally considered to be in a better position than a consumer to obtain insurance for product-related losses because he can either self-insure or enter into one insurance contract covering all consumers. See Thomas Lundmark The Restatement Of Torts (Third) And The European Product Liability Directive, 5 D.C.L. J. Int'l L. & Prac. 239, 265 (1996) and Hans Claudius Taschner, Harmonization of product liability in the European Community, 34 Tex. Int'l L. J. 21, 28-29 (1999). However, neither manufacturers nor insurers are able to spread the risk indefinitely because the risks they face are not predictable and heterogeneous. See Robert G. Berger, The impact of tort law development on insurance: the availability/affordability crisis and its potential solutions, 37 Am. U. L. Rev. 285 (1988).

[213] Jane Stapleton, Bugs in Anglo-American products liability, 53 S. C. L. Rev. 1225, 1232 (2002). See also Josephine Liu, Two roads diverged in a yellow wood: the European Community stays on the path to strict liability, 27 Fordham Int'l L J. 1940, 2005-2006 (2004) considering that this showed that the EC learned its lesson from the United States. For an opposite view considering that the European Community followed the U.S. model see James A. Henderson, Jr. & Aaron D. Twerski, What Europe, Japan, and Other Countries Can Learn From the New American Restatement of Products Liability, 34 Tex. Int'l L.J. 1, 13-14 (1999). See also Gregory G. Scott, Product Liability Laws In The European Community In 1992, 18 Wm. Mitchell L. Rev. 357, 400 (1992) and Lawrence C. Mann and Peter R. Rodrigues, The European Directive on Product Liability: the promise or progress ?, 18 Ga. J. Int'l & Comp. L. 391, 403 (1988).

[214] Restatement (Second) of Torts Section 402A Comment i (1977). Geraint G. Howells & Mark Mildred, Is European Products Liability More Protective Than The Restatement (Third) Of Torts: Products Liability?, 65 Tenn. L. Rev. 985, 992 (1998). See Jane Stapleton, Bugs in Anglo-American products liability, 53 S. C. L. Rev. 1225, 1232 (2002) noting that the Directive is like the Restatement Second in certain aspects such as the lack of separate treatment of product defects or the definition of defectiveness. See also Aaron D. Twerski & James A. Henderson, Jr, Manufacturers' Liability for Defective Product Designs: The Triumph of Risk-Utility, 74 Brook. L. Rev. 1061, 1063 (2008-2009).

[215] However, given that the Restatements are not binding, not all U.S. jurisdictions adopted §402A (or some other version of strict product liability). For example, the states of Delaware, Massachusetts, Michigan, North Carolina, Virginia and North Carolina did not adopt it. See Anita Bernstein, L'harmonie Dissonante: Strict Products Liability Attempted In The European Community, 31 Va. J. Int'l L. 673, 710-711 (1991). Claims under strict liability and under negligence co-existed and both tort theories could be brought parallel to actions under contract law. See Hartwin Bungert, Compensating harm to the defective product itself -- A comparative analysis of American and German products liability law, 66 Tul. L. Rev. 1179, 1191 (1992).

[216] See Jane Stapleton, PRODUCTS LIABILITY, 68 (1994). See also S. Mark Mitchell, A Manufacturer's Duty to Warn in a Modern Day Tower of Babel, 29 Ga. J. Int'l & Comp. L. 573, 581 (2001).

liability law in the United States.[217] During the 1970s and early 1980s, courts in the United States increasingly questioned the strict product liability system and this system experienced a crisis during the mid-1980s when insurance costs led regulators and scholars[218] to reconsider its merits. At the same time, courts in the United States were increasingly reconsidering strict liability for design defects and the duty to warn.[219] In design defect cases, courts replaced the consumer-expectations test with a risk-utility test based on balancing principles -- the essence of a negligence-based model. With respect to the duty to warn, courts began to conclude that there should be no such duty when it comes to unforeseeable risks and that the duty should relate only to product risks that the manufacturer could discover given the state of the scientific and technical knowledge available at the moment the product was placed into circulation. Thus, as they reconsidered product liability standards, U.S. courts were increasingly questioning strict liability and introducing negligence principles in their opinions.[220]

This evolution culminated with the introduction of a negligence-based system proposed by the Third Restatement in the 1990s.[221] The negligence-based product

[217] This may also explain why defect was thought as a unitary concept so that products were either too dangerous (defective) or safe enough (non-defective). David G. Owen, The evolution of products liability law, 6 Rev. Litig. 955, 986 (2007). See also Aaron D. Twerski & James A. Henderson, Jr, Manufacturers' Liability for Defective Product Designs: The Triumph of Risk-Utility, 74 Brook. L. Rev. 1061, 1063 (2008-2009) noting that despite not differentiating between sub-categories of product defects, the drafters of section 402A seemed to have relied on different subsets of defect cases for which risk-utility analysis was applied.

[218] Gary T. Schwartz, The Beginning and Possible End of the Rise of Modern American Tort Law, 26 Ga. L. Rev. 601, 683-99 (1992), and David G. Owen, The Fault Pit, 26 Ga. L. Rev. 703, 705-10 (1992).

[219] See Joachim Zekoll, American Law in a Time of Global Interdependence: U.S. National Reports to the XVIth International Congress of Comparative Law: Section II Liability for Defective Products and Services, 50 Am. J. Comp. L. 121 (2002) discussing the standards applied in design defect and failure to warn cases.

[220] David G. Owen, The evolution of products liability law, 6 Rev. Litig. 955 (2007).

[221] See also Aaron D. Twerski & James A. Henderson, Jr, Manufacturers' Liability for Defective Product Designs: The Triumph of Risk-Utility, 74 Brook. L. Rev. 1061, 1063, 1080-1087, 1094, 1098, 1104 and 1106 (2008-2009) presenting the design defect test adopted in the different U.S. states and noting that the majority of U.S. stated adopted a risk-utility test with the application of the requirement of the availability of a cost-effective reasonable alternative design.

liability regime proposed by that Restatement remains the norm in most U.S. states today.[222]

By mirroring the U.S. product liability regime at the moment when it was being reconsidered, redesigned and finally modified, the European Directive's drafters opened themselves up to criticism.[223] On the other hand, the Directive's defenders argued that adopting the fading U.S. model as the Directive's reference would not necessarily lead to the same problems that the U.S. was then experiencing -- problems that stemmed, it was argued, more from other aspects of the U.S. legal system than from the strict liability standard itself.[224] Moreover, it was argued that the strict liability standard would make the European system friendlier to injured victims. Twenty years later, it is not clear that the product liability directive has accomplished this goal.[225]

The product liability directive refers to strict liability in its preamble and in its body. The preamble states that

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[222] Despite the shift back to negligence that the Restatement Third represented, strict liability for defective products and liability for negligence coexist or through case law as they have merged into a single cause of action. See Joachim Zekoll, American Law in a Time of Global Interdependence: U.S. National Reports To The XVIth International Congress Of Comparative Law: Section II Liability for Defective Products and Services, 50 Am. J. Comp. L. 121 (2002). See also David G. Owen, Defectiveness Restated: Exploding The "Strict" Products Liability Myth, 1996 U. Ill. L. Rev. 743, 745 (1996). See also James A. Henderson, Jr. & Aaron D. Twerski, Doctrinal Collapse in Products Liability: The Empty Shell of Failure to Warn, 65 N.Y.U. L. Rev. 265 (1990); William Powers, Jr., A Modest Proposal to Abandon Strict Products Liability, 1991 U. Ill. L. Rev. 639 and Alan Schwartz, The Case Against Strict Liability, 60 Fordham L. Rev. 819 (1992).

[223] See generally James A. Henderson, Jr. & Aaron D. Twerski, What Europe, Japan, and Other Countries Can Learn From the New American Restatement of Products Liability, 34 Tex. Int'l L.J. 1 (1999) arguing that the adoption of a strict the product liability regime made Europe move further -instead of closer- from the U.S. position.

[224] Anita Bernstein, L'harmonie Dissonante: Strict Products Liability Attempted In The European Community, 31 Va. J. Int'l L. 673, 710-711 (1991).

[225] Up to today, it is not clear that the primary choice of injured victims of product-related accidents in Europe is litigation. The European Commission, aware that there may be a problem of victims in litigating, has taken steps to facilitate and ensure consumer's access to justice. See the Communication from the Commission, "Action plan on consumer access to justice and the settlement of consumer disputes in the internal market," COM (96) 13 final (1996). This document can be found in http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:1996:0013:FIN:EN:PDF. See also Howells, Geraint, EC ACCESS TO JUSTICE FOR CONSUMERS, for a brief overview of the initiatives adopted by the European Commission regarding consumer's access to justice. This document is available at http://www.iaclaw.org/Research_papers/ecaccesstojustice.pdf.

> liability without fault on the part of the producer is the sole means of adequately solving the problem, peculiar to our age of increasing technicality, of a fair apportionment of the risks inherent in modern technological production.[226]

At the same time, the body of the Directive, in its article 1, provides that "the producer shall be liable for damage caused by a defect in his product" -- which clearly defines a strict liability regime. Section 402A of the Restatement (Second) established that one who sells a product in a defective condition, thus making it unreasonably dangerous to the user or consumer or his property is liable to the user or consumer for injuries or property damage caused by the product regardless of the level of care he or she has exercised.[227] Under §402A of the Restatement (Second), liability is imposed when the seller is in the business of selling the product that causes the injury and the product reaches the user in substantially the same condition in which it is sold. Therefore, non-professional sellers do not fall within the scope of section 402A. The determination that a product is "unreasonably dangerous" depends upon whether the product has adequate warnings or instructions, and whether it is reasonably designed.[228]

The general liability statement set forth in article 1 of the product liability directive is similar to section 402A of the Restatement (Second) in that both provisions suggest that sellers are liable for injuries caused by product defects regardless of "fault" or other negligence considerations.[229] In this sense, the Directive aimed to maximize consumer protection by ensuring that injured victims are awarded damages regardless of producers' fault or the level of care adopted.[230]

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[226] Pmbl paragraph 2 of the Product liability directive
[227] §402A of the Restatement (Second) of Torts.
[228] Gregory G. Scott, Product Liability Laws in The European Community In 1992, 18 Wm. Mitchell L. Rev. 357, 359 (1992).
[229] Gregory G. Scott, Product Liability Laws in The European Community in 1992, 18 Wm. Mitchell L. Rev. 357, 360 (1992).
[230] Hence, the conusmers' and users' prima facie case involves proving damaage, defect and causation between them but not the producer's fault. See Patrick Thieffry, Philip Van Doorn and Simon Lowe, Strict Product Liability in the EEC: Implementation, Practice and Impact on U.S. Manufacturers of Directive 85/374, 25 Tort & Insurance Law Journal 65, 68 (1989-1990). David. W. Lannetti, Toward a Revised

One of the main factors that seems to have influenced the drafters' decision to introduce strict product liability in Europe is the important distinction between risk and loss.[231] The drafters believed that loss resulting from an accident should be imposed on product manufacturers through liability given that they are the ones capable of spreading the cost of liability among product consumers and of internalizing the cost of the expected liability by including it in the price or by buying insurance against it.[232]

Despite the enthusiasm for strict product liability among the drafters of the Directive and other European authorities, the Directive also includes references to a "fair apportionment of risks" between product manufacturers and consumers and product users[233] -- a reference that seems to undercut strict liability because strict liability, by definition, does not imply any apportionment of risks. Moreover, this tendency to apportion risks among producers and consumers is reflected in other provisions of the Directive, which include implicit notions of negligence.[234] In this sense, even without expressly modifying their stated strict liability principles,[235] the Directive's drafters seem, at the very least, to have implicitly watered them down.

Definition of "Product" Under the Restatement (Third) of Torts: Products Liability, 35 Tort & Ins. L. J. 845, 888 (2000).

[231] Anita Bernstein, L'harmonie Dissonante: Strict Products Liability Attempted In The European Community, 31 Va. J. Int'l L. 673, 701 (1991).

[232] See Patrick Thieffry, Philip Van Doorn and Simon Lowe, Strict Product Liability in the EEC: Implementation, Practice and Impact on U.S. Manufacturers of Directive 85/374, 25 Tort & Insurance Law Journal 65, 68 (1989-1990) arguing that the availability of liability insurance for manufacturers was one of the arguments used in support of the introduction of strict liability. See also M. Rotchild & J. Stiglitz, Equilibrium in competitive insurance markets: an essay on the economics of imperfect information, 90 Quarterly Journal of Economics, 629-649 (1976). See generally Hal Varian, INTERMEDIATE MICROECONOMICS, A MODERN APPROACH, 220 (4 ed. 1996) (1987).

[233] Pmbl. para 2 of the product liability directive. See Geraint Howells, Europe's Solution to the Product liability phenomenon, 20 Anglo-Am. L. Rev. 204, 206 (1991) suggesting that the Directive has not provided a solution to the products liability phenomenon in terms of distribution of product risks.

[234] See infra for a discussion of the negligence elements of the Directive.

[235] Mathias Reimann, Liability for Defective Products at the Beginning of the Twenty-First Century: Emergence of a Worldwide Standard?, 51 Am. J. Comp. L. 751, 776-777 (2003).

3 Products Covered by the Directive

The European product liability directive overlaps with the domestic liability laws of the different member states. This has a number of practical consequences in terms of application, and often leads to confusion. For example, one body of law may appear to be applicable to a given suit based on the type of product at issue, while another body of law may appear to be equally applicable to that suit based on the type of harm involved. This kind of overlap has often made it often difficult to determine the scope of the definitions and concepts that must be applied to particular cases.

This problem has been particularly acute when it comes to the definition of a product itself. Domestic legislation generally included such a definition at the time when the Directive was being drafted, and there was debate over how the Directive should deal with this issue. Many suggested that the scope of the Directive should be the same as that of the laws generally regulating the consequences of injuries and torts.[236] However, the European Commission believed that the Directive should impose only a product-related regime. The Commission, therefore, viewed the definition of a product to be necessary in order to specify which damage claims could be brought under the Directive and which would have to be brought under domestic law. Ultimately, the Directive included a definition that limited its scope to movable products, including those incorporated into immovables or other movables.[237]

The strong farming lobby of the 1980s successfully pressured European authorities to ensure that primary agricultural products (although not products that had undergone initial processing)[238] were excluded from mandatory coverage of the

[236] Some of the controversies and discussions were still in place after the Directive had been adopted. M. Goyens, Directive 85/374/EEC on Product Liability: ten years after (Centre de Droit de la Consommation, Louvain-la-Neuve, 1996).
[237] Article 2 of the product liability directive.
[238] "Primary agricultural products" were defined as "the products of the soil, of stock farming and of fisheries."

Directive's strict product liability regime.[239] Game was also excluded. The agricultural sector argued that imposing strict liability for agricultural products could become a strong burden if these products were not industrially manufactured. It was up to the member states to decide whether they would subject agricultural products to the liability regime established by the Directive.[240] Greece, Luxemburg, Sweden and Finland were the only member states to include agricultural products within the scope of the product liability directive in their transposition laws.

In 1986, however, Europe witnessed the first diagnosis of Bovine Spongiform Encephalopathy (BSE), commonly known as mad cow disease. This disease, which is fatal to cows and is linked to similarly dangerous diseases in other livestock and in humans, led to widespread fears over beef consumption -- and food safety in general -- in Europe and throughout the world.[241] In 1996, European authorities created a Temporary Committee of Inquiry into BSE, which drafted a number of proposals that the European Parliament adopted.[242] The most remarkable of these proposals was the Committee's 1997 recommendation that the product liability directive be amended to include damages caused by agricultural products.

This amendment was made applicable to primary agricultural products and game placed into circulation on or after 1 January 1999[243] and thus ended the discretion previously given to member states on the matter.

Today, the Directive defines products in a very broad manner by referring to all "movables."[244] This includes finished goods, as well as raw materials and components

[239] Article 2 of the product liability directive
[240] Article 15 (1)(a) of the product liability directive.
[241] Some authors considered that the BSE crisis showed how vulnerable interdependent economies were to risks inherent to modern societies affecting their neighboring states, which can no longer be managed at the domestic level and require transnational responses. See Christian Joerges, Law, science and the management of risks to health at the national, European and international level - stories on baby dummies, mad cows and hormones in beef, 7 Colum. J. Eur. L. 1, 9 (2001).
[242] Resolution of 19 February 1997 on the results of the Temporary Committee of inquiry into BSE, O.J. C 85, (17.3.97).
[243] Council Directive 99/34/EC, OJ L 141, 4.06.99.

incorporated in a finished product.[245] Moreover, the concept of a movable does not correspond exactly to the traditional notion of a consumer product and it is often necessary to look at the different definitions of movables provided in the domestic laws of the member states.[246] For example, electricity is specifically mentioned in the definition as a movable,[247] and the definition would seem to extend to such other utilities such as gas and water. At the same time, however, services *per se* are not covered by the Directive,[248] and there is further ambiguity over whether the Directive extends to such things as intellectual products.

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[244] See Christopher Hodges, PRODUCTS LIABILITY EUROPEAN LAWS AND PRACTICE, Sweet & Maxwell, London (1993) and Christopher Hodges, Reform of the Product Liability Directive 1998-1999, 3, Cameron McKenna (1999) arguing that the concept of product included in the product liability directive is ambiguous and difficult to specify. See also Gary T. Walker, The Expanding Applicability of Strict Liability Principles: How Is a "Product" Defined?, 22 Tort & Ins. L.J. 1, 2 (1986), arguing in favor of a predictable interpretation of product.

[245] See Gregory G. Scott, Product Liability Laws In The European Community In 1992, 18 Wm. Mitchell L. Rev. 357, 362-363 (1992) arguing that if the concept of product under the Directive included finished goods, raw materials and components incorporated to a finished product, such concept was broader than the concept of product defined under the §402A which considers a product "any product (sold) in a defective condition . . . if (a) the seller is engaged in the business of selling such a product, and (b) (the product) is expected to and does reach the user or consumer without substantial change in the condition in which it is sold."

[246] Patrick Thieffry, Philip Van Doorn and Simon Lowe, Strict Product Liability in the EEC: Implementation, Practice and Impact on U.S. Manufacturers of Directive 85/374, 25 Tort & Insurance Law Journal 65, 70 (1989-1990).

[247] But it should be noted that if electricity was defective at the time of putting into circulation -- article 6 -- then there would not be liability for subsequent disruptions in supply. Most courts have understood that "electricity is a service, not a product." However, it would appear that the provision will require interpretation, for example, as to when current becomes "electricity" for purposes of the Directive. Spanish jurisprudence includes some cases where drops in electricity voltage caused damages to the plaintiff or where interruptions of the electrical service caused damages. For drops in the electricity voltage see Winterthur Seguros, S.A. v. Gesa Endesa (electricity supplier), Court of appeals of the Balearic Islands 17.7.07 (JUR 2007\317144; Hon: María Rosa Rigo Rosselló) and Ocaso S.A. de Seguros and Reaseguros v. Endesa Distribución Eléctrica, S.L. (supplier), Court of Appeals of the Balearic Islands 20.4.07 (JUR 2007\281413; Hon: Covadonga Sola Ruiz). In both cases, the supply of electricity was interrupted and when resumed there was a high-tension that caused damages to certain products owned by the plaintiff. The court held the electricity company liable for those damages and awarded compensation to the victim. For interruptions of service see Nicasio Celdrán Atienza, S.A. v. Iberdrola Distribución Eléctrica, S.A. (supplier), Court of Appeals of Murcia 1.2.06 (JUR 2006\68585; Hon: Fernando López del Amo González) and Espasir Viaje, S.L. v Endesa Distribución Eléctrica (supplier), Court of appeals of Barcelona 25.1.2005 (JUR 2005\146169; Hon: Mª Jesús Jurado Cabrera). In these cases, the interruptions of the electricity service caused damages to some products owned by the plaintiffs. The courts awarded damages for the damages suffered by the victim due to the defective electricity.

[248] There is currently no Directive or European regulation dealing with liability for defective services. Several drafts have been passed (the last one the Commission's proposal presented on March 5, 2004 COM(2004)) but the difficulty to agree upon a text suggests how difficult is becoming for member states to regulate this issue in a common manner. There have been proposals suggesting to define product in such a

In addition to covering movables in general, the Directive also covers movable goods that have been incorporated into immovables or other movables.[249] Consequently, producers of final products are liable for harm caused by defective components they include in a final product,[250] although not for the damage to the defective product itself.[251] From the consumer/user's perspective, the distinction between a defective final product and a defective product component does not have much impact. Under the Directive the consumer may seek compensation from the manufacturer of either the component or the final product, and it is often easier to sue the final product manufacturer since claimants generally lack the expertise and information necessary to determine that harm was caused by a particular product component or to establish the identity of that component's manufacturer.[252]

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ways that could include intangible as well as tangible items. In this sense, the product/service distinction would not become relevant any longer and this would be important in Europe given the difficulty to regulate and impose liability for defective services. David. W. Lannetti, Toward a Revised Definition of "Product" Under the Restatement (Third) of Torts: Products Liability, 35 Tort & Ins. L. J. 845, 889 (2000). Services are to be covered by the proposed Directive on liability of supplies of services: draft at O.J.18.1.91, 91/C 12/11. However, such Directive has never been in effect and is still subject to debate. The distinction between products and services has often been questioned. See David W. Lannetti, Toward a Revised Definition of "Product" under the Restatement (Third) of Torts: Products Liability, 35 Tort & Ins. L.J. 845, 865-870, 887 (2000) arguing in favor of abandoning the difference between product and service and arguing in favor of a unified liability regime under the U.S. Uniform Commercial Code.

[249] Article 2 of the product liability directive.

[250] Under domestic contribution rules, product manufacturers will be able to seek contribution and recover the liability award paid for the damages caused by the defect in the product component.

[251] Article 9(b) of the strict liability directive does not provide compensation for the damages caused to the defective product itself but in the case that a claimant could identify the defective component and its manufacturer, he/she could bring a claim against the manufacturer of the defective component and recover the loss caused for damage to the defective product itself. However, there are Spanish cases where, even acknowledging that the product liability directive does not provide for such compensation, courts awarded damages for the harm suffered to certain products such as a truck caused by a defective break system. Jesús Manuel v. Autos Lobelle, S.L. and Nissan Motor España, S.A., Court of Appeals of La Coruña 25.4.06 (JUR 2006\152372; Hon.: José Ramón Sánchez Herrero).

[252] The damage to the product itself is excluded from the scope of the Directive. For an analysis of the treatment of the recoverability of physical damage to the product itself in the United States and Germany see Hartwin Bungert, Compensating harm to the defective product itself – A comparative analysis of American and German products liability law, 66 Tul. L. Rev. 1179 (1992).

4 Producers and other Actors Subject to the Strict Liability Regime

Because the product liability directive is one of the major instruments of the European product regulation and because its drafters wanted to facilitate consumers' ability to obtain compensation from potential tortfeasors, the scope of the concept of producer under the Directive embraces as many participants of the manufacturing process as possible.[253] This makes it easy for consumers to bring their product claims against the maximum number of potential tortfeasors.[254] This is often referred to as the channeling of liability in the product liability directive.[255]

The Directive's definition of producer is quite similar to the definition of "seller" in the Restatement (Second) in the sense that it encompasses all persons in the chain of production, from the producer of raw materials to the retailer.[256] It subjects to primary liability the producer of the product but also all parties that present themselves as producers -- for example importers into the European Community -- and that give the public the impression that they are the producers[257] as well as any party putting its name, trademark, or distinguishing mark on a product causing the user to believe it is the producer.[258] At the same time, the concept of producer does not embrace all entities involved in the pre-manufacturing process. Designers, for instance, are not included.

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[253] Article 3 of the product liability directive defines producer as the

> "*the manufacturer of a finished product, the producer of any raw material or the manufacturer of a component part and any person who, by putting his name, trade mark or other distinguishing feature on the product presents himself as its producer*."

[254] Christopher J. S. Hodges, Product Liability in Europe: Politics, Reform and Reality, 27 Wm. Mitchell L. Rev. 121, 122 (2000).

[255] Jane Stapleton, Products Liability In The United Kingdom: The Myths Of Reform, 34 Tex. Int'l L. J. 45, 52 (1999).

[256] Restatement (Second) of Torts §402A. See also Gregory G. Scott, Product Liability Laws In The European Community In 1992, 18 Wm. Mitchell L. Rev. 357, 361-362 (1992).

[257] Article 3(1) of the Directive. Judgment of the European Court of Justice (Fifth Chamber) of 10 May 2001, Henning Veedfald v Arhus Amtskommune. Reference for a preliminary ruling: Hojesteret – Denmark; Case C-203/99. European Court reports 2001 Page I-03569. 2001 ECJ CELEX LEXIS 6690.

[258] This is the so called "own-brand producer." See Jane Stapleton, Products Liability in The United Kingdom: The Myths of Reform, 34 Tex. Int'l L. J. 45, 52 (1999).

In most product liability cases, consumers do not interact with the product's (or its component parts') manufacturers and therefore generally cannot identify them. In order to avoid placing injured victims in a defenseless situation, the product liability directive expressly provides that the party responsible for placing the product in the European market for the first time[259] is liable for the potential damages caused by it.[260] This includes manufacturers of products produced in the European Union and also importers of producers produced outside of the European Union boundaries but marketed within the European Union market. The importers considered producers under the Directive are the ones who introduce the product into the European market for the first time. The movement of the product from one member state to the other within the European Union market is not considered an import under the meaning of the Directive.

Sometimes, though, consumers will not be able to identify the producer or the importer of the product. In order to protect injured victims in those cases and facilitate their pursuit of a product claim, the Directive holds each supplier of the marketing chain, including the retailer, subject to liability.[261] However, the position of producers and suppliers is not equivalent: suppliers are liable only in cases when it is not possible to identify the producer.[262] Only in such cases will the supplier be treated as the producer.[263]

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[259] Section 2 of article 3 of the Directive places liability also on any person who imports into the community a product for sale, hire, leasing, or for its distribution in the course of his business. Court of Justice of the European Communities, Opinion of Mr. Advocate General Van Gerven delivered on 15 December 1988. Criminal proceedings against Esther Renee Bouchara, nee Wurmser, and Norlaine SA., Case 25/88. Reference for a preliminary ruling: Tribunal de grande instance de Bobigny - France. 1988 ECJ CELEX LEXIS 7211.

[260] This sometimes makes it difficult for injured victims to sue the importer, especially when this is based in another member state because of the different civil procedure laws of the different member states and the multi-jurisdictional structure of some of them. Geraint Howells, COMPARATIVE PRODUCTS LIABILITY, 31, Darmouth publishing Company Limited (1993).

[261] Article 3(3) of the product liability directive.

[262] The Directive requires the supplier or other known members in the distribution chain to provide to the injured consumer with the identity of the producer within a reasonable period of time. If the supplir can name one of the primarily liable parties he will be discharged from liability. See Jane Stapleton, Products Liability In The United Kingdom: The Myths of Reform, 34 Tex. Int'l L. J. 45, 52 (1999) and Lucille M. Ponte, Guilt By Association In United States Products Liability Cases: Are The European Community And Japan Likely To Develop Similar Cause-In-Fact Approaches To Defendant Identification?, 15 Loy. L.A. Int'l & Comp. L.J. 629, 652 (1993).

Hence, suppliers are treated as the manufacturers and importers but only in a subsidiary way, whenever the manufacturer or importer cannot be identified or whenever the supplier has sold the product already knowing that it was defective.[264] Through this liability structure, a consumer will always have an EU-domiciled defendant against whom to bring a claim and, if appropriate, enforce a judgment.

The Directive provides two major exceptions to its general inclusiveness of producers and other agents subject to liability. First, the Directive excludes from liability importers that merely transport a product between member states as opposed to those who import from outside the European Union. Presumably, this does not present a large problem for consumers, because European law allows them to easily enforce judgments anywhere in the European Union.[265] Because of this enforcement capability, it should generally be just as easy to pursue compensation from a European manufacturer, or from the party that imports a product into the European Union from outside, as from an intra-Union importer. Because that same capability does not exist in relation to manufacturers based in most countries outside of the European Union, the parties that import products

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[263] In the European Court of Justice Preliminary ruling of Interpretation in the case C 402/03 Skov Æg v. Bilka, it was held that an intermediary such as a retailer could not be strictly liable instead of a producer under the Directive 85/374/EEC. The Court understood that the Directive 85/374/EEC intended complete harmonization of liability for defective products in Europe and consequently, member states could not have a system of no fault or strict liability for defective products of persons other than those defined by the Directive itself. Nor could member States transfer the liability of the producer to other persons such as retailers. But the Court did state that member States were free, under the Directive, to have a liability system in which a supplier or retailer was liable under negligence or fault.

[264] For example, in Jean L.B. v. Goyo e Hijos C.B. (retailer), Court of Appeals of Santa Cruz de Tenerife 23.9.01 (JUR 2001\18469; Hon: Pilar Aragón Ramírez). In this case, the plaintiffs brought an action against the product retailer and the court dismissed the claim because the product manufacturer was perfectly identified and therefore the product claim should have been brought against him instead of against the product retailer. See also Segurcaixa, S.A. de Seguros y Reaseguros v. SMEG España, S.A. (supplier), Court of Appeals of Barcelona, 29.11.04 (AC 2004\2017; Hon: Laura Pérez de Lazarraga Villanueva). In this case, the court dismissed the plaintiff's product claim brought against the product supplier because both the product manufacturer and the importer of the product could be identified.

[265] The Brussels Convention on jurisdiction and the enforcement of judgments in civil and commercial matters, September 27 1968 [Official Journal C 189 of 28.07.1990]. The Brussels Convention regulates the courts with jurisdiction in civil or commercial legal disputes between individuals residing in different member states of the European Union and the European Free Trade Association and includes rules regarding the recognition and enforcement of foreign judgments.

from outside the European common market are the ones exposed to liability under the Directive.

The second exception to the Directive's general inclusiveness is that when a product is delivered and the producer is unknown, the supplier is treated as its producer unless the supplier can identify the actual producer.[266]

It is not uncommon for an injured victim to pursue his or her product liability claim against two or more potential tortfeasors. As already noted, one of the major goals of the product liability Directive is to ensure that injured victims are able to obtain compensation for the harm they suffered. For that reason, in cases where there are multiple defendants, the Directive makes them jointly and severally liable. This allows the victim to recover full damages from any one of the defendants and therefore be assured of compensation despite not knowing which defendant caused the damage and to what extent.[267] The Directive does not deal with issues regarding how these defendants are to ultimately apportion liability among themselves or how the paying defendant should seek contribution from the other tortfeasors. Instead, the Directive leaves these issues to each state's domestic law.[268]

In Spain, Law 22/94 transposed the Directive and included a joint and several liability for damages caused by multiple tortfeasors in its article 7.[269] The law then refers to domestic regulation to determine how a tortfeasor who pays on behalf of other

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[266] Article 3(3) of the product liability directive.

[267] Article 5 of the product liability directive. See also Preamble paragraph 5. The joint and several liability is without prejudice of any applicable domestic provisions regarding contribution between them. See Mercedes v. Instaladores C.C.C., S.L. (supplier), Court of Appeals of the Balearic Islands 28.12.04 (JUR 2005\38399; Hon: Santiago Oliver Barceló) where the court held joint and severally liable the manufacturer of a defective water boiler and the supplier/installer of the boiler for having installed it incorrectly. The contribution among them was to be determines in application of domestic regulation in a subsequent lawsuit. See also Jesús María M. C. v. Conal Hispania, S.A. and Celaya Parreño, S.L., Court of Appeals of Burgos 16.12.03 (JUR 2003\43604; Hon: Ildefonso Barcalá Fernández de Palencia) where the court held the manufacturer and the subcontractor -- who had the duty to supervise and ensure the product had the safety the consumer was entitled to expect -- of a platform in a wine store were joint and severally liable for the harm caused by it to the injured victim when it broke.

[268] Article 5 of the strict product liability Directive.

[269] Today, law 22/94 has been overruled by the RDL 1/2007 and provides, in its article 132, that whenever damages are caused by multiple tortfeasors this will be jointly and severally liable.

tortfeasors may seek contribution from the others.[270] Under the Spanish civil code, when the obligation among the tortfeasors is joint and several, the injured victim may file a claim against any of the tortfeasors or against all of them[271] and the payment of one of them reduces or extinguishes the obligation of the others.[272] The procedural aspects, such as whether all tortfeasors should be sued jointly in the same legal process or whether a judgment against one of them extinguishes any potential claim against the others are also governed by domestic law. In Spain, under the current rules of civil procedure, an injured victim would have to sue all the tortfeasors who might be held joint and severally liable so that they can take part on the judicial process and defend their position and their possible non-liability.[273] Hence, if one of the tortfeasors is not part of the judicial process

[270] Article 143 of RDL 1/2007 provides a three year period for the paying tortfeasor for seeking contribution from the other jointly and severally liable tortfeasors. The RDL, though, does not specify how this contribution should be done. It should be noted that the product liability directive in its article 12 expressly declares that contractual limitations between producers will be null and void.

[271] Article 1137 Civil Code states that

> *"La concurrencia de dos o más acreedores o de dos o más deudores en una sola obligación no implica que cada uno de aquellos tenga derecho a pedir, ni cada uno de éstos deba prestar íntegramente, las cosas objeto de la misma. Sólo habrá lugar a esto cuando la obligación expresamente lo determine, constituyéndose con el carácter de solidaria."*
>
> *"The concurrence of two or more creditors or of two or more debtors in one obligation does not imply that each of them would have the right to request, or have to comply with, the object of the obligation in full. The performance of the obligation in full by any of the parties will have to be expressly established, becoming the character of the obligation in solidarity."*

[272] Article 1145 CC

> *"El pago hecho por uno de los deudores solidarios extingue la obligación. El que hizo el pago sólo puede reclamar de sus codeudores la parte que a cada uno corresponda, con los intereses del anticipo.*
> *La falta de cumplimiento de la obligación por insolvencia del deudor solidario será suplida por sus codeudores, a prorrata de la deuda de cada uno"*
>
> *"The payment made by one of the solidary debtors extinguishes the obligation. The debtor who made the payment could claim against the co-debtors the share that would correspond to each of them, with the adequate interests.*
> *Non-compliance with the obligation because of insolvency of one of the solidary debtors will be replaced by his co-debtors, in proportion to the debt of each of them."*

[273] Article 542.1 of Law 1/2000 of January 7 of Civil Procedure (BOE 7, of January 8, 2000 pp. 575-728. amendment of errors BOE num. 90, de 14-04-2000, p. 15278 and BOE num. 180 of July 28, 2001, p. 27746). This article, regarding the obligation of the joint and severally liable debtor establishes that

> *"Las sentencias, laudos y otros títulos ejecutivos judiciales obtenidos solo frente a uno o varios deudores solidarios no servirán de título ejecutivo frente a los deudores solidarios que no hubiesen sido parte en el proceso."*

it will not be possible to seek payment from him.[274] At the same time, a judgment against one of the tortfeasors will be binding on the others who are part of the judicial process regarding the existence of the obligation but not its content.

Even though this procedure may differ from one member state to another and its application presents potential problems -- particularly with regard to the Directive's harmonization goal -- the second report of the Commission justified the continuation of the joint and several liability rule among potential tortfeasors. This rule remains in force today.[275]

4.1 Who contributes to the physical creation of the product

The concept of producer has what could be called a physical production side and a marketing or trade side. With regard to the physical production of the product itself, the product liability directive considers producers both manufacturers of final products and manufacturers of components or product parts, as already noted.[276]

> *"The judgments, awards and other judicial rights obtained only against one or some of the joint and severally liable debtors will not be an executive title against the other debtors who were not part in the judicial process."*

This is a novelty of this law of civil procedure of 2000 given that the former Law of Civil Procedure of 1881, in its article 421 established that filing a claim against any of the joint and severally liable tortfeasor was enough and the judgment against all of them -- even if not part of the procedure -- was binding against them. After the Spanish Constitution was passed, in 1978, this article contradicted article 24 of the Constitution whereby no-one can be punished without having been able to defend and have been afforded fair justice. Therefore, this article was amended and modified in the new law of 2000. Today it is necessary to file the damage claim against all the tortfeasors so that they can take part in the process and therefore be obliged to pay. The judgment stating the obligation to all tortfeasors will be binding despite their participation in the judicial process but this judgment will not be enforceable against those who have not taken part in it.

[274] Article 542.1 Law 1/2000 of Civil Procedure.

[275] Green paper Liability for defective products presented by the Commission on July 28, 1999, COM(1999)396 final, at 20. This document can be found at http://europa.eu/documents/comm/green_papers/pdf/com1999-396_en.pdf

[276] Article 3 of the product liability directive.

The Directive does not define what constitutes an act of manufacture. From the wording of the Directive and its context it can be understood that the manufacturer is equivalent to the producer of a finished product or of component parts[277] but not someone who solely installs or repairs a product that is already in its finished state -- unless this partly modifies the product by replacing parts or installing new parts.[278]

At the same time, manufacturers of component parts and raw materials are liable for the harm caused by the defect in these product components as long as they render the finished product defective as well.[279] However, the manufacturers of product components are exempt from liability whenever the defect "is attributable to the design of the product in which the component has been fitted or to the instructions given by the manufacturer of the product."[280] Such definition covers people who extract, process, refine or assemble raw materials.[281]

In light of this definition, it is foreseeable that component manufacturers will be interested in receiving detailed contractual specifications and instructions from the final-product manufacturers regarding the components needed and the use for which the

[277] See James A. Henderson, Jr., Sellers Of Safe Products Should Not Be Required To Rescue Users From Risks Presented By Other, More Dangerous Products, 37 Sw. U.L. Rev. 595, 611-612 (2008) noting that producers of components parts should only be held liable for the harm caused by a defect in the final product to the extent that the product component and the final product jointly and synergistically present higher risks than each of them separately. Henderson argues that if the product component is not defective but the final product is defective; liability should not be imposed on manufacturers of component parts.
[278] Such person would be liable for defective services if the Directive proposal (Commission's proposal presented on March 5, 2004 COM(2004)) would be adopted.
[279] Lockatrucs v. Goodyear Dunlop Tires, S.A. (manufacturer), Nirvauto, S.A. y Direcauto, S.L, (importer). Court of Appeals of Zaragoza 10.2.04 (JUR 2004\92259; Hon: Antonio Luis Pastor Oliver) where the court held the importer of a final product liable for the harm caused by the defect in a component part that rendered the final product defective.
[280] Article 7(f) of the product liability Directive.
[281] See Guido Alpa, Manufacturer, Importer and Supplier Liability in Italy Before and After the Implementation of the E.E.C. Directive on Damages for Defective Products, 6 & 7 Tul. Civ. L.F. 233, 237-238 (1991-92). Alpa has raised the question of how to categorize suppliers of computer software, considering that liability should be "extended to the manufacturer of a machine which contains defective software and is therefore unsafe."

product is ultimately intended. Such information may help reduce the risk of liability resulting from the production of a defective component.[282]

4.2 Any person who presents himself as its producer

In many cases, the name of an individual or entity written on the product or on the label or other written materials accompanying the product provides the only information readily available to a consumer/user regarding who might be liable for injuries that the product causes. The product liability directive imposes strict liability on any party that presents itself as the producer of the product by putting its name, trademark or other distinguishing feature of the product.[283] This provision is most relevant in cases where the consumer does not know the actual product manufacturer.

4.3 Any person who imports into the community a product for sale, hire, lease or any form of distribution in the course of his business

The product liability directive also subjects to strict liability the importer of the product into the European Union, regardless of where within the Union this importat takes place.[284] In general, given the difficulty of victims in identifying product manufacturers, especially foreign producers, it is useful to be able to bring a claim against

[282] A supplier should ideally keep copies of all product information and advertising so as to avoid a potential "failure to warn" case.
[283] Article 3(1) of the product liability directive. See James A. Henderson, Jr., Sellers Of Safe Products Should Not Be Required To Rescue Users From Risks Presented By Other, More Dangerous Products, 37 Sw. U.L. Rev. 595, 610 (2008) arguing that trademark licensors who do not participate in the manufacture or distribution of the product should not owe any duty to the potential victim and hence should not be subject to liability for risks it does not and cannot control.
[284] Article 3(2), 3(3) of the product liability directive. See Gregory G. Scott, Product Liability Laws In The European Community In 1992, 18 Wm. Mitchell L. Rev. 357, 361-362 (1992).

the person who initially places the product into the Union.[285] This provision is a consequence of the structure of the European Union, where trade between member states is considered trade within a single market and so it does not matter in which state the actual importat from outside the Union took place.[286]

Allowing victims to sue such importers ensures that there is some potential defendant within the European Union boundaries who is primarily liable as a producer. This is of great help for victims who are relieved of having to identify and bring a claim against the foreign manufacturer and who can therefore avoid foreign law issues, problems of enforceability of a judgment and high costs.

This obligation imposed on importers might seem too strict and disproportionate. Besides any fairness considerations, however, the obligation is actually quite consistent with the position in which European law generally places importers, treating them more strictly than intra-Union distributors. For example, the European Economic Community allowed the imposition on importers and domestic manufacturers of the obligation of retaining (and facilitating the evaluation of) available documents about the characteristics of their products.[287] The failure to fulfill this obligation would result in the application of

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[285] See Lockatrucs v. Goodyear Dunlop Tires, S.A. (manufacturer), Nirvauto, S.A. y Direcauto, S.L, (importer). Court of Appeals of Zaragoza 10.2.04 (JUR 2004\92259; Hon: Antonio Luis Pastor Oliver) where the court held the importer of a final product into the European union market liable for the harm caused by the defect in a component part that rendered the final product defective.

[286] The concept of importer into the European Community raised some interpretation issues that led the European Commission to take legal actions against France in two different cases. The European Court of Justice, in a joined opinion that Mr. Advocate General Geelhoed delivered on 18 Septembre 2001; Commission of the European Communities v French Republic. Case C-52/00. 2001 ECJ CELEX LEXIS 6747; 2002 ECR I-3827, where the European Commission brought an action against the French Republic under Article 226 EC for failure to fulfill obligations when transposing the Directive into French national law and the case Court of Justice of the European Communities. Opinion of Mr. Advocate General Van Gerven delivered on 15 December 1988. Criminal proceedings against Esther Renee Bouchara, nee Wurmser, and Norlaine SA., Case 25/88. Reference for a preliminary ruling: Tribunal de grande instance de Bobigny - France. 1988 ECJ CELEX LEXIS 7211 where the European Court of Justice understood that France was treating French producers and importers under different standards than the ones applied to the European producers.

[287] Court of Justice of the European Communities. Opinion of Mr. Advocate General Van Gerven delivered on 15 December 1988. Criminal proceedings against Esther Renee Bouchara, nee Wurmser, and Norlaine SA., Case 25/88. Reference for a preliminary ruling: Tribunal de grande instance de Bobigny - France. 1988 ECJ CELEX LEXIS 7211. P 25 Citing the judgment of 17 December 1981 in Case 272/80, (1981)

stricter rules of criminal liability than those applicable to the distributor of domestic products. Thus, extra-Union importers were subject to a higher degree of care than intra-Union distributors.[288] Nevertheless, such measures were considered extraordinary in the sense that they needed to be proportionate to the goal they pursued and could be adopted as long as they were not inherently discriminatory for the importer or for the imported products.[289]

Importers do not bear an absolute responsibility for the products they import to the Union market. For instance, in cases where the manufacturer does not make it possible to verify whether the products conform to the domestic rules of the importing country -- either because it does not want to provide the information or because it does not provide the documents including this information -- the importer may be required to provide a product sample to determine such conformity and determine the liability of the producer. Similarly, whenever the importer has reason to doubt the accuracy of the documents supplied by the manufacturer, member states may require the seller of those products to verify a sample of them and determine whether the information given to the importer is accurate.

Considering the product liability directive's purpose of facilitating victim's compensation, it would not seem consistent to impose liability on importers to the European common market and yet leave exempt distributors within this internal market. However, importers and distributors are not subject to the same liability standard. While importers are primarily responsible for harm caused by the defective products they import

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ECR 3291, paragraph 15, and the Opinion of Mr Advocate General VerLoren van Themaaat in Case 124/81 Commission v United Kingdom (1983)ECR 248, and at p. 249.

[288] Court of Justice of the European Communities. Opinion of Mr. Advocate General Van Gerven delivered on 15 December 1988. Criminal proceedings against Esther Renee Bouchara, nee Wurmser, and Norlaine SA., Case 25/88. Reference for a preliminary ruling: Tribunal de grande instance de Bobigny - France. 1988 ECJ CELEX LEXIS 7211. P 26.

[289] Court of Justice of the European Communities. Opinion of Mr. Advocate General Van Gerven delivered on 15 December 1988. Criminal proceedings against Esther Renee Bouchara, nee Wurmser, and Norlaine SA., Case 25/88. Reference for a preliminary ruling: Tribunal de grande instance de Bobigny - France. 1988 ECJ CELEX LEXIS 7211 p14.

into the European market, distributors or suppliers within the Union have secondary liability where the product is imported into the Community and it is not possible to identify who imported it.[290] Hence, a supplier will not be liable if he informs the victim of the identity of the producer.[291] But the Directive provides that suppliers will be liable "even if the name of the producer is indicated"[292] so that they do not avoid being held liable by identifying a producer who is outside the Community. This liability structure could lead to somehow counter-intuitive results in cases where, for example, the product supplier could not identify the importer but could identify the foreign producer and therefore avoid secondary liability while leaving the victim in a complicated situation to bring a claim.

4.4 Product suppliers whenever the product manufacturer cannot be identified

The drafters of the product liability directive seem to have been well aware that globalization and the context of international trade imply that very often consumers do not know who the product manufacturer is. For that reason, the product liability directive includes mechanisms for cases in which the producer cannot be identified[293] and places secondary liability on each supplier in the chain of distribution, regardless of their level of care.[294]

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[290] Article 3(3) of he product liability directive. See also Gregory G. Scott, Product Liability Laws In The European Community In 1992, 18 Wm. Mitchell L. Rev. 357, 361-362 (1992).
[291] Article 3 of the product liability directive.
[292] Article 3(3) of the product liability directive.
[293] Article 3(3) of the product liability directive. This Article represents a significant administrative and financial burden for members of the supply chain because if suppliers or importers cannot pass liability up the chain they need to access to information in order to be able to establish that either the product was not defective; that it was defective but that the defect did not exist at the time of supply or that they did not know about the product risks in order to be able to use the development risks defense. Such information will be quite difficult to obtain from the product manufacturer and will represent a significant burden for the members of the supply chain.
[294] Article 3(3) of the product liability directive.

The term "supplier" embraces intermediate sellers, including wholesalers and retailers, and perhaps even other parties with distribution functions.[295]

There is no specific mention in the product liability directive of how it is to be established that the producer could not be identified.[296] Therefore, it is not clear whether there is a burden on the claimant to prove this or just to declare it. This issue has been addressed by the different member states, which have created domestic mechanisms so that whenever the injured person cannot identify the product manufacturer, he or she can request anyone in the chain to identify others further up the chain, the idea being that this request will go on until the victim will be able to identify the producer.[297]

In Spain, for example, article 138.2 of RDL 1/2007 establishes liability for the supplier whenever the producer or importer of the product cannot be identified within three months by either the injured victim or the supplier.[298] Further, if the supplier has sold the product knowing the existence of the defect, it will be liable as the product manufacturer or the importer but will have a contribution claim against these entities for

[295] The paragraph 5 of the Preamble of the Directive seems to suggest a broad interpretation of the concept of supplier when it establishes that "in situations where several persons are liable for the same damage, the protection of the consumer requires that the injured person should be able to claim full compensation for the damage from any one of them."

[296] The European Court of Justice has established that domestic regulation could not expose producers and suppliers to the same primary liability standard. See paragraph 37 of Case C-402/03, Skov Æg v. Bilka Lavprisvarehus A/S and Bilka Lavprisvarehus A/S v Jette Mikkelsen and Michael Due Nielsen on a Reference for a preliminary ruling from the Vestre Landsret where the court stated that

> "*it follows that the Directive must be interpreted as precluding a national rule under which the supplier is answerable without restriction for the liability of the producer under the Directiv*e."

[297] In fact, some member states such as France or Denmark did not transpose this provision into their domestic laws correctly. France placed suppliers under the same strict liability as product manufacturers and Denmark subjected suppliers' liability only to the provisions of domestic law and not under the subsidiary liability established by the Directive. See Commission v. France, C-52/00 (2002) ECR I-3827 and Skov AEG v. Bilka Lauprisvarenhus A/S C-402/03 (2006) 2 CMLR 16, at [17].

[298] This provision was established in article 4.3 of law 22/94 transposing the product liability directive. For cases applying this article see Julián v. Autoservicios Miguel, Court of Appeals of Tenerife 9.12.05 (JUR 2006\69428; Hon: Modesto Blanco Fernández del Viso) and Ramón and Seguros A, S.A. v. C (supplier), Court of Appeals of Barcelona 10.5.00 (EDJ 2000\48626; MP: Dolors Montolió Serra). In these cases, the Court of Appeals of Barcelona and Tenerife held a product supplier liable for the harm suffered by the victim because he did not identify the product manufacturer within the three months provided by the law.

the compensation paid to the victim.[299] Beyond these specific situations, the supplier or product seller will be liable under contract law or under the liability provisions of the Spanish civil code.[300]

Under the product liability directive, whichever member of the supply chain identifies the producer, that member alone will be able to avoid liability. Given the great incentives this gives suppliers to identify the producer or to provide any other name in the supply chain, it would be very suitable if liability would be dependent on the ability to correctly identify the producer or a previous supplier, even when in good faith. Otherwise such system would lose its purpose. These mechanisms created either by the Directive or by the member states aim to provide some kind of equitable solution to the unfairness that would result from imposing liability on retailers for defects of which they could not possibly have been aware of. This is particularly true for retailers who sell products in sealed packages.

From a practical perspective, this means that in order to avoid liability, firms have to keep records of their transactions and the product they supply in order to be able to point to whoever is responsible for the defect and therefore avoid liability. Nevertheless, the burden to show the damage, the defect and the causal relationship between defect and damage still remains on the consumer.[301]

5 Plaintiffs Protected by the Directive

The product liability directive does not specify that the claimant need be a consumer, user or purchaser of the product or have any proprietary interest in it. The

[299] When selling the product knowing the existence of a defect, the supplier is not liable secondarily but it is put in the same position as the producer or the product importer. See RDL 1/2007, addendum to law 22/94. (Disposición Adicional Única).
[300] Article 1902 of the Spanish Civil Code.
[301] Article 4 of the product liability directive.

body of the Directive refers to "injured person" while the preamble refers to "consumers," which are not equivalent concepts.[302] It seems reasonable to understand that all these potential victims are embraced by the product liability directive and may be entitled to bring a claim for the damages they suffered due to a defective product. Under the Directive, the categories of plaintiffs entitled to bring claims are diverse and the differences between them relate to the damages to which they are entitled. So while consumers-purchasers will be able to recover for property damage, an injured innocent bystander will be able to claim only the personal damages suffered.[303] In any case, the final identification of the victim entitled to compensation, though, will be determined by the laws of each member state.[304]

In Spain, the different laws dealing with product liability reflect different approaches: while the LGDCU was applicable to consumers and users[305] article 129 of the RDL 1/2007 is applicable to consumers, users and bystanders.[306]

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[302] Article 4 of the product liability directive does not define the central term *consumer*. Marshall S. Shapo, Comparing Products Liability: Concepts in European and American Law, 26 Cornell Int'l L.J. 279, 283 (1993).

[303] Article 9(b)(ii) of the product liability directive. Similarly, the Restatement Second section 402A also left the definition of the scope of plaintiffs for courts – comment o Restatement (Second) of Torts§402A- and courts established that purchasers of the product as well as bystanders fell within the scope of section 402A of the Restatement (Second), either under negligence or strict liability. See Richard W. Wright, The principles of product liability, 26 Rev. Litig. 1067, 1071 (2007). In contrast, the Restatement Third does not include a reference to bystandards even though they seem to be included under the liability for harm to "persons." See Restatement (Third) of Torts: Products Liability, § 1. See also Mark A. Geistfeld, Principles of Product liability 16, 252 (2006).

[304] Court of Justice of the European Communities, Opinion of Mr Advocate General Ruiz-Jarabo Colomer delivered on 14 December 2000; Henning Veedfald v Arhus Amtskommune. Reference for a preliminary ruling: Hojesteret. Case C-203/99. 2000 ECJ CELEX LEXIS 7596; 2001 ECR I-3569.

[305] Article 25 of the Law 26/1984, of July 19, of the General Defense of Consumers and Users (LGDCU) (BOE nums. 175 and 176, of July 24, 1984).

> *"El consumidor y el usuario tienen derecho a ser indemnizados por los daños y perjuicios demostrados que el consumo de bienes o la utilización de productos o servicios les irroguen salvo que aquellos daños y perjuicios estén causados por su culpa exclusiva o por la de las personas de las que deba responder civilmente."*
>
> *"Consumers are users are entitled to compensation for the harm suffered as a consequence of the consumption of goods or the use of products or services except in cases where those damages were caused exclusively by the fault of the injured victim or by the fault of the individuals for whom the victim should be liable for."*

[306] Article 129.1 of RDL 1/2007 focuses on the damages caused by the defective product and the private use of the product and does not refer to who might be the individual suffering harm caused by the product defect. Specifically, article 129.1 states that

The determination of the scope of the plaintiffs protected by the product liability directive is an important issue for the effectiveness of the strict liability regime established by it. Tortfeasors need to be able to assess the expected liability to which they are exposed, especially considering that it is strict, so that they may make informed decisions about purchasing insurance.[307] Foreseeability is a crucial element in order to be able to adjust the insurance premiums and buy insurance according to the expected liability to which potential tortfeasors are exposed.[308] In addition, the effectiveness of strict liability depends on whether the injured victim is a product buyer (a consumer), a product user or a bystander given that when deciding whether to buy the product, the consumer discounts the risk of harm form the product price and hence strict product liability is more attractive for him.[309]

5.1 The plaintiff's prima facie case: damage, defect and causation

In order to bring a claim under the product liability directive, victims need to show evidence of a prima facie product liability case, which consists of: proving they

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"El régimen de responsabilidad previsto en este libro comprende los daños personales, incluida la muerte, y los daños materiales, siempre que éstos afecten a bienes o servicios objetivamente destinados al uso o consumo privados y en tal concepto hayan sido utilizados principalmente por el perjudicado (...)."

"The liability regime established in this book includes liability for personal injury, including death, and material damages to property provided that these affect goods and services objectively intended for private use or consumption and that are mainly used by the injured victim (…)."

[307] Richard Posner, ECONOMIC ANALYSIS OF LAW, Aspen eds. 177, 184 (6th ed.) (2003).

[308] James Henderson, Revising Section 402 A: the limits of tort as social insurance, 10 Touro L. Rev. 107, 117-20 (1993-1994).

[309] A. Mitchell Polinsky, and William P. Rogerson, Products Liability, Consumer Misperceptions and Market Power, 14 Bell J. Econ.2, 588-589 (1983).

suffered damages, that the product was in a defective condition and that there is a causal relationship between the product defect and the harm they suffered.[310]

5.1.1 Damages

The damages covered by the Directive are "death or personal injury" or the "damage to, or destruction of, any item of property other than the defective product itself, with a lower threshold of 500 ECU."[311]

For damages other than these ones, the Directive preserves the application of "national provisions relating to non-material damage,"[312] that is, domestic contractual and non-contractual law in force in each member state. Therefore, under the Directive, the victim's recovery and the applicable law depend upon the nature of the damage and not on the product which caused the damage.

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[310] Article 4 of the product liability directive. The principle of plaintiff's burden of proof of causation is established in all European countries. Christopher J S Hodges, Product Liability In Europe**:** Politics, Reform And Reality, 27 Wm. Mitchell L. Rev. 121, 122 (2000).

[311] Article 9(a) of the product liability Directive defines damages. The Directive refers to ECUS. The ECU was the first attempt to a common European currency but was rejected in 1997, when it was decided that the name of the European currency would be Euro, instead of Ecu. Since then, all measurements of European legal texts that were done in Ecus were supposed to be understood as expressed in Euros given that one Ecu was equivalent to one Euro. In Spain, the conversion to the Directive's threshold was 65.000 pesetas included in article 10 of law 29/1994 that became 390,66 euros after having done the currency conversion.

[312] Article 9 of the product liability directive. Thus, pure economic loss must be claimed under contract or fault liability, if it is available under domestic law. Additionally, under Article 13 of the product liability Directive preserves the "rights" derived from "*the rules of the law of contractual or non-contractual liability or a special liability system existing*." In Spain Article 9 of the Directive was transposed in article 10 of the law 22/94 – today article 145 RDL 1/2007. This law interacts with contract law and more specifically, with article 1101 of the Civil code regarding compensation for damages caused by breach of contract; the general warranty clause for product defects of article 1484 of the Spanish Civil Code and with law 23/2003 of July 10th regarding warranties of consumer goods.

The Directive sets out the compensable damages but domestic legislatures determine their specific content and domestic courts must then interpret their legislatures' pronouncements in light of the wording and purpose of the Directive[313] in each case.[314]

Compensation for pain and suffering or non-material damage are not covered under the Directive but can be compensated, where available, under domestic law.[315] However, except for the non-pecuniary loss governed solely by domestic law, European member states may not reduce the scope of compensable damages under the product liability directive.[316] This implies that domestic legislators may provide for compensation of pain and suffering,[317] pure economic loss or loss of profit, and may establish coordinating systems with other compensation systems such as private or public insurance. Domestic regulation will be applied regarding rules for coordinating the compensation received by the victim from different sources.[318] Regardless of the determination made by domestic courts and legislatures, injured victims must be provided full compensation to ensure that the application of domestic law does not impair the effectiveness of the Directive.[319]

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[313] See for example, the judgment in Case 14/83 Von Colson and Kamann 1984 ECR 891, paragraph 26 regarding the determination of the purpose of the Directive.

[314] Article 1 and 9 of the product liability directive. See also European Court of Justice, Judgment of the Court (Fifth Chamber) of 10 May 2001. Henning Veedfald v Arhus Amtskommune. Case C-203/99. 2001 ECJ CELEX LEXIS 6690; 2001 ECR I-3569.

[315] Article 9 of the Directive. See the European Court of Justice judgment in the Case C-365/88 Hagen 1990 ECR I-1845, paragraph 20 See also Court of Justice of the European Communities; Opinion of Mr Advocate General Tizzano delivered on 20 September 2001. Simone Leitner v TUI Deutschland GmbH & Co. KG. Case C-168/00. 2001 ECJ CELEX LEXIS 6656; 2002 ECR I-2631.

[316] Article 9 of the product liability directive.

[317] Marta v. AEI Inc. (manufacturer) and Collagen Biomedical Aesthetic Iberica, S.A. (importer), Court of Appeals of Pontevedra 14.10.05 (JUR 2006\101870; Hon: Jaime Carrera Ibarzábal) where the court considered the possibility of providing compensation for pain and suffering to the victim under article 1902 of the Spanish Civil Code in application of article 15 of Law 22/94, for the damages suffered by the victim due to the removal of mammal prosthesis made with soybean oil.

[318] In Spain, for example, this will imply seeking compensation under the Civil code -- contractual in article 1101 CC and followings or extra-contractual 1902 and following -- and any specific regulation of the damage suffered where available.

[319] Article 9 of the product liability directive. See the opinion of Mr Advocate General Ruiz-Jarabo Colomer delivered on 14 December 2000 in the case Henning Veedfald v Arhus Amtskommune. Reference for a preliminary ruling: Hojesteret. Case C-203/99. 2000 ECJ CELEX LEXIS 7596; 2001 ECR I-3569. In the Case C-203/99 the European Court of Justice established differences between the personal injury and the property damage concepts. In that case, the question before the Court was whether the damage caused

The interaction of two regulatory bodies sometimes based on different principles -- strict liability and negligence -- might result in each one canceling out the potential benefits of the other while simultaneously making it more difficult for manufacturers to anticipate and internalize the expected liability to which they are exposed.[320] Despite the Directive's harmonization goal, the interaction between community and domestic law has raised some divergences regarding damages awarded to injured victims[321] because community law does not provide full compensation to victims, who must then turn to domestic law whenever possible. In this sense, even though the Commission considered that the amount of damages awarded in individual cases would not differ substantially among member states,[322] further comparative research suggests that significant variations exist.[323]

a. Compensable damages

The difficult task of determining compensable damages under the Directive was addressed by the European Court of Justice in Henning Veedfald v Arhus

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to the kidney, which made it unusable for a transplant, has to be construed, in relation to the intended recipient of the organ, as personal injury or as damage to an item of property for the purposes of Article 9 of the product liability directive. Considering the fact that a human organ does not fulfill the requirements laid down by Article 9(b)(i) and (ii) in order for there to be damage to an item of property, - that the item must be of a type ordinarily intended for private use or consumption and that it must have been used by the injured person mainly for that purpose - the Court ruled that Article 9 of the product liability directive should be construed as meaning that damage caused to a human organ at the time when it is removed from the body of a donor for immediate transplantation into another persons body is covered by the expression damage caused by personal injuries but not by the expression damage to, or destruction of, any item of property. Therefore, the damage caused to a human organ which had been removed from the body of the donor for immediate transplantation into the body of the recipient was to be considered personal injuries.

[320] But if victims to potential damages under each regime were different such interaction would not be a problem. See Juanjo Ganuza and Fernando Gomez, Caution, children crossing: heterogeneity of victim's costs of care and the negligence rule, Volume 1: Issue 3, Article 3, Review of Law and Economics (2005).

[321] Geraint G. Howells, The rise of European Consumer Law -- Whither National Consumer Law?, 28 Sydney Law Review 63-88, 74 (2006).

[322] European Commission Explanatory Memorandum, E.C. Bull. Supp. L11 para.21 (1991).

[323] Even though oldated today, see Personal Injury Awards in E.C. Countries, McIntosch and Holmes, Lloyd's of London Press Ltd. (1990).

Amtskommune.[324] In this case, the European court laid down the different legislation applicable depending on the type of damages suffered by the injured victim. For damages covered specifically by the product liability directive, the Directive is to be the exclusive source of law, while for other types of damages domestic regulation is applicable.[325]

The damages that give rise to a claim under the Directive are damages of an amount exceeding 500 euros consisting in death or personal injuries and damage to, or destruction of, an item of property, other than the defective product itself.[326] Damage to the defective product itself, thus, potentially could be claimed under the domestic law of the member state.[327]

With respect to property damage, the Directive distinguishes between damage to property for professional or for private use[328] and only provides a claim for damages that arise from a product "of a type ordinarily intended for private use or consumption" and "used by the injured person mainly for his own private use or consumption."[329] Thus, only individuals not using the product professionally -- and not corporations -- can claim damages under the Directive.[330] Consequently, damage to personal property will be

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[324] Henning Veedfald v Arhus Amtskommune C203/99 (2001) Judgment of the Court (Fifth Chamber) of 10 May 2001.

[325] Henning Veedfald v Arhus Amtskommune C203/99 (2001). See also Whittaker, Simon, LIABILITY FOR PRODUCTS: ENGLISH LAW, FRENCH LAW AND EUROPEAN HARMONIZATION, 503, Oxford: Oxford University Press (2005).

[326] Article 9 of the product liability directive Court of Justice of the European Communities, Opinion of Mr Advocate General Ruiz-Jarabo Colomer delivered on 14 December 2000; Henning Veedfald v Arhus Amtskommune. Reference for a preliminary ruling: Hojesteret. Case C-203/99. 2000 ECJ CELEX LEXIS 7596; 2001 ECR I-3569. See the U.S. equivalent in East River S.S. Corp. v. Transamerica Delaval, Inc. 476 U.S. 858 (1986) where the United States Supreme Court denied recovery for the damage to the ship turbines allegedly caused by the defect in the turbines themselves.

[327] Jesús v. Garlovi S.A. and Citroën Hispania S.A., Court of Appeals of Asturias 23.2.00 (JUR 2000\124793; Hon: José Manual Barral Díaz) where the court, in application of Spanish law (the LGDCU of defense of users and consumers) and article 1902 of the Spanish Civil Code awarded compensation to the victim for the damages to the defective vehicle and in application of Law 22/94, awarded compensation for the property damage caused by the defective vehicle.

[328] Article 9(b). Damages to property in professional use continue to be covered by the domestic liability rules of each Member State. See THE BOUNDARIES OF STRICT LIABILITY IN EUROPEAN TORT LAW, Franz Werro And Vernon Valentine Palmer, (Eds.) Durham, N.C.: Carolina Academic Press, 437 (2004).

[329] Article 9 of the product liability directive.

[330] See Luis Alberto v. Construcciones Arssis, S.L. (supplier), Simex (manufacturer), Court of Appeals of Valencia 20.7.06 (JUR 2007\5615; Hon: Manuel José López Orellana), Maxi and Isabel, S.L. and Mutua

recoverable under the Directive and damages to commercial property will not.[331] Such limitations aim to "avoid litigation in an excessive number of cases."[332]

Additionally, the Directive imposes a compulsory damage threshold of 500 euros that must necessarily be included in the domestic regulation.[333] This provision has proved controversial[334] and in some cases member states have been reluctant to transpose it.[335]

In cases where damages are higher than the threshold, the producer must pay only the excess amount; the first 500 euros of damages are thus non-recoverable under the product liability directive even by a successful plaintiff.

The European Commission and the European Court of Justice have repeatedly stated that this threshold should not be seen as affecting victims' rights of access to the courts. Instead, they have said it should be understood merely as a mechanism to avoid an excessive number of claims under the product liability directive by filtering out those involving only minor material damages. They have also characterized the threshold as a way to reduce moral hazard problems by encouraging potential victims to exercise care, even when potential damages are low.

General de Seguros v. EDESA, Sociedad Cooperativa (manufacturer), Court of Appeals of Burgos 13.2.03 (JUR 2003\122404; Hon: Ildefonso Barcalá Fernández de Palencia), Hércules Hispano, S.A. v. Comercial Naranjo (seller). Court of Appeals of Las Palmas 22.3.01 (JUR 2001\170616; Hon: Juan José Cobo Palma). In all these cases, the Courts of Appeal affirmed the dismissal of the plaintiff's claim by the trial court because Law 22/94 was not applicable to a case involving a product for professional use.

[331] Court of Justice of the European Communities, Opinion of Mr Advocate General Ruiz-Jarabo Colomer delivered on 14 December 2000; Henning Veedfald v Arhus Amtskommune. Reference for a preliminary ruling: Hojesteret. Case C-203/99. 2000 ECJ CELEX LEXIS 7596; 2001 ECR I-3569.

[332] Preamble of the product liability directive.

[333] Article 9(b). See also European Court of Justice Cases, Judgment of the Court (Fifth Chamber) of 25 April 2002. Commission of the European Communities v Hellenic Republic. Case C-154/00. 2002 ECJ CELEX LEXIS 2955; 2002 ECR I-3879. In this case, the Hellenic Republic contended that its interpretation of the Directive was based on the fact that in its Green Paper of 28 July 1999 on liability for defective products the Commission proposed that the threshold of EUR 500 be abolished and considered that the existence of this threshold created an unfair inequality as between consumers and, by depriving the victim of a right of action, infringed the fundamental right of access to the courts, as guaranteed by Article 6 of the European Convention for the Protection of Human Rights and Fundamental Freedoms of 4 November 1950. See also, COM(1999) 396 final. The European Court of Justice did not agree.

[334] See, in particular, Case C-236/88 Commission v France 1990 ECR I-3163, paragraph 19.

[335] Commission v. France C-52/00 (2002) ECR I – 3827 at (17-20) and Commission v. Greece, C -154/00 (2002) ECR I – 3879.

This exclusion does not mean that damages under 500 euros are not compensable at all. Injured victims might still bring actions for such damages under contract law or non-contractual liability to the extent available.

In sum, the Directive allows victims to claim compensation for damages to or for the destruction of any physical property[336] worth at least 500 euros provided that the product was intended for private use and was used by the injured person mainly for his or her own private use and consumption.

b. Cap on Damages

The product liability directive does not cover all kinds of damages nor all aspects related to them. It is for domestic courts to apply their domestic legislation on the issue and determine the specific amount of damages that a certain victim will be awarded and whether there is any limitation on this amount.

The Directive does not specify how domestic courts should determine the amount of damages to award to a victim but in its article 16.1 it allows member states to introduce damages caps. According to this article

> Any Member State may provide that a producer's total liability for damage resulting from a death or personal injury and caused by identical items with the same defect shall be limited to an amount which may not be less than 70 million ECU.

From the wording of article 16.1 of the product liability directive it can be seen that the caps provision refers to ECUS,[337] that should be understood to be set at 70 million euros.[338]

[336] Other than the defective product itself.
[337] See Article of 2 of Council Regulation (EC) No 1103/97 of 17 June 1997 on certain provisions relating to the introduction of the euro, Official Journal L 162, 19/06/1997 P. 0001 - 0003**,** "(…) this means that one ECU in its composition as a basket of component currencies will become one euro."

Damages caps are optional provisions that member states may include in their domestic laws transposing the Directive if they choose to.[339] As of today, such caps have been introduced only by Germany and Spain,[340] and in both cases without much impact.[341] In Germany, the introduction of caps was based on the argument that liability needed to be limited in some way.[342] However, as of today, there has been no case of a German court referring to the damages that would have been awarded but for this provision. The same has been true for Spain. The Spanish legislature has seemed to consider that the introduction of a damage cap protects tortfeasors from potentially infinite damage awards. For accidents subject to strict liability the Spanish legislature has repeatedly introduced damage caps, damage guidelines or both.[343] The effect of such caps in Spain, like in Germany, has been remarkably limited.

In fact, when the damage caps provision was included in the draft Directive in 1985 it was assumed that it would be temporary. The idea was that ten years after the approval of the Directive, the Commission would evaluate the effect of this limitation on the protection of consumers and the functioning of the internal market and it would make

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[338] In Spain, the conversion of the damage cap of 10.500.000.000 pesetas set by article 11 of the law 22/1994, which transposed the strict product liability Directive, was determined by article 25 of Law 46/1998 of December 17 of 1998 regarding the introduction of the Euro. Council Regulation 2866/98/CEE of December 31, 1998 established the conversion rated between the currencies of the different member states and the euro and set that one euro was equal to 166, 386 pesetas and therefore the damage cap resulted in 63.106.270, 96 euros.

[339] Article 16.1 of the product liability directive allowing a possibility of introducing a cap on damages and article 15.1 of the Directive, allowing member states to introduce the development risks defense are the only two provisions of the Directive that are not compulsory for member states.

[340] See the Report from the Commission on the Application of Directive 85/374 on Liability for Defective Products, COM (2000), 893 final at 19-20. This Report lists Portugal as well but in 2001, in the Act 131/2001 of April 24, Portugal repealed such provision and now the damage cap is no longer in force.

[341] John Meltzer Reform Of Product Liability In The EU: New Report Finds General Satisfaction, 71 Def. Counsl. J. 42, 49-50 (2004).

[342] Regarding pharmaceutical products, the cap was established in 200 million Deutsche Marks (100 million Euros). See Report from the Commission on the Application of Directive 85/374 on Liability for Defective Products, COM (2000), 893 final at 19-20.

[343] An example of a law with a limitation of damages through damage caps is the law 22/1994 transposing the product liability directive today overruled by RDL 1/2007. Regarding damage award guidelines it is worth mentioning the Royal Law Decree RDL 1/1994 of June 20, approving the General Law on Social insurance (BOE 154, p. 20658 of June 29, 1994). The text of the Royal Decree is available at http://www.boe.es/aeboe/consultas/bases_datos/doc.php?id=BOE-A-1994-14960. The law 48/1960 of July 21th of aerial navigation combines both techniques of damage caps and damage awards guidelines.

recommendations regarding its continued necessity in one of its regular required reports to the European Council.[344] Even though this limitation on damages could potentially compromise the Directive's founding principle of uniformity among the different member states, the three reports that the Commission has presented evaluating the performance of the Directive and suggesting possible modifications have not included any proposal regarding the damage caps.[345] Hence, this optional provision is still in place today.

Some have suggested that maintaining the damage caps might be explained by their expected effect on insurance premiums.[346] To the extent the caps limit the amount of insurance coverage needed, they could reduce companies' insurance costs.

The damage caps included in the product liability directive are applicable only to the kind of accidents regulated by the Directive and the laws transposing it, which means "death and permanent injuries"[347] caused by a certain kind of product and a certain product defect.[348] Taking into account that pain and suffering are not compensable under the product liability directive, any limitation on damages becomes a cap for the injured victim when seeking compensation for personal and material damages suffered. As mentioned earlier, the product liability directive does not preclude the application of domestic regulation regarding damages not covered by the Directive. When a law

[344] According to Article 100 of the E.E.C. Treaty, the Commission will determine whether to repeal a provision or not.
[345] The first report regarding the application of the Directive was issued in 1995, COM (1995) 617 final. The second report was presented in the year 2000, COM (2000) 893 final, and the third and last report was presented in 2006, COM (2006) 496 final. None of these three reports include any proposal of modification or suppression of the damage cap. The only modification proposal was made by the European Parliament that proposed to increase the damage cap to 140 million euros. Given the scarce application of the cap in force, such proposal has never been adopted. See the European Commission's Green Paper on Liability for defective products, COM (1999) 396 final at 25. The paper is available at http://europa.eu/documents/comm/green_papers/pdf/com1999-396_en.pdf.
[346] Christopher Hodges, Reform of the Product Liability Directive 1998-99, 8, Cameron McKenna (1999).
[347] Article 9.1 of the product liability directive.
[348] See Article 16.1 of the product liability directive noting that the cap is applicable for "identical" products and for the same defect.

different from the Directive is applied, the Directive's damage caps provision is not applicable to damages compensable under domestic law.

Regarding the tortfeasors subject to the damage caps, the limitation is applied to each manufacturer or importer and not to all of them as a whole whenever they are producing or selling identical products.[349] In the case of holding corporations, the cap is to be applied to each corporation within the group and not to all of them as a whole.

The individualized application of damage caps to a single accident is consistent with the joint and several allocation of damages among the product manufacturer and the importer.[350] If both respond jointly and severally, a single damage cap is applied and the internal distribution of the damages will be determined by the domestic rules of each member state. If the damage cap were to be applied to each of them, the total damages for the victim could end up larger than the cap set by the Directive.

5.1.2 Defect

The Directive provides that a product is defective when it does not fulfill the consumers' expectations of the product's safety. Given the importance of this issue, it will be discussed separately in section 6 of this chapter.

5.1.3 Causation

[349] For an explanation of how this issue is solved in Spanish law see L. Fernando Reglero Campos (Coord.), TRATADO DE RESPONSABILIDAD CIVIL, 1425-1517, 3ª ed. (Cizur Menor, Thomson-Aranzadi) (2006).
[350] Article 7 of the product liability directive.

The final element of the plaintiff's prima facie product liability case under the Directive is providing evidence of the causal relationship between the product defect and the harm suffered.[351]

This element is of special importance in the liability context given that strict liability is a system that rests mostly on causation considerations[352] and the difficulty of establishing this crucial element could become a barrier to recovery in some cases, thereby undermining the consumer protection goal of the overall regime.[353] Despite this reliance on causation it is often considered that strict liability is cheaper and easier to administer than negligence-based liability systems given that negligence-based systems require proof not just of causation but also of what constitutes reasonable behavior in a given context.[354]

However, even if from this perspective strict liability seems to be a more cost-effective liability system than its alternatives, determining causation is not without difficulties. The proof of causation is generally presented as a two step analysis: first, whether but for the product's defect, the harm would not have occurred (cause-in-fact) [355] and second, whether the product was the proximate cause of the harm suffered..[356] Under the product liability directive the plaintiff is required to prove both types of causation: cause in fact -- but-for causation -- and proximate cause. If the plaintiff succeeds in establishing both causation elements, causation will be satisfied. The product liability

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[351] Article 4 of the Directive. See in general Thomas Lundmark, The Restatement of Torts (Third) and the European product liability Directive, 5 D.C.L. J. Int'l L. & Prac. 239, 253 (1996).
[352] Franz Werro, Tort Law at the Beginning of the New Millennium. A Tribute to John G. Fleming's Legacy, 49 Am. J. Comp. L. 147, 157 (2001).
[353] See generally Andrew C. Spacone, Strict Liability in the European Union - Not a United States Analog, 5 Roger Williams U. L. Rev. 341, 369 (2000). See also Geraint G. Howells & Mark Mildred, Is European Products Liability More Protective Than The Restatement (Third) Of Torts: Products Liability?, 65 Tenn. L. Rev. 985, 994 (1998).
[354] Jeffrey J. Rachlinski, Symposium: Responsibility And Blame: Psychological And Legal Perspectives: Misunderstanding Ability, Misallocating Responsibility, 68 Brooklyn L. Rev. 1055, 1076-1077 (2003).
[355] See James A. Henderson Jr., Richard N. Pearson, John A. Siliciano, THE TORTS PROCESS, Aspen, 101 referring to actual causation or general causation and 467-468 discussing the causation element in product liability cases (6th ed.) (2003).
[356] See James A. Henderson Jr., Richard N. Pearson, John A. Siliciano, THE TORTS PROCESS, Aspen, 257-258 and 467-468 (6th ed.) (2003).

directive adequately sets forth causation so that the requirements that define the harm for which defendants are liable are identified. Requiring only but-for causation alone would allow an infinite and unlimited number of potential claims from victims given that commercial activities present risks could be but-for causes of some kind of loss. At the same time, requiring proximate cause, would limit the expected claims and expected liability to which defendants would be exposed to.[357]

Although these elements appear easy to separate from a theoretical perspective, they are very difficult to distinguish in practice before a court, especially in cases where there are potentially concurrent causes of a victim's injury.

Under the product liability directive, the problem is, then, to determine the causation requirements in a way that does not rely on a determination of the defendants' negligence, given that this would obviously contradict the strict liability nature of the regime.[358] This is especially relevant given that in some Spanish cases, causation has been the element that has been used by courts to presume defect -- through a Res Ipsa Loquitur causation analysis -- and thereby impose liability.[359]

The product liability directive includes different burdens of proofs and the tests necessary to meet them must be clearly be distinguished. First, the defect test requires a showing that the product does "not provide the safety which a person is entitled to expect."[360] Whether there is a "causal relationship between defect and damage"[361] will determine causation in the specific case and whether the defendant knew or should have known of the product defect in light of the technical and scientific knowledge available is

[357] James A. Henderson, Jr., Why negligence dominates tort, 50 U.C.L.A. L. Rev. 377, 391-392 (2002).
[358] James A. Henderson, Jr., Why negligence dominates tort, 50 U.C.L.A. L. Rev. 377, 391-392 (2002).
[359] See Reamar, S.L. vc. Suministros de Pintura Juan Carlos Jiménez, S.L. (supplier) and Alp Reveton, S.L., Court of Appeals of Valencia 25.4.06 (JUR 2006\207061; Hon: Enrique Emilio Vives Reus) and Jesús Carlos y Andrés v. Citroën Hispania, S.A, Court of Appeals of Barcelona 21.4.05 (JUR 2005\122401; Hon: Josep Llobet Aguado). In these cases, the Courts of Appeal presumed the product defect based on the proof of causation and the damages suffered by the victim.
[360] Article 6.1 of the product liability directive.
[361] Article 4 of the product liability directive.

the standard to determine the development risks defense in the member states that have included it in their transposition laws.[362]

Hence, under the Directive causation is established whenever the injured victim can prove a causal relationship[363] between the product defect and the harm suffered by the victim and when in addition, the tortfeasor cannot claim any defense under the product liability directive and be discharged from liability.[364]

5.2 Timing of claims

Apart from the victim's prima facie case, the Directive also establishes timing requirements that place limits on product liability claims.[365] These consist of a period of limitation and a period of repose.[366]

5.2.1 Limitation

The limitation period or statute of limitations of an injured victim is an area in which European and domestic regulations interact. The product liability directive includes some determinations as to limitation periods and the domestic law of each member state also regulates this area through general statutes of limitations.

[362] Article 7 (e) of the product liability directive.
[363] Article 4 of the product liability directive.
[364] The product liability directive, in its article 7, provides for several defenses that if alleged and proved, exempt defendants from potential liability.
[365] Geraint Howells, COMPARATIVE PRODUCTS LIABILITY, 43, Darmouth publishing Company Limited (1993).
[366] Article 17 of the product liability directive. These provisions are not applicable retroactively so are applicable only to damages that took place after the Directive entered into force – after the transposition law was adopted in each member state. In the case where the harm was caused by a defective product before the products liability directive entered into effect, this could not be applied and such liability should be established under the domestic rules of each country.

The Directive sets a three-year period for the injured victim to bring a claim. These three years are to be counted from the day on which the plaintiff becomes aware, or should reasonably become aware, of the damage, the defect, and the identity of the producer.[367] Domestic laws relating to the suspension or interruption of the limitation period are still applicable and are not to be affected by the Directive.[368] The specifications of how this limitation period is to be applied are based on domestic laws.

This provision is relatively liberal toward plaintiffs because the limitation period does not begin to run until both the defect and the identity of the producer are known by the plaintiff. This double requirement could eventually result in considerable difficulties in determining the precise date upon which the limitation period begins to run.[369] In fact, in practice the three-year limitation period might become *de facto* a much longer period for cases involving, for example, chemicals, fibers and drugs, in which plaintiffs do not become aware of harm until years after exposure. For example, it is easy to think of relatively common situations in which a plaintiff knows of the harm, such as an illness, but is not aware that a product is the cause of that harm. In that context, the requirement of knowledge of the origin of the harm could be considered equivalent to the knowledge of causation. In those cases, courts will consider the moment when it is reasonable for a plaintiff to have knowledge of the identity of a particular producer in a chain of suppliers and whether the injured victim inquired about the identity of the producer from a given supplier or the person who supplied that supplier with a product. Such determinations, though, will have to be done on a case by case basis.

5.2.2 Repose

[367] Article 10(1) of the product liability directive.
[368] Article 10(2) of the product liability directive.
[369] Christopher Hodges, EUROPEAN REGULATION OF CONSUMER PROTECTION SAFETY, 86-87, Oxford University Press (2005).

A statute of repose is distinguishable from a statute of limitations in that a statute of repose eliminates all rights to a legal claim after a specified time.

Under article 11 of the product liability directive a victim has a ten year period after which his or her rights are extinguished.[370] This period starts from the date on which the producer placed into circulation the actual product that caused the damage. Note that this is different from the date on which a product of that type (but not the actual product) was first introduced in the market.

The preamble identifies a linkage between this provision and other parts of the product liability directive that deal with advances in product development and observes that products "age in the course of time, higher safety standards are developed and the state of science and technology progresses" and for that reason, "it would not be reasonable to make the producer liable for an unlimited period for the defectiveness of his product."[371] This repose period seems not to admit any exception.

This ten year period represents a significant restriction compared to the repose rules in some jurisdictions, and particularly given that in cases of personal injuries caused by medical products, the damage may be latent and not manifest itself for many years.[372] Additionally, it may sometimes be difficult to identify and determine the producer or the date on which the product was put into circulation. The Directive is silent on whether the burden of proof is to lie on the plaintiff or on the defendant in establishing these facts.

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[370] Article 11 of the product liability directive. Hence, during this ten year period, producers will be required to maintain sufficiently detailed records that may be crucial when determining whether liability should be imposed. See Lucille M. Ponte, Guilt By Association In United States Products Liability Cases: Are The European Community And Japan Likely To Develop Similar Cause-In-Fact Approaches To Defendant Identification?, 15 Loy. L.A. Int'l & Comp. L.J. 629, 652 (1993).

[371] Preamble of the Directive, paragraph 12.

[372] See Gabino and Marcelina v. Cerámica Malpesa, S.A. (manufacturer), Court of Appeals of Jaén 5.11.03 (JUR 2003\71326; Hon: Jesús María Passolas Morales) where the court understood that the 10 year statute of limitations was not applicable because the victim suffered continued damages and the statute of limitations was to be applied from the moment where the harm was final.

6 The Concept of Defect

One of the pillars of any product liability system is the determination of defectiveness. This element is crucial to whether liability may subsequently be imposed for the harm caused by the product. In this respect, the Directive again is not creative but instead merely follows the U.S. model proposed by section 402A of the Second Restatement.[373]

The product liability directive, in parallel to the Second Restatement, does not distinguish among types of product defects. Product liability cases in the United States, though, have differentiated between three different kinds of defects: manufacturing defects, design defects and defects in the warnings and instructions.[374]

The determination of whether a product is defective is done by adopting the consumer expectations test.[375] The Directive refers to this test in two different places. First, the preamble declares that

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[373] § 402A of the Restatement (Second) of Torts reads as follows:

> *"(1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if*
> *(a) the seller is engaged in the business of selling such a product, and*
> *(b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold".*

See also James Henderson Jr., Aaron D. Twerski, What Europe, Japan, And Other Countries Can Learn From The New American Restatement Of Products Liability, 34 Tex Int'l L J 1, 11 (1999) and Patrick Thieffry, Philip Van Doorn and Simon Lowe, Strict Product Liability in the EEC: Implementation, Practice and Impact on U.S. Manufacturers of Directive 85/374, 25 Tort & Insurance Law Journal 65, 71 (1989-1990).

[374] Restatement (Third) of Torts: Products Liability (1998) § 1 cmt. a. See also Aaron D. Twerski & James A. Henderson, Jr, Manufacturers' Liability for Defective Product Designs: The Triumph of Risk-Utility, 74 Brook. L. Rev. 1061, 1063 (2008-2009) noting the differences between the Restatement Second and the Restatement Third regarding differentiating between sub-categories of product defects.

[375] James Henderson Jr., Aaron D. Twerski, What Europe, Japan, And Other Countries Can Learn From The New American Restatement Of Products Liability, 34 Tex Int'l L J 1, 13-14 (1999). See also Restatement (Second) of Torts § 402A and cmts. a & m (1965) regarding the lack of differentiation between product defects and cmts g & i regarding the implementation of the consumer expectations test.

" (…) the defectiveness of the product should be determined by reference not to its fitness for use but to the lack of the safety which the public at large is entitled to expect (…)"[376]

Second, in its body -- in its article 6 -- the product liability directive states that

"(…) a product is defective when it does not provide the safety which a person is entitled to expect, taking all circumstances into account.(…)"[377]

Hence, the essential element of the defectiveness standard is the expectation of consumers, the content of which is controversial and difficult to determine,[378] and there is no risk-utility balancing of the costs and benefits to product sellers and users. But the expectation of consumers is not the only element to consider given that "all relevant circumstances" are also mentioned.[379] These relevant circumstances include (1) the presentation of the product to the consumer, which refers to the producer's obligation to provide proper information with respect to the product risks and use, (2) the product's reasonably expected use, and (3) the timing of the product's placement into circulation, which will determine the moment at which to evaluate the product's safety.[380]

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[376] In light of the different defectiveness tests in products liability in the U.S., it is interesting to see that the drafters of the Directive did not consider possible alternatives such as the Reasonable Alternative Design test applied today in some U.S. jurisdictions. For a critical analysis of the Consumer Expectations' test see James A. Henderson Jr. & Aaron D. Twerski, A Proposed Revision of Section 402A of the Restatement (Second) of Torts, 77 Cornell L. Rev. 1512, 1532-34 (1992) advocating for "reasonableness as the governing standard for liability in design defect and failure to warn cases.".

[377] Article 6 of the Directive. See also Geraint G. Howells & Mark Mildred, Is European Products Liability More Protective Than The Restatement (Third) Of Torts: Products Liability?, 65 Tenn. L. Rev. 985, 994 (1998).

[378] Michael R. Will, Liability for failure to warn in the European Community, 6 B.U. Int'l L. J. 125, 131(1988).

[379] Preamble of the product liability directive. See Geraint Howells, COMPARATIVE PRODUCTS LIABILITY, Darmouth publishing Company Limited, 36 (1993). See also Patrick Thieffry, Philip Van Doorn and Simon Lowe, Strict Product Liability in the EEC: Implementation, Practice and Impact on U.S. Manufacturers of Directive 85/374, 25 Tort & Insurance Law Journal 65, 71 (1989-1990) and William E. Westerbeke, Reasonable Alternative Design: A. Design-Based Liability in American Products Liability Law: The Reasonable Alternative Design Requirement, 8 Kan. J.L. & Pub. Pol'y 66, 119 (1998).

[380] Article 6 of the product liability directive.

6.1 Mirroring the past? The introduction of the consumers' expectation test

The different defectiveness tests generally aim to achieve an optimal degree of product safety and thereby minimize the amount of product-related accidents by balancing the social interest in having safe products in the market with the consumer's individual interests in using these safe products.[381] Even though the goals of the different available defectiveness tests are similar, the mechanisms they use are quite different.

The risk-utility test compares the risks presented by a certain product with the utility of its use.[382] Whenever the risks of a certain product -- not of that specific product but the risks of that product category -- are higher than the utility of its use, the product will be considered defective and producers will be liable for any harm resulting from this defective product.[383] However, this kind of analysis, without providing a defectiveness standard, is equivalent to finding whether a product category is "good for society" or not and whether the product should be marketed at all.[384]

In order to move from a product category analysis to a specific product analysis, the risk-utility test must be applied together with a defectiveness standard. One such standard is the reasonable alternative design.[385] Under this analysis, a product is deemed defective when the plaintiff can prove the "availability of a technologically feasible

[381] For an economic analysis of liability for defective products see Steven Shavell, AN ECONOMIC ANALYSIS OF ACCIDENT LAW, 58-60, Cambridge: Harvard University Press (1987).
[382] The use of the risk-utility test as a test of product defect is not unanimous. See David G. Owen, Toward a proper test for design defectiveness: "Micro-balancing" costs and benefits, 75 Tex. L. Rev. 1661 (1997) criticizing the vagueness of the risk utility test and its application in design defect cases and arguing for the application of a macro balance of the risk utility test to evaluate a product category and the application of a micro-defectiveness test in the form of an alternative design. See also Richard A. Epstein, The risks of risk/utility, 48 Ohio St. L. J. 469, 470 (1987) arguing in favor of the adoption of rules given their reliability as well as flexibility as opposed to the application of balancing tests, the application of which is often unpredictable.
[383] James A. Henderson Jr., Aaron Twersi, PRODUCTS LIABILITY: PROBLEMS AND PROCESS, 229, Aspen Publishers (5th Ed) (2004).
[384] See David G. Owen, Toward a proper test for design defectiveness: "Micro-balancing" costs and benefits, 75 Tex. L. Rev. 1661 (1997) arguing for the introduction of aggregate considerations and a macro-balancing risks and benefits of a product when determining its defectiveness.
[385] The risk-utility test alone was very difficult to implement so that an objective defectiveness test is necessary. See Richard W. Wright, The principles of product liability, 26 Rev. Litig. 1067 (2007).

practical alternative design that would have reduced or prevented the plaintiff's harm."[386] Whenever this alternative is available, the product is considered defective.[387] This test has been often criticized for the high burden of proof it imposes on injured victims who sometimes do not have the information available for creating and proving that such alterative design exists and is feasible.[388]

Another defectiveness standard is the consumers' expectations test. Under this analysis, the safety a reasonable consumer is entitled to expect[389] hinges on what consumers actually expect from a product and what consumers ought to have the right to expect.[390] In the case that these two expectations were different, the consumer expectations test considers the product defective if it does not fulfill the expectations a consumer was entitled to have.[391] In order to shape these expectations and bring consumers' actual expectations in line with what it is deemed that they ought to expect, the producer has incentives to provide necessary information in the form of instructions for safe use and warnings about the product hazards so that the expectation of consumers

[386] The plaintiff's burden of proof under the Restatement (Third) requiring proving the availability of a reasonable alternative design that would reduce or avoid foreseeable risks of harm has been controversial given that such requirement could preclude otherwise valid claims from jury consideration as well as would require plaintiffs to retain an expert witness that could increase significantly their litigation costs. See James A. Henderson, Jr., Aaron D. Twerski, The Products Liability Restatement In The Courts: an Initial Assessment, 27 Wm. Mitchell L. Rev. 7, 11-12 (2000). See also James A. Henderson Jr., Aaron Twersi, PRODUCTS LIABILITY: PROBLEMS AND PROCESS, 173, Aspen Publishers (5th Ed) (2004) and Richard W. Wright, The principles of product liability, 26 Rev. Litig. 1067, 1086 (2007).

[387] Hence, when courts determine the products design defect based on the risk-utility test might use one of these two alternative judgments: either that the product should have been manufactured with a reasonably safer design or that it should not have been marketed at all. See James A. Henderson, Jr., Aaron D. Twerski, The Products Liability Restatement In The Courts: an Initial Assessment, 27 Wm. Mitchell L. Rev. 7, n7 (2000).

[388] Douglas A. Kysar, The Expectations Of Consumers, 103 Colum. L. Rev. 1700, 1720 (2003).

[389] James Henderson Jr., Aaron D. Twerski, What Europe, Japan, And Other Countries Can Learn From The New American Restatement Of Products Liability, 34 Tex Int'l L J 1, 18 (1999).

[390] Geraint G. Howells & Mark Mildred, Is European Products Liability More Protective Than The Restatement (Third) Of Torts: Products Liability?, 65 Tenn. L. Rev. 985, 997 (1998).

[391] See, for example, the Spanish case Antonio and Antonia v. Manufacturas A., S.A. (manufacturer) and Seguros M., SA. (manufacturer's insurer), Appeals Court Baleares 28.3.00 (EDJ 2000/18237, Hon. Miguel Ángel Aguiló Monjo) where a folding chair suddenly and unexpectedly folded and trapped one of the fingers of the plaintiff's three year old daughter, part of which had to be amputated. The court, applying article 3.1 of law 22/94 transposing the product liability directive held that the chair did not reach the level of safety the consumer was entitled to expect and consequently deemed it defective. The chair manufacturer was liable for the payment of 7.111,25 € to the parents and legal representatives of the injured victim.

includes all product risks.[392] Adequate product labels are also of great importance. One of the major criticisms of this test is that the definition of product defectiveness is made by reference to an expectation rather than to a scientific test of safety and that it allows producers to transfer risk to consumers/users under certain circumstances.[393] Further, the expectations considered are the ones of the consumer, leaving aside bystanders even though they too are protected by the product liability directive and hence entitled to claim damages for the harm caused by the defective product.[394]

6.1.1 The Directive's inspiration: the U.S. experience with the Restatement (Second)

It seems quite clear that the Directive's drafters looked to the U.S. experience with the Second Restatement of Torts during the 1980s and early 1990s.[395] As discussed above, the Second Restatement predicated strict liability for the harm caused by defective products upon a finding that a product was "in a defective condition unreasonably dangerous to the user or consumer."[396] Under the Second Restatement, defectiveness was

[392] See Paula Giliker, Strict Liability for Defective Products: The Ongoing Debate, 24 Business Law Review 4, 87-90, 89 (2003) arguing that a court, when determining defectiveness, may consider the level of product risks and the defendant's steps adopted when providing information regarding the product risks. See also James A. Henderson, Jr., Sellers Of Safe Products Should Not Be Required To Rescue Users From Risks Presented By Other, More Dangerous Products, 37 Sw. U.L. Rev. 595, 600 (2008) noting that the required warnings should be limited to the risks presented by the product and should not be extended to risks of other products used or assembled together with the safe product.

[393] For a defense of the adequacy of the consumer expectation test as a test for defect. See Marshall S. Shapo, Comparing Products Liability: Concepts in European and American Law, 26 Cornell Int'l L. J. 279, 292 (1993) claiming that this test is entirely adequate in product liability cases in an age of technology and development of modern techniques and despite of the increase of complexity of products.

[394] Richard W. Wright, The principles of product liability, 26 Rev. Litig. 1067, 1122 (2007).

[395] Gregory G. Scott, Product Liability Laws In The European Community In 1992, 18 Wm. Mitchell L. Rev. 357, 360, 364 (1992) pointing out that it is important to notice that even though the regimes are remarkably similar, there are significant differences such as the concepts on which they are grounded. So while the basic key terms in the Restatement (Second) were "seller," "product," and "defective condition unreasonably dangerous" under the Directive, the relevant terms are "producer," "product," and "defect"

[396] § 402A of the Restatement (Second) of Torts reads as follows:

to be determined based on the expectation of consumers; so injured victims were required to bring evidence that the product was both defective and unreasonably dangerous.[397]

The consumer expectations test tends to be strongly linked to strict liability,[398] in that it focuses on the product as an object in the hands of the consumer and does not consider negligence -- or the defendant's conduct in general -- as design defect cases often do. This relationship between strict liability and the consumer expectations test can be seen in the comments to the Second Restatement, which state that the product is considered defective if "it (was) ... in a condition not contemplated by the ultimate consumer, which will be unreasonably dangerous to him."[399] A product is considered unreasonably dangerous if it is "dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases the product, with the ordinary knowledge to the community as to its characteristics."[400] A manufacturer's liability, thus, hinges on questions about the consumer, not the manufacturer and its potential fault.

6.1.2 The crisis of the consumers' expectations test in the United States

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"(1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if
(a) the seller is engaged in the business of selling such a product, and
(b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold".

[397] There was a lot of debate concerning the application of §402A. Some scholars argued that this section of the Restatement (Second) was misread. See Douglas A. Kysar, The Expectations of Consumers, 103 Colum. L. Rev. 1700, 1702 (2003). Others claimed that this cestion left a broad scope of discretion to courts when determining defectiveness based upon such standard. See W. Page Keeton, Products Liability - Design Hazards and the Meaning of Defect, 10 Cumb. L. Rev. 293, 312-13 (1979). This debate culminated in the 80s, when the risk-utility test was considered a better alternative to the consumer expectations test. For a more detailed description of the historical products liability evolution see Richard A. Epstein, MODERN PRODUCTS LIABILITY LAW, 9-67, Greenwood Press (1980).

[398] The consideration of the consumer expectations test as a strict form of liability is still controversial. See also Jane Stapleton , PRODUCT LIABILITY, 234-236 (London 1994) analyzing the link between strict liability and the consumers' expectation test controversial. See also W. Page Keeton, Products Liability--Design Hazards and the Meaning of Defect, 10 Cumb. L. Rev. 293, 300-02 (1979) arguing that consumer expectations reflect the warranty heritage left in strict products liability.

[399] Restatement (Second) of Torts § 402A cmt. g (1965).

[400] Restatement (Second) of Torts § 402A cmt. i (1965).

Unlike in Europe, where the Directive and its legislative history provide little insight as to what the content of the test apart from the fact that the European Commission views it as an objective test,[401] there has been extensive debate about the exact meaning of the consumer expectation test in the United States.[402]

Many U.S. courts have found the test unworkable because, while it is easy to recite, it is difficult to apply in practice.[403] This may explain why, in light of the controversial nature of the consumers' expectation test, many states have opted for a more objective measure, such as the so-called risk-utility test,[404] the reasonable alternative design test or other variations on this theme.[405] Under the risk-utility test, the

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[401] The Commission has repeatedly stated the consumer expectations' test is an objective test for defectiveness. See Green Paper at 6.

[402] See Daniel Schwartz, A Products Liability Theory for the Judicial Regulation of Insurance Policies, 48 William and Mary Law Review 1389, 1400 (2007). This article is available at http://ssrn.com/abstract=923423 defending the better performance of the risk-utility test compared to the consumer expectations test. See also Andrew C. Spacone, Strict Liability in the European Union - Not a United States Analog, 5 Roger Williams U. L. Rev. 341, 354-355 (2000) for an analysis of the practical problems of application within the context of the European Union. See also Marianne Corr, Problems with the EC Approach to Harmonization of Product Liability Law, 22 Case W. Res. J. Int'l L. 235, 238-39 (1990).

[403] See Mary J. Davis, Design Defect Liability: In Search of a Standard of Responsibility, 39 Wayne L. Rev. 1217, 1236 (1993) and William Powers, Jr., A Modest Proposal to Abandon Strict Products Liability, 1991 U. Ill. L. Rev. 639, 653-54 (1991) arguing that most design cases involve complex features for which there are no unique consumer expectations and hence it is difficult to provide a standard to a court. See also Jeffrey Stempel, Unmet Expectations: Undue Restriction of the Reasonable Expectations Approach and the Misleading Mythology of Judicial Role, 5 Conn. Ins. L. J. 181, 182 (1998-99) describing the reasonable expectation test as a defective test that has revealed attractive to academics but has faced resistance by the courts. See also Gregory G. Scott, Product Liability Laws In The European Community In 1992, 18 Wm. Mitchell L. Rev. 357, 364 (1992). For an opposite view arguing that the concept of defect does not have practical difficulties for courts. See Hans Claudius Taschner, Product Liability in Europe: Future Prospects, in EEC STRICT LIABILITY IN 1992, 81, Practising Law Institute ed. (1989).

[404] See W. Kip Viscusi, Reforming Products Liability 1-13 (1991) advocating for the use of risk-utility analysis in products liability cases. See also Aaron D. Twerski & James A. Henderson, Jr, Manufacturers' Liability for Defective Product Designs: The Triumph of Risk-Utility, 74 Brook. L. Rev. 1061 (2008-2009) noting that the marginal application of the risk-utility test involves the reasonable alternative design test and that the majority of U.S. states have adopted the risk-utility/reasonable alternative design test and not the consumers' expecations test. See also John F. Vargo, The Emperor's New Clothes: The American Law Institute Adorns a "New Cloth" for Section 402A Products Liability Design Defects--A Survey of the States Reveals a Different Weave, 26 U. Mem. L. Rev. 493 (1996) challenging the view of ALI reporters' that the burden on plaintiffs to show the availability of an alternative-design is shared by the different U.S. states.

[405] See Thomas Lundmark The Restatement Of Torts (Third) And The European Product Liability Directive, 5 D.C.L. J. Int'l L. & Prac. 239, 253 (1996) for a discussion of the various tests for defect across the different U.S. states. See also Kim D. Larsen, Strict products liability and the risk-utility test for design defect: an economic analysis 84 Columbia Law Review 8, 2045-2067 (1984) arguing against the imposition

utility of the product is weighed against the risks inherent in its use.[406] Among the factors considered are the usefulness and desirability of the product, the likelihood and seriousness of an injury, the availability of an alternative product, the possibility of the manufacturer to eliminate the unsafe characteristics of the product, the user's ability to avoid the danger, the user's awareness of the danger, and the manufacturer's ability to spread losses through pricing and insurance.[407] The risk-utility test is most commonly used in design defect cases where the ordinary consumer could not have an expectation of a certain relevant safety feature of the product.[408]

The Third Restatement adopted a kind of risk-utility test,[409] which is the reasonable alternative design test under which the plaintiff must prove that the danger of the product is outweighed by the cost of avoiding the danger, taking several "neutral" criteria into consideration, such as the availability of an alternative, feasible design.[410]

The consumer expectations test provides consumers with a right to expect that products will not harm them. In contrast, the risk-utility test relies on a reasonableness standard based on a balancing of the advantages and disadvantages of the defendant's design compared with an available, safer alternative design offered by the plaintiff.[411]

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of liability based on the risk-utility test in design defect cases where there is no evidence of an available alternative design.

[406] PROSSER AND KEETON ON TORTS, § 99, at 699 (1984) "Under this test, a product can be said to be defective in the kind of way that makes it 'unreasonably dangerous' if a reasonable person would conclude that the danger-in-fact, whether foreseeable or not, outweighs the utility of the product."

[407] PROSSER AND KEETON ON TORTS, § 99, at 699 (1984).

[408] David A. Urban, Custom's Proper Role in Strict Product Liability Actions Based on Design Defect, 38 UCLA L.Rev. 439, 456-58 (1990) discussing the functioning of the risk-benefit and consumer expectations test for defects in design of products.

[409] David G. Owen, The evolution of products liability law, 6 Rev. Litig. 955, 980 (2007).

[410] Restatement (Third) of Torts: Products Liability § 2 reporter's note to cmt. d (1998). See also Aaron D. Twerski & James A. Henderson, Jr, Manufacturers' Liability for Defective Product Designs: The Triumph of Risk-Utility, 74 Brook. L. Rev. 1061 (2008-2009) noting that ten years after the adoption of the Restatement (Third) of Torts, the risk-utility test, that entails the reasonable alternative design test has been broadly adopted by the courts of the different of the U.S. states. See also John F. Vargo, The Emperor's New Clothes: The American Law Institute Adorns a “New Cloth” for Section 402A Products Liability Design Defects--A Survey of the States Reveals a Different Weave, 26 U. Mem. L. Rev. 493 (1996) for an opposing view than the one of the reporters of the Restatement (Third).

[411] James Henderson Jr., Aaron D. Twerski, What Europe, Japan, And Other Countries Can Learn From The New American Restatement Of Products Liability, 34 Tex Int’l L J 1, 16-17 (1999).

The consumer expectations test for defect in product design cases has been vigorously debated and broadly discredited in the United States given the significant flaws it presents. Among these are its uniform treatment of different defect types, the vagueness of its content, and its reliance on intuition in application. [412]

The European product liability directive, by adopting the consumer expectations test as the test for defect, suffers from all of these flaws.[413] Worse, there is an additional element that makes the application of this defectiveness test even more problematic under the Directive: the Directive does not differentiate between manufacturing defects, defects of design, and defects in warnings and instructions,[414] and it fails to specify a standard by which to measure the safety that could be expected of a given product.[415] The Directive establishes only that a defective product is one that does not meet "the safety which a person is entitled to expect taking into account (particular factors)."[416] No guidelines are provided to aid in determining what the expectations of the consumers are,[417] an

[412] Geraint G. Howells & Mark Mildred, Is European Products Liability More Protective Than The Restatement (Third) Of Torts: Products Liability?, 65 Tenn. L. Rev. 985, 994 (1998).

[413] Some authors argue that under the Directive, a product is almost considered defective just with the fact of having caused the harm to the consumer. See Michael G. Faure, Product Liability and Product Safety in Europe: Harmonization or Differentiation?, Kylos, vol 53, 467-508, 489 (2000). Other authors suggest that in light of the uncertainties derived from the application of the consumer expectations test, European judges will do a broad balancing costs and benefits which will result in the use of negligence considerations. See Jane Stapleton, Products Liability In The United Kingdom: The Myths Of Reform, 34 Tex. Int'l L. J. 45, 53-54 (1999).

[414] The regulation of the Directive contrasts with the regulation under the Restatement (Third), that establishes different types of product differents and require different liability rules and standard for defect for each of them. See Jane Stapleton, Bugs in Anglo-American products liability, 53 S. C. L. Rev. 1225, 1243 (2002) and Joachim Zekoll, American Law in a Time of Global Interdependence: U.S. National Reports to the XVIth International Congress Of Comparative Law: Section II Liability for Defective Products and Services, 50 Am. J. Comp. L. 121, 124 (2002). See also Aaron D. Twerski & James A. Henderson, Jr, Manufacturers' Liability for Defective Product Designs: The Triumph of Risk-Utility, 74 Brook. L. Rev. 1061, 1063 (2008-2009).

[415] When forming expectations, consumer will use the product information they have . So the European Commission has introduced regulation in order to prevent misleading advertisement. See Hans Claudius Taschner, Harmonization of Product Liability Law in the European Community, 34 Tex. Int'l L.J. 21, 30 (1999).

[416] See Jane Stapleton, Products Liability In The United Kingdom: The Myths Of Reform, 34 Tex. Int'l L. J. 45, 53 (1999). The differentiation between types of product defects has been widely welcome by the European doctrine on products liability. See Solé Feliu, Josep, El concepto de defecto del producto en la responsabilidad civil del fabricante, 569 et seq., Valencia, Tirant lo Blanch (1997).

[417] The Directive 84/450/EEC of 10 September 1984; Relating to the approximation of the laws, regulations and administrative provisions of the Member States concerning misleading advertising (Offical Journal

especially important issue in light of the different cultural and educational backgrounds of European consumers.[418]

The consumer expectations test is intended to be applied as objectively as possible by detaching the relevant consumer from the actual injured victim and thus avoiding case-by-case determinations. The relevant expectations are not the plaintiffs' but those of the public at large, reflecting the expectations of potential victims of the harm caused by the defective product.[419] This is not to say that the specific injured consumer is irrelevant. While the victim's expectations are not at issue, his circumstances are to be taken into account.[420]

The vagueness and broad judicial discretion that this standard provides to courts generate difficulties both from the perspective of the injured victim and from the perspective of the potential defendant.[421] For victims, it is difficult to anticipate what safety expectations will be deemed reasonable given existing variation among consumers in terms of the amount of knowledge about product defects and the risks inherent in a product being used in a given situation. It is also difficult to formulate the expectation test in the case of injured bystanders -- i.e., people who have not purchased a given product and thus are completely unfamiliar with its risks but are nonetheless injured by it.[422]

1984, L 250, p 17) prescribes a series of legal measures which the Member States must adopt to protect the public against misleading advertising.

[418] James Henderson Jr., Aaron D. Twerski, What Europe, Japan, And Other Countries Can Learn From The New American Restatement of Products Liability, 34 Tex Int'l L J 1, 19 (1999).

[419] Article 6 of the product liability directive is thought to target the average consumer, not the specific injured victim. Professor Taschner, one of the drafters of the Directive, considers that the question should not be the one "of the individual injured party with his subjective expectations," nor even of "the expectations of a specific group of consumers," but of "what the community as a whole considers to be right." See Hans Claudius Taschner, Product Liability in Europe: Future Prospects, in EEC STRICT LIABILITY IN 1992, 83, 89, Practising Law Institute ed. (1989).

[420] Some authors have criticized this difference by claiming that in practice it is difficult to differentiate between the abstract expectations of the average consumer. See James A. Henderson Jr., and Aaron D. Twerski, Achieving Consensus on Defective Product Design, 83 Cornell L. Rev. 867, 881 (1998).

[421] Given the broad judicial discretion that the consumer expectation test provides to judges, some authors have understood that the Directive's standard was circular. See Jane Stapleton, PRODUCT LIABILITY, 234 London: Butterworths (1994).

[422] Geraint G. Howells & Mark Mildred, Is European Products Liability More Protective Than The Restatement (Third) Of Torts: Products Liability?, 65 Tenn. L. Rev. 985, 995 (1998).

Ascertaining reasonable safety expectations for consumers is difficult enough; it may be impossible for bystanders whose encounter with the product is essentially accidental.[423] Finally, the application of the consumer expectations test also presents difficulties for defendants because of the remarkable degree of uncertainty it involves: depending on how the typical or reference consumer is defined, a product will or will not be deemed defective.[424] What is more, this reference consumer need not even have to be within the manufacturer's target market.

In light of the problems of defining the specific content and application of the test, courts end up determining defectiveness by combining the idea of an abstract reference consumer with a consideration of the actual consumer's circumstances on a case-by-case basis. But they do this with little guidance from the Directive.[425] This has led some domestic courts of different member states to require proof that the manufacturer could feasibly have designed the product more safely; it has led others to introduce care elements in the determination of the liability of the producer.[426]

This inadequate application of the defectiveness test has caused some to believe that the risk-utility test is better suited than the consumer expectations test for design defect cases in Europe. This may be particularly true for certain kinds of cases, such as complex design cases, where it is difficult to apply the consumer expectation test because

[423] See Richard W. Wright, The principles of product liability, 26 Rev. Litig. 1067, 1122 (2007) criticizing the defectiveness standard under the product liability directive and deeming it inadequate given that it does not consider all potential product victims such as bystanders.

[424] The application of the consumer expectations test seems so suggest that this uncertainty seems to be possible to overcome by providing enough information to the consumer so that product risks are open and obvious. For early literature on the issue see Alvin S. Weinstein, Aaron D. Twerski, Henry R. Piehler and William A. Donaher, PRODUCTS LIABILITY AND THE REASONABLY SAFE PRODUCT: A GUIDE FOR MANAGEMENT, DESIGN, AND MARKETING, 45-46, New York: Wiley-Interscience Publication (1978).

[425] James Henderson Jr., Aaron D. Twerski, What Europe, Japan, And Other Countries Can Learn From The New American Restatement Of Products Liability, 34 Tex Int'l L J 1, 14, 18 (1999).

[426] See Jane Stapleton, Products Liability In The United Kingdom: The Myths Of Reform, 34 Tex. Int'l L. J. 45, 53-54 (1999) and Thomas Lundmark, The Restatement Of Torts (Third) And The European Product Liability Directive, 5 D.C.L. J. Int'l L. & Prac. 239, 254 (1996).

consumers are simply unlikely to have defined expectations about the specific safety of the product in question.[427]

Because of the nature of the consumer expectation test, it is difficult to derive general guidelines and specifications for its application. Ultimately, liability comes to be based on emotion, culture and the personal circumstances of the injured victim. In this sense it is quite vague[428] despite the intention for it to be applied on an "objective" basis by courts and not on the standard of the individual plaintiff's subjective experiences.[429]

The danger of case-by-case determinations of the consumer expectations test is especially relevant and complicated in the European context in light of the social and cultural diversity and of the different safety expectations of the consumers of the different European member states. It does not seem reasonable to assume that each European consumer will have the same expectation regarding a given product. Therefore, it does not seem possible to consider that a unique, reasonable, Europe-wide standard exists. In principle, this should not be a problem for individual victims because domestic courts are the ones that assess the expectations that the consumer is entitled to have and these courts can simply focus on the expectations of their own state's consumers without taking into account the potentially different expectations of consumers in other European member

[427] William E. Westerbeke, Reasonable Alternative Design: A. Design-Based Liability in American Products Liability Law: The Reasonable Alternative Design Requirement, 8 Kan. J.L. & Pub. Pol'y 66, 66 (1998).

[428] Judicial discretion is inherent to any legal rule. However, the risk-utility standard for defective design cases is said to rely less on intuition in its application than the consumer expectations given that it identifies the factual data relevant to determination of design defectiveness. See James Henderson Jr., Aaron D. Twerski, What Europe, Japan, And Other Countries Can Learn From The New American Restatement Of Products Liability, 34 Tex Int'l L J 1, 19 (1999).

[429] See Henderson, James A. Jr., Twerski, Aaron D., Achieving Consensus on Defective Product Design, 83 Cornell L. Rev. 867, 882 (1998) arguing that risk-utility analysis provides an objective design defect standard that does not depend on personal or psychological expectations..Regarding psychological perceptions and subjectiveness iun determining standards of defectiveness see in general Paul Slovic, SMOKING: RISK, PERCEPTION & POLICY, THOUSAND OAKS, Calif.: Sage Publications (2001); BEHAVIORAL LAW AND ECONOMICS, Cass R. Sunstein ed., (2000); Christine Jolls et al., A Behavioral Approach to Law and Economics, 50 Stan. L. Rev. 1471 (1998) and Cass R. Sunstein, Behavioral Analysis of Law, 64 U. Chi. L. Rev. 1175 (1997).

states.[430] However, this has a direct consequence for potential tortfeasors: a product may be deemed defective in one member state and not in another.

In addition to the diverse consumer profile within Europe, the language of the Directive is broad and varied enough to jeopardize any “objective” application of the test. While the preamble refers to "the safety which the public at large is entitled to expect," article 6(1) refers to "the safety which a person is entitled to expect." If the language of the preamble is to be followed, the question would appear to be a relatively objective one or at least one dependent on the opinions of substantial majorities as opposed to the expectations of a single individual, whether real or prototypical.[431] Courts are not limited to the factors established in Article 6 of the product liability directive and are not told what weight to give to each factor. Howeber, when the wording of Article 6 is taken into account, the preamble’s desired objectiveness disappears because the special circumstances of the injured consumer in court are also relevant.[432]

Last, a final structural problem presented by the consumer expectation test is that even though it captures individuals’ different attitudes towards risk,[433] it implicitly relies on an exogenous image of the product risks and features and therefore on exogenous product expectations that supposedly consumers are able to create.[434] Our rationale as

[430] However, if we accept this diversity and therefore, this different standard, the harmonization goal once more is put under question.

[431] Despite of this effort to reach an abstraction of the expectations of the average consumer and its expectations, there are authors who understand that the risk-utility test will always be a more objective test given that it includes scientific considerations. See Henderson, James A. Jr., Twerski, Aaron D., Intuition and Technology in Product Design Litigation: An Essay on Proximate Causation, 88 Geo. L.J. 659, 681 (2000).

[432] For all of these reasons, some U.S. scholars have concluded that the consumers’ expectastions test does not represent a feasible alternative to the risk-utility test. See James A. Henderson, Jr. & Aaron D. Twerski, Arriving at Reasonable Alternative Design: The Reporters' Travelogue, 30 U. Mich. J.L. Reform 563, 572 (1997).

[432] Douglas A. Kysar, The Expectations Of Consumers, 103 Colum. L. Rev. 1700, 1767 (2003).

[433] Douglas A. Kysar, The Expectations Of Consumers, 103 Colum. L. Rev. 1700, 1767 (2003).

[434] The consumer expectations test provides its own correction mechanism regarding market manipulation because if consumers are manipulated by the manufacturer and therefore their perception of the product risk was distorted, they would be entitled to compensation in case they product did not meet their safety expectations. The problem with this issue is that if we assume that the product that caused harm is sold in a competitive market and therefore has a substantial amount of perfect substitutes, the image and the expectations that the consumer would have regarding the safety of the product would be created by the

consumers is not independent of the inputs we receive from society as a whole, from manufacturers in particular or from our individual characteristics. That is not to say that individuals are totally manipulated and unable to have individual thoughts regarding consumption, products and safety.[435] But all the weight of the consumers' expectations test for defectiveness relies on the external and exogenous expectations of the "reasonable consumer," that will determine the product safety a consumer is entitled to expect.

6.1.3 The United States moves on: What about Europe?

The controversy that the consumer expectations test has raised in the United States, especially as a test for product design cases,[436] has led different U.S. jurisdictions to look for a more objective test that would not be subject to the difficult determination of the specific content of the consumer expectations test.[437] During the 1980s, U.S. courts started applying a test that balanced costs and benefits,[438] believing that such a test was

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industry and not by the specific manufacturer. In this case, imposing liability on the manufacturer of the product -- that may not even be responsible for the expectation that the consumer has about the product -- might not be the best solution. On the market manipulation problem in product cases see Jon D. Hanson & Douglas A. Kysar, Taking Behavioralism Seriously: The Problem of Market Manipulation, 74 N.Y.U. L.Rev. 630 (1999) and Jon D. Hanson & Douglas A. Kysar, Taking Behavioralism Seriously: Some Evidence of Market Manipulation, 112 Harv. L. Rev. 1420 (1999).

[435] See generally Douglas A. Kysar, The Expectations of Consumers, 103 Colum. L. Rev. 1700 (2003).

[436] James Henderson Jr., Aaron D. Twerski, What Europe, Japan, And Other Countries Can Learn From The New American Restatement Of Products Liability, 34 Tex Int'l L J 1, 13-14 (1999).

[437] Jane Stapleton, PRODUCT LIABILITY, London; Boston: Butterworths, 236 (1994). For an overview of the developments of the American Law Institute in the subject of product liability and a proposal on how the ALI should address this issue at the Restatement (Third) See Marshall S. Shapo, In Search of the Law of Products Liability: The ALI Restatement Project, 48 Vand. L. Rev. 631 (1995).

[438] The risk-utility analysis is based on a balance of the costs and benefits of a product design cases. The most influential development of the risk-utility test in the U.S. is the model suggested by Wade where he established the relevant parameters that should be taken into consideration when qualifying a product as defective:

> (1) The usefulness and desirability of the product - its utility to the user and to the public as a whole.
>
> (2) The safety aspects of the product - the likelihood that it will cause injury, and the probable seriousness of the injury.

more objective than the consumer expectations test. This evolution culminated with the proposal made by the reporters of the Third Restatement, who suggested the adoption of a risk-utility analysis as the standard of product defectiveness to replace the consumer expectations test. The risk-utility test proposed by the Third Restatement consisted in showing the existence, availability and feasibility of a reasonable alternative product design that was reasonably cost effective and made the product safer.[439] If such alternative design existed, the product is deemed defective.[440] Despite the theoretical advantages of the reasonable alternative design suggested by the Third Restatement, its application has also been controversial and some U.S. jurisdictions have decided to continue applying the consumer expectations test.[441]

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(3) The availability of a substitute product which would meet the same need and not be as unsafe.
(4) The manufacturer's ability to eliminate the unsafe character of the product without impairing its usefulness or making it too expensive to maintain its utility.
(5) The user's ability to avoid danger by the exercise of care in the use of the product.
(6) The user's anticipated awareness of the dangers inherent in the product and their avoidability, because of general public knowledge of the obvious condition of the product, or of the existence of suitable warnings or instructions.
(7) The feasibility, on the part of the manufacturer, of spreading the loss by setting the price of the product or carrying liability insurance.

See John W. Wade, On the Nature of Strict tort Liability for Products, 44 Miss. L. J. 825, 829 (1973). See also John W. Wade, Strict Tort Liability of Manufacturers, 19 Sw. L.J. 5, 17 (1965) for an earlier version of a similar list of factors. See also Montgomery and Owen, Reflections on the Theory and Administration of Strict Liability for Defective Products, 17 S.C.L. Rev.803 (1976).

[439] Restatement (Third) of Torts: Products Liability § 2 reporter's note to cmt. d (1998). See also James A. Henderson, Jr. & Aaron D. Twerski, Achieving Consensus on Defective Product Design, 83 Cornell L. Rev. 867, 910 (1998) considering that the defective product design problem was solved with the adoption of a risk-utility test that was thought to be more objective.

[440] Restatement (Third) of Torts: Products Liability § 2b (1998)

> *"(a product) is defective in design when the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the seller or other distributor, or a predecessor in a commercial chain of distribution, and the omission of the alternative design renders the product not reasonably safe."*

Some consider that the reasonable alternative design test imposes and excessive burden on injured victims who have to show the availability of such alternative product design. See Thomas Lundmark, The Restatement Of Torts (Third) and the European Product Liability Directive, 5 D.C.L. J. Int'l L. & Prac. 239, 249 (1996).

[441] See Douglas Kysar, 103 Colum. L. Rev. 1700, 1728 (2003) presenting a complete overview of the cases of the different jurisdictions rejecting the adoption of the reasonable alternative design test and arguing in favor of the consumer expectations test. See also Aaron D. Twerski & James A. Henderson, Jr, Manufacturers' Liability for Defective Product Designs: The Triumph of Risk-Utility, 74 Brook. L. Rev. 1061, 1180 and following (2008-2009) presenting the defectiveness tests adopted by the different U.S. states and arguing that the risk-utility test, that inevitably results in the application of the reasonable alternative design test, has been the defectiveness test adopted by the majority of the courts of the different U.S. states.

The U.S. jurisdictions that apply the reasonable alternative design test do not apply it uniformly to all defect types. In contrast to the Second Restatement, the Third Restatement differentiates between three major product defects types: manufacturing defects, defects of design and defects related to the failure to warn or to instruct.[442] These categories generally respond to the different natures of the defects and the different standards of proof they require. In the Third Restatement, manufacturing defects are subject to strict liability, whereas liability for defects in product design hinges on the availability of a cost effective reasonable alternative design – meaning a safer design.[443] In other words, product design cases are subject to a negligence-based test.[444] Negligence is also the liability system applied to defects relating to failure to warn and to instruct given that courts analyzing such defects compare the instructions and warnings provided by the manufacturer with the ones that should have been given to product users regarding product risks.[445] Overall, it is possible to qualify the liability regime established by the Third Restatement as a negligence-based system.[446]

The definition and differentiation between kinds of product defect is also one of the aspects where the current European product liability system followed the structure of the Second Restatement of Torts. However, since 1985 when the product liability directive was adopted and subsequently transposed in the domestic law of the different member states, it has not evolved and has not incorporated the relevant and significant

[442] Restatement (Third) of Torts: Products Liability § 2 (1998).
[443] See Joachim Zekoll, American Law in a Time of Global Interdependence: U.S. National Reports To The XVIth International Congress Of Comparative Law: Section II Liability for Defective Products and Services, 50 Am. J. Comp. L. 121, 124 (2002) arguing that the availability of a safer cost effective alternative design is not uniformly applied to design defect cases and stating that when the product is by itself unreasonably dangerous showing the availability of a safer alternative design should not be necessary.
[444] Restatement (Third) of Torts: Products Liability § 2 reporter's note to cmt. d (1998).
[445] See James A. Henderson, Jr., Sellers Of Safe Products Should Not Be Required To Rescue Users From Risks Presented By Other, More Dangerous Products, 37 Sw. U.L. Rev. 595 (2008) noting that product manufacturers should only be required to warn of product risks presented by the product they manufactured.
[446] See in general, James A. Henderson, Jr., Why negligence dominates tort, 50 U.C.L.A. L. Rev. 377 (2002).

differences of each kind of product defect.[447] The product liability directive does not differentiate between product defects, their potentially different standards of proof or even the diverse liability systems they would be subject to according to their characteristics.[448] The product liability Directive refers only to defect and it has been left to the scholars and courts of the member states to flesh out the different product defects, their defectiveness standards and the different contents of the consumer expectations test as applied to each kind of product defect.

The Spanish jurisprudence contains numerous examples of judgments where courts differentiate between product defects. The manufacturing defect cases are generally straightforward and courts tend not to discuss whether the expectations of consumers were fulfilled or not. In these cases, courts generally require evidence that the specific product that caused the harm was different and less safe than others of the same product series. If the product that caused damages to the victim is more dangerous than the other products of the same series, the product is deemed defective. Examples of manufacturing defect cases in Spain can be found in cases dealing with fireworks[449] and

[447] In fact, the differentiation between product defects and their potentially different standard of proof or liability regime they should be subject to has not been one of the aspects the European Commission has suggested to take into account in the different reports it has issued regarding the application and improvement of the product liability directive in the member states.

[448] Despite the Directive's uniform treatment of product defects, from an economic perspective, design defects, defective warnings and manufacturing defects are different with respect to their accident costs. Their basic difference is that while in manufacturing defect cases the total amount of non-negligence accident damages is relatively small in comparison to the product's production costs, in design defects and defective warning situations, the amount of non-negligent damages is potentially very high. This analysis has led some authors to argue that strict liability could be imposed for manufacturing defect cases but that it should not be extended to design defect and defective warning cases. See, for example, John Cirace, A Theory of Negligence and Products Liability, 66 St. Johns L. Rev. 1, 71 (1992).

[449] See, for example, Tomás v. Pirofantasía Multimedia S.L. (producer), Centro Asegurador Baeza (the manufacturer's insurer), Casimiro, owner of Comercial Alegre Carnaval (retailer),SAP Alicante 10.1.03 (JUR 2003\114114; MP: José María Rives Seva). In this case, the court applied article 1902 of the Spanish Civil Code and held the manufacturer liable for the harm suffered by the injured plaintiff who lost some part of his right-hand fingers as a consequence of the explosion of a defective firecracker, that exploited right when it was lighted and not after a few seconds. In the case Rafael v. Comisión Fallera San Vicente-Marvá, Centro Asegurador, Cía. de Seguros y Reaseguros, S.A. y Pirotecnia Zaragozana, S.A, AP Valencia 13.4.00 (AC 2000\3794; MP: Vicente Ortega Llorca), the court, again applying article 1902 of the Spanish Civil Code, held that the firework had a manufacturing defect and awarded damages for the injured victim, who suffered several injuries while filming a fireworks display.

defective food products.[450] It is worth noting that in some cases, when the other elements of the victim's prima facie case are present and have been proved, Spanish courts presume the existence of a manufacturing defect and award compensation to the injured victim.

A surprising aspect of the Spanish product liability jurisprudence is the relative lack of design defect cases as compared to cases dealing with other kinds of defects. Spanish courts tend not to get involved in discussions of whether the product design fulfilled the expectations to which consumers are entitled, whether a reasonable alternative design is available or whether the product design complies with the risk-utility test. Very few cases could be qualified as product design cases in Spain's almost 20-year history of jurisprudence applying the law transposing the product liability directive. Three design cases may be highlighted: First is a case in which a three year-old child died of asphyxiation while eating a candy. The Spanish Supreme Court imposed liability, holding that the candy was too big for children of that age and should have been made smaller to be safer.[451] A second interesting product design case is a case in which a six-month old baby died when his head was caught between his crib's bars.[452] The Spanish Supreme Court held the product manufacturer liable for not designing the crib with a

[450] For example, in María Luisa L.V. v. Repostería Martínez, SA y Allianz Compañía de Seguros y Reaseguros, S.A., SAP La Coruña 21.6.02 (AC 2002\1348; MP: Rafael Jesús Porto García) the injured victim broke a tooth while eating a cookie that contained two stones of sugar that were formed during a defective manufacturing process. In application of Law 22/94 that transposed the product liability directive, the court awarded damages of 8.000 € to the victim.

[451] See Luis A.M. and Josefina V.M. v. Interdulces, SA (importer) and Ana María G.J. (retailer), STS 10.6.02 (RJ 2002\6198; MP: Román García Varela). The Supreme Court awarded 36.060 € to the parents of the victim considering the candy defective but also considered the child's parents negligent given that they should have been aware that the candy was too dangerous for his child's consumption. Using contributory negligence considerations the Supreme Court reduced the damage award requested - 62.896 € - by the child's parents. (Note: a literal translation of the concept of concurrencia de culpas is contributory negligence. However, its application is equivalent to U.S. comparative negligence analysis). For a comment on this case see Antoni Rubí and José Piñeiro, Muerte de un niño asfixiado con un caramelo, comentario a la STS, 1ª, 10.6.2002, indret working paper 123 (2003). This paper can be found at http://www.indret.com/pdf/123_es.pdf.

[452] See Supreme Court, 1ª Chamber, 25.5.1996, Arsenio R.V.c. Roma 40 Bebés e Hiperbebé and Cunitor S.A. (num. 4853) (Hon. Alfonso Barcalá Trillo Figueroa). The court also considered the baby's parents contributory negligent because their conduct constituted "some negligence" ("cierta negligencia por parte de los familiares" FD 4º).

smaller distance between the bars to prevent such an accident. It also held the product retailer jointly liable. The third case is one that can be characterized as a design defect case even though the court did not explicitly describe it as such. This is a case dealing with the "Superchupinazo,"[453] a firework with an ignition mechanism that caused an explosion to occur, severely injuring the hands and faces of the people manipulating it.[454] The Court of Appeals of Valencia held the product manufacturer liable. This product has finally been withdrawn from the market.

It is interesting to note that these design cases share some characteristics in common: two of them deal with products that caused harm to children -- in two of these cases there are babies or small children involved -- and courts also found that plaintiffs had been contributorily negligent and consequently reduced the compensation awarded for the damages suffered. At the same time, none of these cases includes a detailed analysis of the defectiveness standard applied to the product or of the expectations consumers were entitled to have. In all of these cases it appears to have been obvious to the courts to suggest that it was relatively easy for the product manufacturer to make the product safer. The courts therefore deemed the products defective and the product manufacturers liable. In none of these cases, though, is there a discussion of what constitutes a design defect and why these products are considered to be defective in design. Up to today, Spanish courts have tried hard to avoid these issues and to avoid getting into these discussions.

Spanish courts have also dealt with numerous cases on defects with respect to instructions and warnings.[455] It is possible to divide the Spanish jurisprudence on this

[453] This is the name of a very popular firework that is commonly used in Spain when cities and villages are celebrating a big festivity, generally organized by the Town hall of these towns.
[454] Court of Appeals of Valencia, Section, 12.7.2001, JUR 2001\279709 and Alicante 10.1.2003, JUR 2003\114114).
[455] In light of the lack of definition of the role of product warnings under the product liability directive, product warnings are likely to be a source of disputes. See Paula Giliker, Strict Liability for Defective Products: The Ongoing Debate, 24 Business Law Review 4, 87-90, 89 (2003). Failure to warn and instruct is also an essential piece of product liability in the U.S. given that it is one of the most common source of

type of defect between cases where products lacked any kind of instructions or warnings,[456] cases where instructions and warnings existed but were incorrect[457] or were in a language other than Spanish,[458] and finally, cases where the warnings and instructions were insufficient and therefore the information was not adequate to prevent the harm they aimed at preventing.[459] In all these cases courts used negligence considerations to determine whether product manufacturers complied with their duty to warn and instruct product users of the risks presented by the products.

This is not the place to present a potentially better alternative defectiveness test in Europe but it is interesting to mention the remarkably different perceptions of the consumer expectations test in the United States and Europe regarding whether it is more consumer friendly than the risk-utility test. While in the United States the consumer

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U.S. products litigation. S. Mark Mitchell, A Manufacturer's Duty to Warn in a Modern Day Tower of Babel, 29 Ga. J. Int'l & Comp. L. 573, 573 (2001).

[456] See for example, Paulino v. Sika, S.A. (manufacturer) and Adicons Canarias, S.L.U (supplier), Court of Appeals of Santa Cruz de Tenerife 19.1.07 (JUR 2007\158172; MP: Concepción Macarena González Delgado) where the court awarded 30.625 € is compensation to the injured victim for the damages suffered because the lack of a label on the product and therefore of information about the product risks deemed it defective.

[457] See, for example, Semilleros Monteplant S.L. c. Futureco S.L. (manufacturer and supplier), Court of Appeals of Barcelona 13.6.05 (JUR 2005\181270; MP: Marta Font Marquina) where, in application of article 3 of law 22/94, the court awarded 481.610,17 € to the user of the plant pesticides she bought from the defendant-manufacturer-supplier for the property damages he suffered caused by an error on the product label regarding the adequate doses of plant pesticides.

[458] See José Ángel T.R. v. José Marcos M.C. (store retailer), Almacenes Sarti, S.L. (supplier) and Alicantina de Juguetes, S.L. (manufacturer), Court of Appeals Cáceres 18.4.02 (AC 2002\1330; MP: Juan Francisco Bote Saavedra) where the court awarded 72.121,45 € in damages to the victim. The court held that the toy, a yo-yo, that caused damages to a woman, was defective because its instructions were not in Spanish, in violation of article 3 of law 22/94 transposing the product liability directive and also of European rule UNE-EN 50-088 that requires information of the product to be at least in the official languages of that member state.

[459] See Miguel G. de A.L. v. Robert Bosch Comercial Española, S.A. (importer), STS 3.12.97 (RJ 1997\8722; MP: Ignacio Sierra Gil de la Cuesta). In this case the injured victim suffered damages in her eye due to an imported machine and did not include sufficient information for its proper use. The court considered the instructions and warnings were insufficient and held the importer liable for 10.000.000 ptas (60.000 euros). See also Javier c. Gregorio y Flamagas, S.A. Lesiones, Court of Appeals of Málaga 7.10.03 (JUR 2004\12120; MP: Inmaculada Suárez Bárcena Florencio); Rosa S.M. v. Distribuidora Internacional de Alimentación, S.A. (DIA), Court of Appeals Barcelona 17.12.01 (JUR 2002\84388; MP: Amelia Mateo Marco) and Agreal v. Sanofi Aventis, S.A., Trial Court number 12 of Barcelona 7.9.06 (EDJ 2006\283594; Hon: Marta del Valle García). The courts in these cases considered the products that caused harms defective in the instructions and warnings stating in all three cases that even though the products included instructions and warnings, they did not inform about certain product risks that finally caused the damages the victims suffered.

expectations test is considered more consumer friendly, Europe seems to believe the opposite.[460] Europeans consider the most consumer friendly test on product defectiveness to be the risk-utility test.[461]

This different perception might be explained by the mixed nature of the defectiveness standard included in the product liability directive. While on first reading the defectiveness standard looks like the consumer expectations test, on a closer look it becomes clear that it also includes elements of the risk-utility test. On one hand, the standard of "the safety which a person is entitled to expect"[462] is basically similar to the consumer expectations test of section 402A of the Second Restatement, which provides that the product "must be dangerous to an extent beyond that which would be contemplated by the ordinary consumer."[463] But at the same time, the definition of a defective condition also includes factors such as the use of the product and the presentation of the product,[464] which are closer to the risk-utility balancing because they require the court to consider the utility of the product and whether the risks were communicated to the buyer.[465] These mixed elements might help explain why Spanish courts avoid getting involved in discussions of definitions and why the perception is that the risk-utility test might be more consumer friendly than the defectiveness test included in the product liability directive.

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[460] Geraint G. Howells & Mark Mildred, Is European Products Liability More Protective Than The Restatement (Third) Of Torts: Products Liability?, 65 Tenn. L. Rev. 985, 996-997 (1998) arguing that such difference of perspective is due to the difference between what we actually expect -- which is what U.S. jurors looked at -- and what the consumer had the right to expect -- which is what European judges will look at.

[461] The European reference of the risk-utility test is the one included in the General Product Safety Directive, which includes a general safety clause for all consumer products. See Council Directive 2001/95/EC of December 3, 2001 on General Product Safety O.J. (L 11) (January 15, 2002). See also Geraint G. Howells & Mark Mildred, Is European Products Liability More Protective Than The Restatement (Third) Of Torts: Products Liability?, 65 Tenn. L. Rev. 985, 996-997 (1998).

[462] Preamble of the product liability directive.

[463] See Restatement (Second) §402A cmt. i.

[464] Article 6 of the directive. See below.

[465] See Gregory G. Scott, Product Liability Laws In The European Community In 1992, 18 Wm. Mitchell L. Rev. 357, 366 (1992) concluding that under the Directive's definition should be easlier for plaintiffs to prove defect than under 402A of the Restatement (Second) because under the Directive it is not necessary to prove that the product is both defective and unreasonably dangerous.

6.2 Other circumstances to be taken into account

6.2.1 The Presentation of the Product

As mentioned above, the expectation of consumers is not the only variable to consider when determining whether a product is defective; "*other circumstances*" must also be taken into consideration.[466]

The very first item the product liability directive refers to is the presentation of the product, which has been interpreted to include the warnings and instructions given to the product user,[467] even though the Directive does not include a specific reference to liability for failure to warn or to instruct of product risks.[468]

The "presentation of the product" is broad enough to be interpreted to mean "product representation,"[469] which would include product marketing, product description, information and warnings about the product and its use as well as the container or the packaging in which the product comes,[470] in case they were found to be inadequate. This phrase seems to include also promotional material from the manufacturer, distributor or retailer and any advertisements of the product as well.

The product presentation is directly related to consumer expectations given that it can either increase or decrease the safety expectations a consumer may have regarding

[466] Article 6.1 of the product liability directive.
[467] As §402A of the Restatement (Second) also includes in the presentation of the product the information provided to consumers and hence relevant when evaluating the expectations of consumers.
[468] Article 6(l)(a) of the product liability directive. Hans C. Taschner, EEC Strict Liability in 1992: The New Product Liability Rules, 371 Practising Law Institute 81, 95-96 (1989). See also Kenneth Ross & Gregory G. Scott, Europe 1992: Warning and Instructions under the Strict liability, Machinery, and proposed Product Safety Directives, 388 PLI/Lit 49 (PLI), 52-53 (1990).
[469] It remains difficult to ascertain what degree of warning would be required in order to avoid being hold liable. See Paula Giliker, Strict Liability for Defective Products: The Ongoing Debate, 24 Business Law Review 4, 87-90, 89 (2003).
[470] S. Mark Mitchell, A Manufacturer's Duty to Warn in a Modern Day Tower of Babel, 29 Ga. J. Int'l & Comp. L. 573, 582-583 (2001).

the product.[471] Typically, advertising and marketing practices will serve to raise expectations about the product in question by stressing its advantages and generally encouraging consumers to have confidence in it.[472]

Product manufacturers are the main sources of information about products but not the only ones. Intermediaries also provide the consumer with such information or warning and they are, therefore treated as if they were the producers when they contribute to shaping the expectations of consumers regarding the product.[473]

An essential parameter for determining the extent to which the presentation of a product has influenced the consumer expectations is the amount of information provided to him or her. Knowing that, producers will try to avoid liability by pointing out as many potential risks as possible in the accompanying information. This leads, sometimes, to too much information, and it can even become counterproductive in the sense of overloading the consumer.[474] The warnings, even though adequate, should be consistent with the goal of promoting product safety by redesigning dangerous products rather than seeking to avoid liability and transferring risk through reliance on the warning having been provided to the consumer.[475]

The product liability directive does not determine the content and scope of the concept of product warnings even though they must aim to reduce the total amount of

[471] In order to determine whether a warning is sufficient in order to provide accurate safety expectations to the public, a court may consider the level of risk involved and the steps taken by the defendant when providing information to consumers and users regarding product risks. See Paula Giliker,, Strict Liability for Defective Products: The Ongoing Debate, 24 Business Law Review 4, 87-90 (2003). See also James A. Henderson, Jr., Sellers Of Safe Products Should Not Be Required To Rescue Users From Risks Presented By Other, More Dangerous Products, 37 Sw. U.L. Rev. 595 (2008) noting that manufacturers should be required to warn about the risks presented by their product but not of other risks beyond these.

[472] Expectations, however, can also be lowered through these practices by suggesting that certain designs are standard, which would create the perception that special safety features are only found on deluxe models. S. Mark Mitchell, A Manufacturer's Duty to Warn in a Modern Day Tower of Babel, 29 Ga. J. Int'l & Comp. L. 573, 582-583 (2001).

[473] For example, doctors are considered intermediaries under the “learned intermediary” theory.

[474] S. Mark Mitchell, A Manufacturer's Duty to Warn in a Modern Day Tower of Babel, 29 Ga. J. Int'l & Comp. L. 573, 579-583 (2001).

[475] A.M. Clark, PRODUCT LIABILITY, 103, Sweet & Maxwell (1989).

injury involved in a dangerous activity.[476] These are also questions left to the courts of the different member states.

However, the product liability directive recognizes that it is not possible to require product manufacturers to warn of every possible danger of a particular product.[477] It therefore addresses the issue of the amount of information that should be provided. Consistent with its defectiveness standard, it requires information regarding the risks involved only in reasonably expected product uses. Consequently, a warning is required whenever a product risk is not obvious and in cases where without the warning the product would be unreasonably dangerous when used according its intended or foreseeable use so that the user can adequately identify, asses and if so wished, avoid or minimize the product risk.[478] Adequate product information can render an otherwise unsafe product safe.

Member states may lay down their own marketing requirements provided that they comply with Articles 30 and 36 of the Treaty of Rome.[479] Those conditions may include imposing a language requirement under which information essential for identifying the product must be provided in the language, or in one of the languages [480] of the State in which the product is placed in the market and that is easily understood by the

[476] Christoph Ann, Innovators In The Crossfire: A Policy Sketch For Unknowable Risks In European And United States Product Liability Law, 10 Tul. Eur. & Civ. L.F. 173 (1995).
[477] See James A. Henderson, Jr., Sellers Of Safe Products Should Not Be Required To Rescue Users From Risks Presented By Other, More Dangerous Products, 37 Sw. U.L. Rev. 595, 596 (2008) arguing against assigning watchdog responsibilities to the sellers of safe non-defective products.
[478] The function of a warning should be to warn users of the risks associated with the product; to instruct users on the safe product uses, and on the operation and maintenance of the product, and to inform users of the consequences of failure to heed the warnings and instructions. See C. J. Wright, PRODUCT LIABILITY: THE LAW AND ITS IMPLICATIONS FOR RISK MANAGEMENT, 123, Blackstone Press. Ltd.(1989).
[479] Articles 30 and 36 of the Treaty of Rome.
[480] See European rule UNE-EN 50-088 requiring product information to be at least in one of the official languages of a member state. See also S. Mark Mitchell, A Manufacturer's Duty to Warn in a Modern Day Tower of Babel, 29 Ga. J. Int'l & Comp. L. 573, 589 (2001). These languages are presumed to be sufficiently known to the purchasing public of a member state State in question and a trader who draws up the mandatory information in one of them must be regarded as having discharged his obligations as against that State. Thus, in the case of multilingual States, information relating to products must not necessarily be given in all the languages. See also Thomas H. Lee, A Purposeful Approach to Products Liability Warnings and Non-English Speaking Consumers, 47 Vand. L. Rev. 1107, 1109 (1994).

consumers in that area.[481] Such language requirements must not constitute a barrier to intra-Community trade must be applied "without distinction to all national and imported products" and must be "proportionate to the objective of consumer protection which they pursue."[482]

6.2.2 Foreseeable Product Uses

As mentioned above, the Directive refers to "the use to which it could reasonably be expected that the product would be put,"[483] an element based on objective reasonableness. Thus, potential victims are not protected against harm caused by possible product misuses, unintended uses, abuses, or reuses.

This requirement implies that producers must bear in mind the foreseeable misuses that the product could have and protect users from the possible injuries resulting from such foreseeable misuses. Product defectiveness will be considered only in cases where a product causes harm to its users while it is being used in a foreseeable way. [484]

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[481] The European Court of Justice has addressed this issue in the case C-33/97, 1999 ECR I-3175, [2000] 2 C.M.L.R. 135 (1999). Court of Justice of the European Communities. Opinion of Mr Advocate General Cosmas delivered on 19 February 1998 in the case Colim NV v Bigg's Continent Noord NV. Reference for a preliminary ruling: Rechtbank van Koophandel Hasselt - Belgium. Case C-33/97. 1998 ECJ CELEX LEXIS 13375; 1999 ECR I-3175 at 33, 40 and 44. In this case, the Court of Justice of the European Communities addressed the issue of whether member states could require imported products to carry certain label information in the language of the area in which the products are sold or in a language that is readily understood by the consumer. The court held that domestic regulation at issue requiring labeling in other languages did not constitute a "technical issue" and was therefore valid. Spanish courts held a manufacturer liable for failure to warn and instruct of product risks in Spanish in the case José Ángel T.R. c. José Marcos M.C. (retailer), Almacenes Sarti, S.L. (supplier) y Alicantina de Juguetes, S.L. (manufacturer), Court of Appeals of Cáceres 18.4.02 (AC 2002\1330; Hon Juan Francisco Bote Saavedra).

[482] See Case C-33/97, 1999 ECR I-3175, [2000] 2 C.M.L.R. 135 (1999), Court of Justice of the European Communities. Opinion of Mr Advocate General Cosmas delivered on 19 February 1998 in the case Colim NV v Bigg's Continent Noord NV. Reference for a preliminary ruling: Rechtbank van Koophandel Hasselt - Belgium. Case C-33/97. 1998 ECJ CELEX LEXIS 13375; 1999 ECR I-3175 p. 40 (135).

[483] Art. 6(1)(b) of the product liability directive. See also PRODUCTS LIABILITY FOR THE GENERAL PRACTITIONER, Colorado Springs, Colo.: Shepard's/McGraw-Hill, 260 (1981) stating that foreseeability is a basic factor of the misuse defense.

[484] The product liability directive is only concerned with safety. Merchantability considerations or fitness for the purpose the product was intended to be used are issues that remain left for domestic law. See

The wording of this "circumstance" presents an extensive set of possible definitions that are left open and will be determined by domestic courts. For example, in the context of products specifically designed for multiple purposes, it is difficult to determine which uses are reasonable and potentially expected or where the product misuse is attributable to the assembler's design or to the instructions given regarding the potential product uses.[485]

6.2.3 The time the product was put into circulation

The last issue laid out in the product liability directive that relates to the consumer expectations test is the question of the moment when the product was put into circulation. This moment is crucial given that the producer will be subject to liability under the product liability directive only from the moment he or she puts the product into circulation, but not before. This is the element that determines the beginning of the period in which liability may be imposed on the product manufacturer. It also determines the beginning of the period in which liability should be computed and extinguished.[486] Any harm caused by the product before it has been put into circulation, caused for example by bad storage would not be the responsibility of the producer.[487] So any defect must be identified when the product is put into circulation and not at the time the damage is caused.

Andrew Geddes, PRODUCT AND SERVICE LIABILITY IN THE EEC, THE NEW STRICT LIABILITY REGIME, 21 Sweet & Maxwell (1992).

[485] In cases where the product defect may be due to the assembler's design of the product, the product liability directive, in its article 7(f) exonerates the manufacturers of the product components from liability.

[486] Article 11 of the product liability directive.

[487] Under Article 6(1)(c) of the product liability directive; the producer is liable only until the moment where he/she puts the product into circulation.

The European Commission thought that it was not necessary to define this concept.[488] To date, however, the European Court of Justice has been requested to interpret and define this phrase twice in cases where, because of internal corporate organization, it was not clear whether the product had been put into circulation. The first case was Henning Veedfald v Arhus Amtskommune.[489] This case involved a hospital that prepared its own solutions, one of which caused damages. The hospital claimed that the product had not been put into circulation because it had not left the sphere of control of the hospital dispensary and therefore, liability should not attach. The second case is a reference for a preliminary ruling from the High Court of Justice of England and Wales, in Declan O'Byrne v Sanofy Pasteur MSD Ltd., Sanofy Pasteur S.A.,[490] where the English court requested the European Court of Justice to define what put into circulation meant within the scope of article 11 of the product liability directive. This case dealt with the issue of whether a product manufactured and distributed within an international group of companies was put into circulation for the purpose of article 11 of the product liability directive.

The European Court of Justice stated that "a product is put into circulation when it is taken out of the manufacturing process operated by the producer and enters a marketing process in the form in which it is offered to the public for sale or consumption."[491] In other words, if a manufacturer of a product hands the product to another corporate branch of the same corporate group and these two branches are not involved in the same manufacturing process, this will constitute putting the product into circulation.

The concept of putting a product into circulation does not only refer to the circulation of the final product. As mentioned above, manufacturers include the producer

[488] Declan O'Byrne v Sanofy Pasteur MSD Ltd, C-127/04 [2006] 2 CMLR 24, at [25]. Sanfoy Pasterus was formerly Aventis Pasteur MSD and Aventis Pasteur S.A.
[489] Henning Veedfald v Arhus Amtskommune. C-203/99 [2003] 1CMLR 41.
[490] Declan O'Byrne v Sanofy Pasteur MSD Ltd., C-127/04 [2006] 2 CMLR 24, at [25].
[491] Declan O'Byrne v Sanofy Pasteur MSD Ltd., C-127/04 [2006] 2 CMLR 24, at [32].

of the final product, component part, raw material and apparent manufacturer as well as others in the same position as the manufacturers, such as suppliers or product importers. Based on the above judgments, the class should also include different corporations within the same corporate holding.

Such definition is broad enough to leave remarkable discretion to domestic courts, which has resulted in different meanings and different judicial interpretation by the jurisdictions of the member states. This diversity has made some authors consider it an unstable criterion.[492]

Additionally, once a product has left the hands of the producer being non-defective, it does not become defective just because the safety expectations of the general public have changed[493] or because a safer product has subsequently been put into circulation.[494] So risks that are discovered after the product has been put into circulation are borne by the consumer or user.[495] The "safety which a person is entitled to expect," determined when the product has been put into circulation tells manufacturers that there will not be liability for having a better -- safer -- product in the market at a later time[496] but also requires manufacturers to be rigorous the first time they put a product in the market.[497]

This provision, though, does not mean that producers will be free from liability after the product has been put into circulation because there is a continuing post-marketing obligation to take into account new information about the product and about new product risks as more products are sold. Further, steps must be taken in warning users or preventing product uses that were discovered as dangerous. However, such

[492] See for example Jane Stapleton, PRODUCT LIABILITY, 336, Butterworths (1994).
[493] Article 6(2) of the product liability directive.
[494] Article 6(2) of the product liability directive.
[495] It would not be possible to hold manufacturers liable for the harm caused by defects that appear after the product has been commercialized because this would imply considering the product risks in hindsight, and not when the information regarding the risks is available to the producer. See BEHAVIORAL LAW AND ECONOMICS, Cass R. Sunstein (Ed.), vol. xiv, Cambridge University Press, Cambridge (2001).
[496] Article 6(2) of the product liability directive.
[497] Article 6 (1)(c) of the product liability directive.

obligations do not derive from the product liability directive but from the product safety regime currently in force in Europe.[498]

7 Defenses

The Directive sets forth a strict product liability regime but in trying to be consistent with the "fair apportionment of risks"[499] principle, it provides several defenses that if alleged and proven by defendants,[500] exempt them from liability[501] as long as two pre-requisites are met: a requirement that the plaintiff is deemed a consumer[502] and that the defendant is part of the traditional chain of distribution.[503]

The defenses established in Article 7 can be categorized in different groups. First, the ones related to the product timing that restrict liability in cases where the defendant did not put the product into circulation, or where the defendant put the product into circulation but where it was not defective when it left the defendant's hands. The second group of defenses relates to the defendant's lack of commercial activity when the product left its hands. The defendant will not be liable when the product was not manufactured for sale or distribution for economic purpose or when it was not manufactured or distributed by the defendant in the course of its business. The last group of defenses are those related to situations where the product is defective but the manufacturer is not liable

[498] See recital 17 and Article 5(1) of the Council Directive 2001/95/EC of December 3, 2001 on General Product Safety O.J. (L 11) (January 15, 2002) regarding post-marketing obligations. See Chapter 5 of this dissertation.
[499] Preamble of the product liability directive.
[500] See European Court of Justice Cases, Judgment of the Court (Fifth Chamber) of 10 May 2001; Henning Veedfald v Arhus Amtskommune. Reference for a preliminary ruling: Hojesteret - Denmark. Case C-203/99. 2001 ECJ CELEX LEXIS 6690; 2001 ECR I-3569.
[501] All of the defenses established in article 7 of the product liability directive are absolute defenses. Hans C. Taschner, EEC Strict Liability in 1992: The New Product Liability Rules, 371 Practising Law Institute 81 (1989), noting that article 7 of the Directive has been worded to give courts a duty of careful review.
[502] As explained earlier consumers should be interpreted in the broad sense to include users, bystanders and injured persons in general. Article 9(b)(ii) of the product liability directive.
[503] Article 3 of the product liability directive.

if the defect is either due to a defective component part or due to the instructions given to the manufacturer to assemble the product; the defect is due to compliance with mandatory regulations issued by public authorities; or the scientific and technical knowledge at the time the product was put into circulation was not such as to enable the manufacturer to discover the existence of the defect.[504]

The product liability directive does not focus only on the manufacturers' conduct but also provides a defense that places its emphasis on victims' conduct.[505] The Directive somehow includes contributory negligence considerations in the sense that the judge may reduce or extinguish the producer's liability if the damage is caused both by a defect in the product and by the act or omission of a third party, including other sellers for whom the injured person is responsible. So if the injured person is partially at fault or solely responsible for the damage he or she suffered, the product manufacturer may reduce or avoid liability to the extent that it is able to show that the claimant was wholly or partly contributory negligent, under each country's domestic rules.[506]

7.1 Defenses related to the time element of liability

7.1.1 The defendant did not put the product into circulation

This defense, established in article 7(a) of the product liability directive, is the other side of the concept presented above regarding "the time the product was put into circulation." This defense aims to exclude from liability any manufacturer of the final

[504] The European Court of Justice has dealt with such defenses in several cases. See, for example, the Opinion of Mr. Advocate General Tesauro delivered on 23 January 1997 in the case of the Commission of the European Communities v United Kingdom of Great Britain and Northern Ireland. Case C-300/95. 1997 ECJ CELEX LEXIS 13458. p3

[505] Article 8(2) of the product liability directive.

[506] Note that, once more, this raises another structural problem since fault is in principle irrelevant under the strict liability regime established by the Directive.

product, component part, or raw material as well as any product supplier or product importer (potentially involving different corporations within the same corporate holding) who has not put the product into circulation or into the marketing stream.[507] Whenever the product has not been put into the distribution chain, no liability will attach.[508]

The term "put into circulation" has been defined differently by the domestic laws of the various member states.[509] The definitions range from (1) voluntarily giving the product through an act and manifests an intention to transfer it to a third party for this party's use or benefit;[510] (2) voluntarily delivering the product to a third party;[511] (3) delivering the product for the use of the buyer[512] or delivering the product to another person in the course of business or incorporated into another product.[513] An alternative view is to consider that the product is put into circulation immediately when it leaves the producer's premises. In any event, whether any contract exists or a payment has been made is irrelevant for this determination. However, the diverse interpretations of this defense by the different domestic courts of the member states is subject to the common conceptual frame determined by the European Court of Justice[514] under which liability attaches only after the product has been put into the marketing stream.

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[507] See O'Byrne v Sanofy Pasteur MSD Ltd, C-127/04 [2006] 2 CMLR 24, at [25] and Henning Veedfald v Arhus Amtskommune. C-203/99 [2003] 1CMLR 41.

[508] This has been emphasized by the European Commission in the Green paper Liability for Defective products (1999), COM(1999)396 final available at http://europa.eu/documents/comm/green_papers/pdf/com1999-396_en.pdf

[509] See Daniel c. Dual Gres, S.A. (manufacturer), Court of Appeals of Castellón 28.2.06 (JUR 2006\185376; Hon Esteban Solaz Solaz). In this case, there were defects in some tales installed in the plaintiff's house. Such tales were given by the manufacturer to the retailer by mistake. The court held that the manufacturer of the tales was not liable because there was no subjective will to put the product into circulation (art. 6.1.a) of law 22/94 transposing the product liability directive.

[510] Belgium, Loi relative à la responsabilé du fair des produits defectueuxm of 25 February 1991, Section 6

[511] Austrian Product Liability Act (Produkthaftungsgesetz, ProdHG) 1988, Federal Act of 21 January 1988. Section 6. Amended 11 February 1993.

[512] Italy, Decreto del Presidente della Repubblica no. 244 of 24 May 1988, section 7 and also the Norvegian Lov om Produktansvar (Product Liability Act) no. 104, of 23 December 1988, sections 1, 2(2). Amended in November 1991 effective January 1 1993.

[513] United Kingdon, Consumer Protection Act 1987, in force on March 1 1988. The term used in section 4 (1)(b) of the United Kingdom Act is "supply," which is defined by section 46 to include selling, buying, lending, exchanging and even giving as a gift.

[514] See O'Byrne v Sanofy Pasteur MSD Ltd, C-127/04 [2006] 2 CMLR 24, at [25] and Henning Veedfald v Arhus Amtskommune. C-203/99 [2003] 1CMLR 41.

7.1.2 The defect which caused the damage did not exist at the time when the product was put into circulation by him or that this defect came into being afterwards

A related defense is that product was not defective when it left the producer's hands.[515] This defense protects a producer where the defect is due to mishandling after leaving the producer's control or when a later step in the distribution chain renders the product defective because someone removed a safety feature or failed to provide instructions for use or warnings. In Spain, courts have interpreted this provision in Juan Ramón c. Goodyear Dunlop Tires España, S.A.[516] where the court held that car tires could not be deemed defective because the alleged defect did not exist at the time the product was put into circulation. The court based its conclusion on a finding that the accident occurred far beyond the product's life – the time of use and the number of kilometers for which the tires had been driven showed they were not defective when put into circulation.

However, it remains to be seen how this defense relates to and interacts with the producer's potential post-sale obligations established by the European product safety regime.[517]

[515] Article 7(b) of the product liability directive.
[516] Juan Ramón c. Goodyear Dunlop Tires España, S.A., Madrid Court of Appeals 20.6.05 (JUR 2005\173118; MP: Juan Luis Gordillo Álvarez Valdés). The court applied article 6.1 of the law 22/94 transposing the product liability directive.
[517] See Chapter 5 of this dissertation. This defense directly relates to recital 17 and article 5(1) of the Council Directive 2001/95/EC of December 3, 2001 on General Product Safety O.J. (L 11) (January 15, 2002). For literature on post-sale duties see Gregory G. Scott, Product Liability Laws in the European Community In 1992, 18 Wm. Mitchell L. Rev. 357, 368 (1992). See also Kathryn E. Spier, Product Safety, Buybacks and the Post-Sale Duty to Warn, Harvard Law and Economics Discussion Paper No. 597 (2009). Available at SSRN: http://ssrn.com/abstract=1023125 discussing the interaction between the warning defense and product liability.

7.2 The defendant's lack of commercial activity

This defense excludes harm caused by products when there is a lack of business activity.[518] The Directive distinguishes between commercial and non-commercial suppliers of goods and protects defendants whose products are manufactured neither for sale nor for distribution for economic purpose nor in the course of business.

U.S. law offers conceptually interesting arguments relevant to this language under what is called the "dual capacity" doctrine.[519] Under this doctrine, courts consider the nature of the activity conducted by the tortfeasor. If this activity is not commercial, the defense is available. The distinction and consequences resulting from this doctrine have neither been regulated nor developed by European courts.

The European Court of Justice has discussed this defense in the context of a case, noted earlier, where a defective product -- a solution prepared for patients -- was manufactured and used in the course of providing a medical service in a public hospital that was financed with public funds, and for which the patient was not required to pay any consideration besides general taxes.[520] Beyond this case there is no case law from the

[518] Geraint Howells and Stephen Weatherill, CONSUMER PROTECTION LAW, 42, Ashgate Publishing Company (2005).

[519] See William Bell et al. v. Industrial Vangas, Inc., 30 Cal. 3d 268, 637 P.2d 266 (1981) where the California Supreme Court solved a case regarding injuries attributed to defects in a tank truck containing flammable gas, that the plaintiff was delivering to a customer of his employer. The employer, who was the defendant in this tort action, had assembled about 200 bulk delivery trucks and used all but four of these in its own operations. The plaintiff filed an action against his employer for strict manufacturer's liability claiming that various products, other than the tank truck, were involved in his accident, including storage tanks, valves, couplings, hoses and other equipment used in the storage and transportation of gas. The trial court granted summary judgment for the employer on the grounds that the employee's exclusive remedy against the employer was the Workers' Compensation Act (Act). However, the appellate court reversed and held that the doctrine of dual capacity permitted the employee to pursue a product liability action against his employer where the employee's injury arose from a separate and distinct relationship. The court held that the Workers' Compensation Act was not the employee's exclusive remedy against the employer and that an employment relationship did not protect the employer from common law liability where the concurrent cause of the injury was attributable to the employer's separate and distinct relationship to the employee as a manufacturer, which invoked a different set of obligations than the employer's duties to its employees.

[520] European Court of Justice Cases, Opinion of Mr Advocate General Ruiz-Jarabo Colomer delivered on 14 December 2000 on the case Henning Veedfald v Arhus Amtskommune. Reference for a preliminary ruling: Hojesteret - Denmark. Case C-203/99. 2000 ECJ CELEX LEXIS 7596; 2001 ECR I-3569. In this

European Court of Justice -- and no precedent in Spanish courts -- interpreting the provision for ordinarily marketed products.

7.3 The product defect was beyond the manufacturer's control

7.3.1 The defect is attributable to the design of the product in which the component has been filtered or to the instructions given by the manufacturer of the product

This defense is important for component manufacturers[521] because they are not liable if the defect arises out of the misuse of the component part by the end producer in two types of situations: first, cases where the defect is due to the design of the product into which the component product is fitted; and second, cases where the defect is due to the specific instructions of the manufacturer of the final product. So if the defect in either the component or the finished product is due to a defect of the final product rather than in the component, then the manufacturer of the final product, and not the manufacturer of the component part, will be liable.

Although the theory of this defense is straightforward, a component manufacturer may face difficulties in meeting the burden of proof unless it keeps detailed records of the design and instructions for safe use which it gives in general, and specifically those given to the final product manufacturer.

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case the European Court of Justice held that Article 7(c) did not extend to public hospitals in which a defective product had been manufactured and used in the course of a medical service and therefore the hospital was liable even if the patient had not paid any consideration for the medical service received.

[521] Article 7(f) of the product liability directive. This defense is omitted form the Norwegian and Swedish legislation. Lov om produktansvar of December 23, 1988 and Produkansvarlag (1992:18) of January 23, 1992.

7.3.2 The defect is due to compliance of the product with mandatory regulations issued by the public authorities

This defense relates to the relevance of safety regulations in the context of product liability. The scope of this defense remains uncertain even today but the idea behind it is that whenever regulatory standards exist, compliance should provide a defense to avoid liability for defective products.[522] However, not all safety standards trigger the defense; rather, it is triggered only by mandatory standards issued by public authorities.

In order to be able to claim this compliance defense, it is necessary to prove that it was not possible to manufacture the product in a non-defective way and at the same time comply with the mandatory safety standards in question.[523] Hence, if the product could have been manufactured in a non-defective manner and still comply with the standards, the defense is not available.[524]

Some courts have held that the violation of voluntary standards might be admissible, but not conclusive evidence of product defectiveness[525] but that the compliance with regulations or mandatory standards or the fact that the product has been licensed or tested is no defense to liability.[526]

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[522] This is a way the European Commission understands encourages compliance with safety standards.
[523] Article 7(d) of the product liability directive. However, it will be necessary to provide evidence to show that the product manufacturer has used all the information available at the time the product was manufactured and therefore that he complied with the state of the art or the state of scientific and technical knowledge of that time.
[524] Hans C. Taschner, EEC Strict Liability in 1992: The New Product Liability Rules, 371 Practising Law Institute 81 (1989) indicating that this provision should be strictly interpreted and very narrowly applied.
[525] This is the interpretations that German and Austrian courts have done of this defense. See Stephan Lenze, Product Safety Regulations and Defect, European Product Liability Review 24, 21 (2006).
[526] But it should be noted that whenever the scientific and technical knowledge did not allow discovering product risks, compliance with mandatory standards may be evidence that there is no product defect and therefore no liability is imposed. See for example Esther v. AEI Inc. (manufacturer) y Collagen Biomedical Aesthetic Iberica, S.A. (importer), Court of Appeals of Vizcaya 20.4.05 (JUR 2005\200889; Hon: María Carmen Keller Echevarría) and Blanca v. Collagen Biomedical Aesthetic Iberica, S.A. (importer), Court of Appeals of Barcelona 4.3.05 (JUR 2005\116914; Hon: Joaquín de Oro-Pulido López).

The introduction of this defense has been justified based on the idea that producers "cannot be placed between disobedience and liability."[527] However, the defense has rarely been applied in the member states. In Spain there is only one case[528] where it is possible to interpret that the court justified not imposing liability on the manufacturer of a defective mammary prosthesis that caused depression on the patient because of compliance with mandatory regulations. In that case, the court held that the product was manufactured according to a mandatory regulation in force in the European community and under the control of health authorities and that, therefore, imposing liability was not justified.

7.3.3 The state of scientific and technical knowledge at the time when the product was put into circulation was not such as to enable the existence of the defect to be discovered.

A particular source of tension between European institutions, governments of the member states, the industry and consumer organizations[529] has been the introduction of a defense whereby product manufacturers may avoid liability whenever the state of scientific and technical knowledge at the time when the product was put into circulation was not such as to enable the existence of the defect to be discovered. This defense is generally known as the development risks defense.[530]

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[527] Hans C. Taschner, EEC Strict Liability in 1992: The New Product Liability Rules, 371 Practising law institute 81 (1989).

[528] See Soledad v. AEI Inc. (manufacturer) and Collagen Biomedical Aesthetic Iberica, S.A. (importer) Court of Appeals of Pontevedra 26.1.04 (JUR 2006\18374; Hon: Margarita Fuenteseca Degenefee) where the court held that the manufacturer of mammary prosthesis was not liable because the product was licensed and approved and complied with the mandatory safety regulations applicable to it.

[529] Consumer representatives objected to the introduction of the “development risks” defense and its introduction resulted in delays in the Directive’s adoption. See Christopher J S Hodges, Product Liability In Europe: Politics, Reform And Reality, 27 Wm. Mitchell L. Rev. 121,126 (2000). See also Geraint Howells, COMPARATIVE PRODUCT LIABILITY, 39-40, Dartmouth Publishing Group (1993).

[530] Article 7(e) of the product liability directive.

The European Commission argued during the drafting process that the product liability regime should be purely strict and that, therefore, the development risk defense should be excluded from the final text of the Directive. The Commission believed that the introduction of such defense represented an overly lax regime with respect to high-risk and high technological industries such as pharmaceuticals and aerospace where the potential harm of products is very large and where the defense would significantly undermine the effectiveness of strict liability. For that reason, in the first draft of the Directive presented in 1976[531] the Commission included a provision whereby the manufacturer of a defective product would be liable for the harm caused by this product regardless of whether the state of scientific and technical knowledge of the risk was available at the moment of marketing the product. This proposal implied that product manufacturers were liable for all risks existing at the time the product was marketed, regardless of whether these risks were known or whether they were discoverable.

Member states, representing the unanimous position of their industries, opposed the idea of holding manufacturers liable for product risks that could not be discovered. During the process of adopting the Directive, the European Parliament, in 1979, through the representatives of the different member states, introduced an exception to this rule.[532] This exception allowed a product manufacturer to avoid liability if it provided evidence that showed that the state of the scientific and technical knowledge was such that the defect was undiscoverable. But this solution was not adopted unanimously and while some states sponsored its introduction, others opposed it.[533] The argument industries

[531] Commission Proposal for a Council Directive Relating to the Approximation of the Laws Regulations and Administrative Provisions of the Member States Concerning Liability for Defective Products, 1976 Directive. 19 O.J. Eur. Comm. (No. C 241) 9 (1976).
[532] Amendment of the Proposal for a Council Directive Relating to the Approximation of the Laws, Regulations and Administrative Provisions of the member States Concerning Liability for Defective Products, O.J. Eur. Comm. C 271, 3 (1979).
[533] Belgium, Denmark, France, Greece, Ireland and Luxembourg opposed the introduction of this limited exception and the Netherlands, Italy and the United Kingdom accepted its introduction. See Solé Feliu, Josep, El concepto de defecto del producto en la responsabilidad civil del fabricante, 474, València, Tirant lo Blanch (1997).

offered was that their limited capacity to acquire knowledge and the constantly changing state of technical knowledge required a reasonable standard that could allow them to avoid liability when it was not possible for them to know about the product risks at the time the product was put into circulation.[534]

Finally, as is often the case with controversial provisions in European agreements, the development risks defense was decided to be neither fully introduced nor fully excluded from the final text of the Directive.[535] The compromise reached[536] was that the final text of the Directive would include a defense under which producers would bear liability for known and therefore quantifiable risks, but not for development risks, that are by their nature, unquantifiable.[537] In this sense, the Directive balanced the costs to producers of acquiring information about risks involved in their products and the costs to consumers of the harm caused by such unknown risks.[538]

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[534] Christopher J.S. Hodges, UNKNOWN RISKS AND THE COMMUNITY INTEREST: THE DEVELOPMENT RISKS DEFENCE IN THE PRODUCT LIABILITY DIRECTIVE, McKenna & Co. (1996).

[535] Josephine Liu, Two roads diverged in a yellow wood: the European Community stays on the path to strict liability, 27 Fordham Int'l L J. 1940, 1953-1954 (2004).

[536] Article 7(e) of the Directive. This defense would be the equivalent to the American "state of the art," which allows manufacturers to avoid liability for unknown product risks at the time of manufacture. This was the provision of the Directive that created the most controversy. Geraint Howells, COMPARATIVE PRODUCT LIABILITY, 39-40, Dartmouth Publishing Group (1993) remarking that inclusion of development risk defense has caused most controversy. See also Anita Bernstein, Looking at Europe for the Difference Between Strict and Fault-Based Liability, 14 Journal of Products Liability 207, 209 (1992).

[537] Articles 15 and 7(e) of the product liability directive. The opinion of Mr. Advocate General Tesauro delivered on 23 January 1997 in the case of the Commission of the European Communities v United Kingdom of Great Britain and Northern Ireland. 1997 ECJ CELEX LEXIS 13458, Case C-300/95. P 22 described the negotiation process of the Directive according to which the Commission's proposal was inspired by the U.S. model for a system of no-fault liability on the part of the producer, which, on the one hand, was regarded as the most suitable means of securing adequate protection for the consumer (fourth recital) and, on the other, was justified by the fact that the producer was the center through which to impute damages, since the producer may include the liability costs as part of his production costs when calculating the price and therefore spread it among all consumers of products which are of the same type but free from defects (fifth recital). See also Geraint G. Howells & Mark Mildred, Is European Products Liability More Protective Than The Restatement (Third) Of Torts: Products Liability?, 65 Tenn. L. Rev. 985, 993 (1998) arguing that the introduction of the "development risk" defense intended to avoid the U.S. product liability crisis.

[538] See Jane Stapleton, PRODUCT LIABILITY, 236-242, Butterworths (1994). This conclusion has been supported by the Study on the economic impact of the development risk clause delivered by Fondazione Rosselli, appointed by the Directorate for the Internal Market of the European Commission (Contract No. ETD/2002/85) (2004). This study, that strongly supported the introduction and maintenance of the development risks defense, concluded that such defense was a fundamental factor to achieve the Directive's goal of balancing the need to preserve incentives to innovation and consumers' interests. This conclusion was based on three arguments: first; that the development risks defense protected incentives to innovate by

This compromise solution included two key elements: first, each member state would have an option to include the defense in its domestic legislation; second, there was a provision stating that the Council of Ministers would review the effect of the defense on consumer protection and on the functioning of the common market[539] and based on those findings, it would then decide whether to include the defense in the final draft of the Directive.[540] This optional provision has, in some respects, diluted the Directive's harmonization goal.[541]

Up to today, Finland,[542] Luxembourg[543] and Norway[544] have excluded the development risks defense from their transposition laws and France, Germany and Spain have excluded its application with respect to specific products: France did not include this defense for products derived from the human body,[545] Germany for pharmaceutical products,[546] and Spain for medicines, foods or food products for human consumption.[547]

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reducing liability for innovation-related risks. Second; that this defense provided reasonably limited liability insurance costs by keeping the litigation at a reasonably low level and finally; that strict liability without such defense would not allow high-tech/high-risk industries to buy insurance coverage at an affordable cost. This document is available at http://ec.europa.eu/enterprise/regulation/goods/docs/liability/2004-06-dev-risk-clause-study_en.pdf

[539] Article 21 of the product liability directive.

[540] During the final phase of approval of the Directive, the development risks defense was still a source of controversy. See Alfred E. Mottur, The European Product Liability Directive: A Comparison with U.S. Law, an Analysis of its Impact on Trade, and a Recommendation for Reform so as to Accomplish Harmonization and Consumer Protection, 25 Law & Pol'y Int'l Bus. 983, 990-91 (1994); John G. Culhane, The Limits of Product Liability Reform within a Consumer Expectation Model: A Comparison of Approaches Taken by the United States and the European Union, 19 Hastings Int'l & Comp. L. Rev. 1, 31 (1995).

[541] Pmbl of the product liability directive. Geraint G. Howells & Mark Mildred, Is European Products Liability More Protective Than The Restatement (Third) Of Torts: Products Liability?, 65 Tenn. L. Rev. 985, 1016 (1998)

[542] Law 698 of 17-8-1990 (Tuotevastuulaki) amended by the Law 8.1.1993/99; 22.10.1993/879 and 27.11.1998/880.

[543] Loi du 21 Avril 1989 relative à la responsabilité du fait des produits défectueux of April 21, 1989 amended by the law 6.12.1989.

[544] Lov om Produktansvar, Act No. 104 of 23 December 1988 (Norsk Lovtidend 1988, Avd. I, p. 1025), as amended by Act No. 40 of 24 June 1994.

[545] Article 1386.12 French Civil Code provides the development risks defense and article 1986-11 that excludes the application of the defense to products derived for human body.

[546] Drug Act of 1976 (Arzneimittelgesetz.) See also BGH Urt. V. 9, 5, 1995-V12R 158/94 Hamm. Where the German Supreme Court held that the development risks defense was not available in manufacturing defect cases. See also Christopher J. S. Hodges, Product Liability In Europe**:** Politics, Reform And Reality, 27 Wm. Mitchell L. Rev. 121, 124 (2000) for a discussion of the European Directive and especially on the implementation of the development risks defense by the different member states.

The transposition and specific content of this defense has not been exempt from debate.[548] The European Court of Justice, in proceedings against France and the U.K., established how and on what terms the defense was to be transposed into the domestic legislation of those member states that chose to adopt it.[549]

The inclusion of this defense in the product liability directive is consistent with its fundamental principle of fair apportionment of risks between consumers and producers so that there is a balance between consumer-safety and commercial -- development interests.[550] The strict liability regime established by the Directive seemed to have shifted the balance of liability in favor of consumer interests given that they were "insured" by producers and other members of the commercial chain. It then became necessary to include this defense -- even if optional -- so as not to impose an overwhelming burden of risk and liability on producers.[551]

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[547] In reaction to the Colza case that caused hundreds of deaths and thousands of people poisoned, these products were left under the scope of the Consumer protection Act of 1984. Article 6.3 of Law 22/1994 transposing the product liability directive (B.O.E. n1 161, 7.7.1994) -- overruled by the RDL 1/2007 in force today -- excludes medical products, food-stuff and food products for human consumption when stating that "que el estado de los conocimientos científicos y técnicos existentes en el momento de la puesta en circulación no permitía apreciar la existencia del defecto." See in contrast María Virtudes c. Rhone Poulenc Rorer, S.A., Court of Appeals of Barcelona 17.11.03 (JUR 2004\5123; Hon: Laura Pérez de Lazarraga Villanueva) where the court does not apply the development risks defense to a pharmaceutical lab because they are strictly liable even for unforeseeable risks.

[548] See John W. Wade, Symposium: The Passage of Time: The Implications for Product Liability: On the Effect in Product Liability of Knowledge Unavailable Prior to Marketing, 58 N.Y.U.L. Rev. 734, 753-754 (1993) arguing that the increase in knowledge about a product between the time it is distributed and the time of trial either in the form of knowledge of new hazards; new means of improving product safety and new product uses should be measured as of the time of distribution and result in liability if the product caused harm.

[549] In a judicial process against France, the European Court of Justice considered that France had not correctly transposed this exception and its domestic law had to be amended to comply with the judgment of the European Court. Commission v. French Republic, Peter Jann, C 52/00, TJCE 25.4.2002. For a comment on this judgment see Seuba Torreblanca, Joan Carles "Las Sentencias del Tribunal de Justicia de las comunidades de 25 de abril de 2002 sobre la Directiva 85/374, de productos defectuosos: una directiva imperativa, no de mínimos", Indret 3/2002. The European Commission also initiated infringement procedures against the U.K. based on Article 169 of the Treaty of Rome understanding that the British transposition of this defense was beyond the scope established by the Directive. See Commission, Ninth Annual Report to the European Parliament on Commission Monitoring of the Application of Community Law - 1991, [1992] O.J. (C 250) 17.

[550] Pmbl of the product liability directive, paragraph 7.

[551] The practical impact of the "development risks" defense lies in the fact that the burden of proving that the problem was not discoverable, given the state of actual and constructive knowledge, is reversed. Under fault liability, the plaintiff has to show that defendant has been negligent, in that his conduct does not conform to the requirement of reasonableness under the "state of the art" which constitutes a breach of his

The defense establishes that in order to avoid being held liable, a producer is required to prove that the objective state of scientific and technical knowledge, including the most advanced level of such knowledge, was not such as to enable the discovery of the existence of the defect.[552] In order for the relevant knowledge to be successfully pleaded against the producer, that knowledge must have been accessible at the time when the product in question was put into circulation.[553]

This defense raises the issue of who should bear the costs of unknown risks at the time of marketing the product. The inclusion of this defense has economic sense given that under strict liability producers are the residual bearers of the costs of the harm caused by the defective product. However, in order for this system to be viable, it is necessary to limit the scope of the risks that the producer will bear so that it can internalize their cost either by investing in safety or by buying insurance against any damage caused by defects in the product.[554] Thus, the producer will not be held liable for all risks; only for the ones it could or should have known of.[555]

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duty of care. Under strict liability, the burden is on the defendant to establish the defense. The reversal of the burden of proof has been made on policy grounds so as to make it easier for people who have been injured by defective products to succeed in making a legal claim. See for example, Amanda v. AEI Inc. (manufacturer) and Collagen Biomedical Aesthetic Iberica, S.A. (importer), Court of Appeals of La Coruña 31.3.04 (JUR 2006\93996; Hon: Mª del Carmen Vilariño López) where the court considered that the defendant did not meet the burden of proving that the state of scientific and technical knowledge was such that he could not know the product risks that finally caused harm and therefore the development risks defense was not applicable. (Article 3 and 6.1(e) of Law 22/94).

[552] This was the definition that the European Court of Justice provided in the Judgment of the Court (Fifth Chamber) of 29 May 1997 in the case Commission of the European Communities v United Kingdom of Great Britain and Northern Ireland, C-300/95. 1997 ECJ CELEX LEXIS 13593; 1997 ECR I-2649. P1. Following this definition see Soledad v. AEI Inc. (manufacturer) and Collagen Biomedical Aesthetic Iberica, S.A. (importer) Court of Appeals of Pontevedra 26.1.04 (JUR 2006\18374; Hon: Margarita Fuenteseca Degenefee) where the court held that the manufacturer of mammary prosthesis was not liable because the product was licensed and approved based on the state of scientific and technical knowledge of the time the product was manufacturer that did not enable the producer to know of the product risks. For a discussion on the possible times for determining available knowledge see John W. Wade, Symposium: The Passage of Time: The Implications for Product Liability: On the Effect in Product Liability of Knowledge Unavailable Prior to Marketing, 58 N.Y.U.L. Rev. 734, 753-754 (1993).

[553] See Franz Werro, Tort Law at the Beginning of the New Millennium. A Tribute to John G. Fleming's Legacy, 49 Am. J. Comp. L. 147, 156 (2001).

[554] Opinion of Mr. Advocate General Tesauro delivered on 23 January 1997. Commission of the European Communities v United Kingdom of Great Britain and Northern Ireland. 1997 ECJ CELEX LEXIS 13458, Case C-300/95. P 22. See also Warren Freedman, DEFENSES TO PRODUCTS LIABILITY: A PRIMER FOR

The content of this defense seems quite intuitive from a theoretical standpoint but its application raises some questions that are relevant both for producers and for injured victims.[556] On one side, it will be crucial to determine the moment when it needs to be decided whether the scientific and technical knowledge was available. On the other, it will be necessary to establish which scientific and technical knowledge will be considered relevant.

The timing of the relevant scientific and technical knowledge is important because of the different moments of putting the defective product into circulation and the moment when the scientific knowledge has advanced enough to allow discovering the defect. Further, it is not only the producer that is responsible for development risks. In cases where risks were unknown or not possible to identify, the importers or finally, the distributors, would also be liable for undiscovered risks at the time of a product's commercialization.[557] The exact moments when these members of the commercial chain are in a position to discover the defect are different and therefore the moment when the scientific and technical knowledge is evaluated is very relevant for these parties.

Given the relevance of time and the ever-changing state of knowledge, the producer is required to show that, in light of the most advanced scientific and technical knowledge objectively and reasonably obtainable, and available to the scientific

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PLAINTIFFS AND DEFENDANTS, Buffalo, NY: William S. Hein, 411-430 (1996) for a very good overview regarding the development risks defense in the different U.S. jurisdictions.

[555] See Franz Werro, Tort Law at the Beginning of the New Millennium. A Tribute to John G. Fleming's Legacy, 49 Am. J. Comp. L. 147, 156 (2001) noting that strict liability should not be imposed unless the defendant engaged in conduct that he knew, or should have known, to be risky and unless this conduct was the exclusive cause of the injury.

[556] See Pablo Salvador Coderch and Solé Feliu, Josep, BRUJOS Y APRENDICES: LOS RIESGOS DE DESARROLLO EN LA RESPONSABILIDAD DE PRODUCTO, Marcial Pons, Madrid/Barcelona (1999). For a comparative study on European law on this issue see van Dam, Cees, EUROPEAN TORT LAW, 1410, Oxford University Press, Oxford (2006).

[557] Article 4.1 (a) and (d) for the producer, 4.2 the importer or 4.3 for the distributor of the General Product Safety Directive.

community as a whole, it was impossible to consider that the product was defective[558] when the product was put into circulation.[559]

But after the product was put into circulation the producer is not relieved from liability; instead the producer has a duty of inspecting the product and informing consumers of the new, known and discovered risks after the product has left its hands under the European product safety regime[560] and the domestic rules of each member state.[561] If the manufacturer knows of new product risks after the product has been put into circulation and does nothing to inform its consumers and prevent any injuries resulting from these new risks, the manufacturer could be held liable for intentional tortuous conduct under domestic civil and penal laws.[562]

If the producer does everything which could reasonably be expected of it and still does not discover the existence of a defect, the "development risk" falls upon the consumer or user rather than on the producer.[563]

Next, it is necessary to establish what knowledge is relevant.[564] Most European countries judge the manufacturer's conduct by reference not only to its actual scientific

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[558] Opinion of Mr Advocate General Tesauro delivered on 23 January 1997, Commission of the European Communities v United Kingdom of Great Britain and Northern Ireland. 1997 ECJ CELEX LEXIS 13458 Case C-300/95. P 22. See Christopher Newdick, Risk, Uncertainty and "Knowledge" in the Development Risk Defence, 20 Anglo-Am. L. Rev. 309 (1991) for a discussion of the standards of "knowledge" or "knowledgeability."

[559] See Commission of the European Communities v. United Kingdom of Great Britain and Northern Ireland; Case C-300/95 (May 29, 1997); paragraph 28.

[560] See Article 5.2 of the General Product Safety Directive 2001/95 of December 3 relative to general product safety.

[561] In the case of Spain, the Civil Code establishes in its article 1902 a duty of informing about new product risks and therefore the manufacturer will have the duty to continue inspecting and developing research to be able to discover new product risks.

[562] In Spain, an intentional conduct resulting in torts is called "dolo" and is regulated both by Spanish Civil Code (Royal Decree of July 24, 1889) and the Organic Law 10/1995, of November 23rd, approving the Spanish Penal Code, BOE num. 281 of 24/11/1995, pages 33987-34058, BOE-A-1995-25444, available at http://www.boe.es/aeboe/consultas/bases_datos/doc.php?id=BOE-A-1995-25444.

[563] Commission of the European Communities, Judgment of the Court (Fifth Chamber) of 29 May 1997. Commission of the European Communities v United Kingdom of Great Britain and Northern Ireland. Case C-300/95. 1997 ECJ CELEX LEXIS 13593; 1997 ECR I-2649.

[564] See Study on the economic impact of the development risk clause as in the Directive 85/374/EEC on the liability for defective products written by Fondazione Rosselli, appointed by the Directorate for the Internal Market of the European Commission (Contract No. ETD/2002/85), at 136 (2004) where the reporters of the study stated that it is necessary to define the state of the art knowledge.

knowledge but also to constructive knowledge -- the knowledge available to it when the product was under development, namely the "state of the art,"[565] -- which includes the facts that are public knowledge within the industry and of which the producer ought to have been aware.[566]

The Directive does not include any guidance on how to determine what constitutes the standards necessary to establish scientific knowledge.[567] These difficulties of interpretation are left to the domestic courts to resolve through case law but they have not yet been generally addressed.[568] The relevance of the determination of the scientific

[565] Under a strict product liability regime, the difference between the two types of knowledge is interesting because the apparent objectivity of strict liability seems to exclude reasonableness considerations. In practice, though, a defendant subject to strict liability has to prove that he could not have discovered the defect by the use of reasonable care. See Christopher Newdick, The Development Risk Defense of the Consumer Protection Act 1987, 47 Cambridge Law Journal 3, 475 (1988).

[566] See Amanda v. AEI Inc. (manufacturer) and Collagen Biomedical Aesthetic Iberica, S.A. (importer), Court of Appeals of La Coruña 31.3.04 (JUR 2006\93996; Hon: Mª del Carmen Vilariño López) where the court considered that the defendant did not prove that the state of scientific and technical knowledge was such that he could not know the product risks that finally caused harm. Therefore, the court understood that the defendant ought to know of product risks and therefore should have discovered them. (article 3 and 6.1(e) of Law 22/94). See Lawrence C. Mann and Peter R. Rodrigues, The European Directive on PL: the promise or progress ?, 18 Ga. J. Int'l & Comp. L. 391, 422 (1988) arguing that setting the development risk defense as a distinct defense from the state of the art sends a confusing signal to parties subject to the product liability directive.

[567] One cause of uncertainty under the Directive is the question as to how the state of scientific and technical knowledge is to be determined. In contrast see the U.S. Supreme Court in Daubert v. Merrell Dow Pharmaceuticals. Inc. 509 U.S. 579 (1993) which redefined the concept of state of scientific knowledge by noting that the material relied upon by expert witnesses in their evaluation of scientific controversies should have had careful review. In the case European Commission v. United Kingdom, C-300/95 [1997] ECR I-2649, para 29, in a proceeding started by the Commission against the United Kingdom, the European Court of Justice pointed out that the relevant state of knowledge is an objective notion that includes "the most advanced level of knowledge" provided that it is accessible when the product is put into circulation. However, it is still unclear if the required knowledge pertains to the general existence of the defect or whether the defect has to be detectable in particular products. See, Franz Werro and Vernon Valentine Palmer (eds.), THE BOUNDARIES OF STRICT LIABILITY IN EUROPEAN TORT LAW, 443, Durham, N.C.: Carolina Academic Press (2004).

[568] See Commission of the European Communities v. United Kingdom of Great Britain and Northern Ireland; Case C-300/95 (May 29, 1997); paragraph 29. In this case, the Commission understood that section 4(1)(e) of the British Consumer Protection Act passed in 1987 transposing the Directive broadened the defense and significantly restricted the scope of liability because the reference to the "producer of products of the same description" introduced considerations regarding whether the producer in good faith could not have discovered the defect. However, the European Court of Justice decided in favor of the United Kingdom and concluded that a producer may avoid liability if he can prove that the state of such knowledge was not such that a producer of products of the same description as the product in question might be expected to have discovered the defect if it had existed in his products while they were under his control was not contrary to the European Regulation. However, allowing taking into account the subjective knowledge of a producer taking reasonable care, compared to the standard precautions taken in the

standard is important because scientific standards, scientific knowledge and legal certainty to impose liability, are concepts that differ.

The concepts of information and knowledge are not equivalent. Facts and data may be known about a product but that may not mean that there is sufficient understanding about their implications and consequences at the time the product is put into circulation. Even having the information about product risks, the defect may still not be possible to discover. It is possible to identify four different situations regarding the interaction between knowledge and discoverability of the risks involved in the product:[569]

a) If the risks are unknown and undiscoverable, the producer could allege this defense because the available scientific procedures would not have permitted discovering the defect prior to the product being put into circulation.[570] In this case, the product defect and the subsequent harm are not attributable to the producer and therefore the victim bears the accident's costs without being entitled to compensation.[571]

b) If the risks were known but undiscoverable, the product defect will be deemed as discoverable because the risks posed by the product were known. These are cases where the producer did not know of the product risks when he put the product into circulation[572] but the victim's losses occurred after the risk was detected. These damages suffered by the victim are compensable but excluded from the scope of this defense because they would result from the failure to warn or instruct of risks known after the product was sold.[573] Additionally fines would be imposed under

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industrial sector in question, stresses particular terms used in the provision without demonstrating that the general legal context of the provision at issue fails to secure effectively the full application of the Directive.

[569] See A.M. Clark, PRODUCT LIABILITY, Chapter 6, Sweet & Maxwell (1989).

[570] Christoph Ann, Innovators In The Crossfire: A Policy Sketch For Unknowable Risks In European And United States Product Liability Law, 10 Tul. Eur. & Civ. L.F. 173 (1995).

[571] At least compensation from the tortfeasor.

[572] Geraint Howells, COMPARATIVE PRODUCT LIABILITY, 29, Dartmouth Publishing Group (1993).

[573] Commission of the European Communities v. United Kingdom of Great Britain and Northern Ireland; Case C-300/95 (May 29, 1997).

the European product safety regulation,[574] which imposes on manufacturers and distributors a duty to inspect and inform of product risks they have knowledge of after they put the product into circulation. Thus, such liability would be derived from the failure to warn and from safety obligations and not from the innovation risk itself.[575]

c) If the risks were unknown but discoverable, a producer will be at fault if it failed to act reasonably in discovering a reasonably foreseeable product risk. Under strict liability, the question will be whether the state of the scientific and technical knowledge was such that the producer could have discovered the defect.[576] In practice this is one of the major issues in product liability litigation.

d) If the risks were known and discoverable, a producer would always be liable under both fault and strict liability, unless the product risks could be communicated to the consumer with instructions and warnings.

The introduction of this defense has been widely controversial[577] beyond the European Union. For many, this defense has been considered incompatible and inconsistent with the strict liability system[578] because of the risk spreading and loss distribution rationales that lie behind it.[579]

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[574] See General Product Safety Directive 2001/95/EC of December 3, 2001 (O.J. (L 11) (January 15, 2002).
[575] The product liability directive does not make explicit reference to failure to warn as a cause of action. See Michael R. Will, Liability for failure to warn in the European Community, 6 B.U. Int'l L. J. 125, 131 (1988). See also James A. Henderson, Jr., Coping with the Time Dimension in Products Liability, 69 Cal. L. Rev. 919, 922 n.5 (1981).
[576] See Amanda v. AEI Inc. (manufacturer) and Collagen Biomedical Aesthetic Iberica, S.A. (importer), Court of Appeals of La Coruña 31.3.04 (JUR 2006\93996; Hon: Mª del Carmen Vilariño López) where the court understood that the defendant should have discovered the product risks and did not prove that the state of scientific and technical knowledge did not prevent him from such discovery (article 3 and 6.1(e) of Law 22/94).
[577] See James A. Henderson, Jr. & Aaron D. Twerski, What Europe, Japan, and Other Countries Can Learn From the New American Restatement of Products Liability, 34 Tex. Int'l L.J. 1, 13-14 (1999) criticizing the introduction of the development risk defense as following the outdated Restatement (Second).
[578] John G. Culhane, The Limits Of Product Liability Reform Within A Consumer Expectation Model: A Comparison Of Approaches Taken By The United States And The European Union, 19 Hastings in t'l & comp L Rev. 1, 35 (1995).
[579] Geraint G. Howells & Mark Mildred, Is European Products Liability More Protective Than The Restatement (Third) Of Torts: Products Liability?, 65 Tenn. L. Rev. 985, 1030 (1998).

This defense undermines the nature of the strict liability regime intended by the product liability directive. Even though this Directive does not establish absolute liability, the strict liability regime is weakened because it provides defendants with a possibility to escape from liability based on fault considerations. However, despite the discussion regarding its nature and the controversy it has generated because it represents the introduction of fault considerations within a strict liability framework, its application focuses mostly on manufacturing defects,[580] and its narrow interpretation by domestic courts has led many practitioners and academics to view the development risk defense as having little practical value to producers.[581]

7.4 Victims' fault: the introduction of contributory negligence considerations

Article 8 of the product liability directive is not a defense in the strict sense but contains two issues regarding liability sharing between the product manufacturer and the injured victim. Section 1 of this article imposes liability on the producer when the damage is caused both by a defect and by the act or omission of a third party.[582] Section 2 of the same article states that such liability "may be reduced or disallowed when, having regard to all the circumstances, the damage is caused by a defect in the product and by

[580] See James A. Henderson, Jr. & Aaron D. Twerski, What Europe, Japan, and Other Countries Can Learn From the New American Restatement of Products Liability, 34 Tex. Int'l L.J. 1, 13-14 (1999) arguing that the language of the development risk defense focuses on manufacturing defects because design defects require a value judgment, a risk-utility judgment given that one "discovers" risks but "evaluates" whether a product's design is defective. These authors suggest that in order to make sense in connection with design and warning defects, the language of article 7(e) should read as "the state of knowledge was not such as to allow the producer to evaluate whether or not the product was defective." However, once more this provisions reflects the adoption of an old-dated §402A of the Restatement (Second) of Torts instead on learning from the U.S. developments since 1965 to correct the deficiencies of §402A dealing with design defects and failures to warn).

[581] LOVELLS, PRODUCT LIABILITY IN THE EUROPEAN UNION: A REPORT FOR THE EUROPEAN COMMISSION, 50 (2003) available at http://ec.europa.eu/enterprise/policies/single-market-goods/files/goods/docs/liability/studies/lovells-study_en.pdf

[582] Article 8(1) of the product liability directive.

the fault of the injured person or any person for whom the injured person is responsible."[583]

Fault is not defined in article 8 even though it is possible to construe its meaning through the different references the product liability directive includes in its preamble when it refers to the victim's fault. First, when it states that despite strict liability, there should be a "fair apportionment of risks between the injured person and the producer," this places the focus both on the producer and on the victim's conduct.[584] At the same time, the preamble also explicitly refers to the contributory negligence of the victim that should be taken into account when determining the specific amount of recovery either by reducing the amount of compensation or by completely eliminating any compensation to the victim.[585]

The consideration of the victim's fault or negligence when reducing the amount of compensation should not be interpreted as introducing either contributory negligence elements or comparative negligence considerations incompatible with the Directive's strict liability system.[586] This issue is important given the evolution of analysis on the efficiency implications of these rules.[587] This "defense" seems to focus on causation and blameworthiness through a comparative causation analysis[588] and not on the parties' fault as would contradict strict liability principles.

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[583] Article 8(2) of the product liability directive.
[584] Directive 85/374 at pmbl., para. 7. See also Marshall S. Shapo, Comparing Products Liability: Concepts in European and American Law, 26 Cornell Int'l L.J. 279, 319 (1993).
[585] Preamble, paragraph 8 of the product liability directive.
[586] Mary J. Davis, Individual and Institutional Responsibility: A Vision For Comparative Fault In Products Liability, 39 Vill. L. Rev. 281, 341 (1994).
[587] See Mireia Artigot-Golobardes, and Gómez-Pomar, Fernando, Contributory and comparative negligence in the law and economics literature, 46-79 in ENCYCLOPEDIA OF LAW AND ECONOMICS: TORTS (Michael Faure, ed.), Edward Elgar (2009). The initial literature on the matter believed that contributory negligence presented greater advantages and led to optimal outcomes. However, this first conclusion was soon challenged by the literature that concluded that under perfect information conditions both rules are equivalent, and when some basic assumptions are relaxed, comparative negligence seems to favor efficiency.
[588] Article 8 of the product liability directive. Geraint Howells, COMPARATIVE PRODUCTS LIABILITY, 45 Darmouth publishing Company Limited (1993).

However, the Directive does not specify how the reduction of liability is to be applied or calculated and this has led to a diverse interpretation and application of this defense by the courts of the member states. It is unclear whether a plaintiff who is fifty-one percent responsible for his injuries will be allowed to receive forty-nine percent of the verdict, or will be totally barred from recovery.[589]

Even though the consideration of the victim's fault is established at the European level, domestic rules are applicable.[590] It is for member states to determine the treatment given to the victim's fault and thereby to establish how the victim's fault is to be determined, evaluated and how responsibility is to be allocated between the producer and the injured victim so that liability is reduced.[591] Most member states have simply transposed the language of Article 8 without going any further.[592] For example, Belgium has transposed the wording of article 8 in its domestic law without any modification or additional consideration.[593] The same is true in Denmark,[594] the Netherlands[595] and Portugal.[596]

Germany has taken a different approach, starting with the fact that its overall approach to products liability is primarily tort-based and not contract-based. For that reason, the German provisions implementing the Directive incorporate the contributory

[589] Gregory G. Scott, Product Liability Laws In The European Community In 1992, 18 Wm. Mitchell L. Rev. 357, 370 (1992).
[590] The national courts have discretion as to the extent to which the producer's liability is to be reduced or extinguished if the injured person is at fault in light of the absence of rules or guidance in the Directive. See PAUL SHERMAN, PRODUCTS LIABILITY FOR THE GENERAL PRACTITIONER, Colorado Springs, Colo.: Shepard's/McGraw-Hill, 251-255 (1981) for a description of the implications of the introduction of contributory negligence and comparative fault considerations.
[591] Mary J. Davis, Individual and Institutional Responsibility: A Vision for Comparative Fault in Products Liability, 39 Vill. L. Rev. 281, 333-334 (1994).
[592] Sandra N. Hurd & Frances E. Zollers, European Community: Council Directive on the Approximation of the Laws, Regulations and Administrative Provisions of the Member States Concerning Liability for Defective Products, 32 Int'l Legal Materials 1347, 1379 (1993).
[593] Loi relative à la responsabilité du fait des produits defectueux, of February 25, 1991.
[594] Lov om Produktansvar No. 371 of June 7, 1989.
[595] Wet Productktenaansprakelijkeid 1990 (Netherlands Product Liability Act), contained in Book 6, Title 3, Chapter 3 §§ 185-193 of the Netherlands Civil Code of 1991 of September 13, 1990.
[596] Decreto-Lei No. 383/89 of November 6, 1989.

fault provisions of the German Civil Code,[597] which reduces the victim's recovery based on his or her contribution to the causation of the damage.[598] Similar causation-based provisions are found in Greece[599] and Luxembourg.[600] Italy[601] is the only country that bars recovery for assumption of the risk, when the injured person used the defective product despite knowledge of its defect or danger.[602]

Spain transposed article 8 of the Directive in article 9 of law 22/94 today article 145 of RDL 1/2007.[603] However, neither the transposition law nor Spanish civil procedure regulation establishes how the reduction of the victim's damages should be done and what parameters should be taken into account. This lack of definition and criterion is also reflected in Spanish jurisprudence. Spanish courts generally do not specify and provide reasoning in support of the reduction of the damage award and it is not strange to find courts referring to fault[604] and to comparative negligence when reducing the damage award.[605] This lack of reasoning offered by the courts is especially

[597] For a general description of German products liability laws, see Joachim Zekoll, The German Products Liability Act, 37 Am. J. Comp. L. 809 (1989). See also Sandra N. Hurd & Frances E. Zollers, European Community: Council Directive on the Approximation of the Laws, Regulations and Administrative Provisions of the Member States Concerning Liability for Defective Products, 32 Int'l Legal Materials 1347, 1372 (1993).

[598] Geraint G. Howells, COMPARATIVE PRODUCT LIABILITY, 154, Dartmouth Publishing Company (1993).

[599] Greek Law 2251/1994.

[600] Loi du 21 Avril 1989 relative à la responsabilité du fait des produits défectueux of April 21, 1989.

[601] Decreto del Presidente della Republica No.244 of May 24, 1988. For an analysis of the Italian transposition of the product liability Directive see Richard H. Dreyfuss, The Italian law on strict products liability, 17 N.Y.L. Sch. J. Int'. & Comp. L. 37 (1997).

[602] Sandra N. Hurd & Frances E. Zollers, European Community: Council Directive on the Approximation of the Laws, Regulations and Administrative Provisions of the Member States Concerning Liability for Defective Products, 32 Int'l Legal Materials 1347, 1379 (1993).

[603] Article 145, named "Culpa del perjudicado" (fault of the injured) of RDL 1/2007 states that

> "*La responsabilidad prevista en este capítulo podrá reducirse o suprimirse en función de las circunstancias del caso, si el daño causado fuera debido conjuntamente a un defecto del producto y a culpa del perjudicado o de una persona de la que éste deba responder civilmente.*."
>
> "*The liability established in this chapter could be reduced or waived depending on the circumstances of the case, if the harm was jointly caused by a product defect and fault of the injured victim or of any person to whom the injured victim would be civilly responsible of."*

[604] Iñigo v. BMW Ibérica, S.A., Court of Appeals of Madrid 23.1.06 (JUR 2006\120705; MP: Ana María Olalla Camarero) where the court did not award full compensation for the damages suffered by the victim because the accident was caused by the victim's fault. The judgment does not include considerations regarding the reduction of the award and the arguments in support of it.

[605] See Francisco V.H. v. Suarep and Lladó, S.A. (retailer) and Chemvic, S.L. (supplier), Court of Appeals of Barcelona 30.5.02 (AC 2002\1211; Hon: Inmaculada Zapata Camacho) and Paula v. Europ S.L. (seller)

delicate in cases where courts consider that the injured victim should not receive compensation because the injuries were caused only by the victim's conduct.[606] In fact, it is possible to find only a few cases in which courts have specified the percentage of compensation reduced and the underlying reasons that justify it.[607]

Most civil law countries in Europe place less emphasis on the victim's fault than do American jurisdictions. This difference is reflected in the European view that the victim's fault is often not considered as a defense, but rather as a means of adjusting plaintiff's recovery, almost as an instrument for assessing damages based on causation principles.[608] This may be due to the fact that that Europeans are more willing to accept responsibility for their conduct when it contributes to the accident. However, as will be developed below, the role of European social insurance systems seems to be crucial for accepting the reduction or the lack of compensation as a consequence of one's fault, without further litigation.[609]

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and Compañía de Seguros MAPFRE, Court of Appeals of Sevilla 25.2.05 (AC 2005\943; Hon: Rafael Márquez Romero). In both these cases, courts understood that the burns the victim suffered in her hands were caused by the concurring "faults" of the product manufacturer and the victim, who did not use the product according to the instructions and warnings that the producer provided. Courts reduced the damage award but did not explicitly state the underlying reasons justifying such reductions.

[606] See Mercedes R.R. v. Fortuna Agrícola, S.L., Spanish Supreme Court 30.9.99 (RJ 1999\7848; MP: Antonio Gullón Ballesteros) where the court considered that the damages suffered had been caused only by the victim's conduct and therefore no compensation was awarded.

[607] See Jesús Luis v. Peugeot España, S.A., Court of Appeals of Madrid 21.3.05 (JUR 2005\107495; Hon: Ramón Ruiz Jiménez). In this case, the court of appeals reduced in 70% the damage award because of the conduct of the injured victim that caused the accident that resulted in damages.

[608] Mary J. Davis, Individual and Institutional Responsibility: A Vision for Comparative Fault In Products Liability, 39 Vill. L. Rev. 281, 337-338 (1994).

[609] See Chapter 7 of this dissertation. See also Andrew C. Spacone, Strict Liability in the European Union - Not a United States Analog, 5 Roger Williams U. L. Rev. 341 (2000).

CHAPTER 3

PROCEDURAL RULES AS BARRIERS TO BRING PRODUCT LIABILITY CLAIMS IN EUROPE

Despite the formal similarities between strict product liability in Europe and in the United States under the Second Restatement, its impact, evolution and consequences have been significantly different. One set of factors that explain the limited impact of strict product liability in Europe are the rules of civil procedure in force in most member states.[610]

In general, when deciding whether to file a claim, plaintiffs consider the likelihood of prevailing in court as well as the amount of damages they suffered and for which they seek compensation.[611] Needless to say, plaintiffs also take into account other parameters such as time, effort, money and emotional distress associated with the legal process. But the probability of prevailing as well as the loss suffered are two of the major factors that directly impact on victims' incentives to bring claims. The rules of civil procedure directly affect the likelihood of the plaintiff prevailing as well as the courts' accuracy in assessing and awarding the damages suffered by the victim.

A number of characteristics found in the U.S. tort litigation system encourage parties to file lawsuits.[612] In contrast, the rules of civil procedure in force in most

[610] See Kip Viscusi, REGULATION THROUGH LITIGATION, AEI Brookings Joint Centre for Regulatory Studies, AEI Press, 1-22 (2002) noting that regulation through private litigation is an American phenomenon.

[611] The result of multiplying the probability of success and the amount of the damage award is the expected value of litigation. If the expected value of the trial is higher than the litigation costs faced by the plaintiff, the plaintiff will have incentives to pursue her claim. If the litigation costs are higher than the expected value of the trial, the victim will decide not to pursue her legal claim. When some assumptions are relaxed and court errors or judgment proof problems are introduced, these results might be modified. See Steven Shavell, FOUNDATIONS OF ECONOMIC ANALYSIS OF LAW, Belknap Press of Harvard University Press, 389-417 (2004).

[612] See the European Commission Green Paper: Access of consumers to justice and the settlement of consumer disputes in the Single market, COM/93/576FINAL, November 16, 1993, 56 (1993). Available at

European member states contain numerous disincentives for plaintiffs, particularly in product liability cases.[613] These include plaintiffs' access to courts, the role of juries in determining liability awards, the attorney compensation system, the distribution of litigation costs among the parties, the potential damage awards, the availability of punitive damages, and the availability of plaintiffs' class actions.

3.1 Jury v. judge

An important difference between civil procedure laws in Europe and the United States is the use of juries in civil cases and hence in deciding liability.

Tort trials in the United States might be decided by a jury formed between 6 and 12 citizens randomly selected to hear a particular case.[614] In cases with a jury, the judge who supervises the trial generally decides questions of law while the jury decides questions of fact.

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http://europa.eu/legislation_summaries/other/l32023_en.htm considering that the situation of product liability in Europe is one of "total underdevelopment". See also Joan T. Schmit, Factors Likely to Influence Tort Litigation in the European Union, The Geneva Papers 31, 304–313, 306 (2006). Similarly, see also Susan Narita, Product Liability Claims in Europe, Swiss Reinsurance Company, Zurich, 35 (1996).

[613] Lucille M. Ponte, Guilt By Association In United States Products Liability Cases: Are The European Community And Japan Likely To Develop Similar Cause-In-Fact Approaches To Defendant Identification?, 15 Loy. L.A. Int'l & Comp. L.J. 629, 657 (1993). See also Susan Narita, Product Liability Claims in Europe, Swiss Reinsurance Company, Zurich, 6 (1996). For an analysis comparing the development of the US and European system see Michael Faure and Ton Hartlief, Toward an expanding enterprise liability in Europe? How to analyze the scope of liability of industrial operators and their insurers, Maastricht Journal of European and Comparative Law, vol. 3, num 3, 235-270, 264-265 (1996). See also Lawrence C. Mann and Peter R. Rodrigues, The European Directive on PL: the promise or progress?, 18 Ga. J. Int'l & Comp. L. 391, 410 (1988).

[614] See Field, Richard H., Kaplan, Benjamin and Clemont, Kevin M., CIVIL PROCEDURE, MATERIALS FOR A BASIC COURSE, 8th ed., 132-134, Foundation Press Thomson Reuters (2003). See also, on jury size, Stephan Landsman, Civil Jury in American, The Law and Contemporary Problems 62: 285, 290-292 (1999)..

European courts do not employ juries for tort suits in either the civil law or the common law states.[615] Civil suits are conducted before the judge[616] and parties exchange and discuss documents, procedural rulings are made, evidence is introduced and testimony is taken until the case is adjudicated.[617] The decision of whether damages should be awarded and if so, in what amount are determined by judges or by tribunals composed by professional judges, depending on the case.[618] Consequently, rules of evidence in Europe can be less sophisticated than in the United States given that there is no need to protect juries against inadmissible evidence.[619]

The sympathy of consumer-jurors for injured victims of product-related accidents is potentially one of the biggest impacts of the role of jurors in liability cases given that they may tend to impose liability influenced by the circumstances of the case by the parties' asymmetry in the specific case.[620] Evidence suggests that because of cognitive and affective elements of the litigation process, the jurors' sympathy towards injured plaintiffs has been crucial when holding defendants liable as well as when determining

[615] Alfred E. Mottur, The European Product Liability Directive: A Comparison With U.S. Law, An Analysis Of Its Impact On Trade, And A Recommendation For Reform So As To Accomplish Harmonization And Consumer Protection, 25 Law & Pol'y Int'l Bus. 983, 1006 (1994).
[616] Susan Narita, Product Liability Claims in Europe, Swiss Reinsurance Company, Zurich, 35 (1996) noting that this contrasts with the role of juries in U.S. civil cases, among them, product liability cases.
[617] This contrasts with the common law process that has been very influenced by the existence of jury trials in civil procedures. Hein Kotz, Civil Justice Systems In Europe And The United States, 13 Duke J. Comp. & Int'l L. 61, 72 (2003).
[618] Juries are unknown in civil suits but some European member states have recently introduced juries in certain type of criminal offenses. See for example, the Spanish Ley Orgánica 5/1995, de 22 mayo regulating juries in criminal cases. See also Sandra N. Hurd & Frances E. Zollars, Product Liability in the European Community: Implications for United States Business, 31 Am. Bus. L.J. 245, 255(1993).
[619] Under certain circumstances, even hearsay evidence is admissible in some member states. See Patrick Thieffry, Philip Van Doorn and Simon Lowe, Strict Product Liability in the EEC: Implementation, Practice and Impact on U.S. Manufacturers of Directive 85/374, 25 Tort & Insurance Law Journal 65, 89 (1989-1990).
[620] William R. Darden, James B. DeConinck, Barry J. Babin and Mitch Griffin, The role of consumer sympathy in product liability suits. An experimental investigation of loose coupling, Journal of business research 22, 65 – 89 (1991). See also Erik Stenberg, Swiss Reinsurance, PL for US exports 01/99, 22. This article can be found in www.swissre.com.

the level of jury awards.[621] The disproportionate damage awards often awarded by juries,[622] contribute to the often perceived unpredictability of the liability system.[623]

Thus, the pro-plaintiff approach often adopted by juries, manifested by their inclination to holding tortfeasors liable for the harm suffered by the victims as well as by their determination of damage awards, directly impact on the decision of an injured victim to pursue her legal claim.[624]

3.2 Pre-trial discovery

Another significant difference between U.S. and European procedural rules that affect the outcome of liability cases is the rules of discovery.[625] Pretrial discovery procedures in the U.S. require parties to make available to the other party, before the trial, information and details they request regarding their legal defense or relevant for the parties' interests

[621] See Kaplan, Martin F., and Kemmerick, G., Juror Judgment as Information Integration: Combining Evidential and Nonevidential Information, J. Personality Social Psychol. 30(1974): 493-499. For examples of the relationship between jurors' and the level of damage awards see Andrew Carl Spacone, The Emergence of Strict Liability: A Historical Perspective and Other Considerations, Including Senate 100. J. Products Liability 8 (1985): l-40 and Jim Thomas, Justice as Interaction: Louse Coupling and Mediations in the Adversary Process. Symbolic Interaction 6 (2): 243-277 (1983).

[622] Some evidence suggests that the more financially sound defendants are, the higher the product liability award is and hence the higher product liability exposure defendant has. See Judith C. Glasscock, Emptying the Deep Pockets in Mass Markets. St. Mary's Law J. 18 (1987): 977-1017 and Andrew Carl Spacone, The Emergence of Strict Liability: A Historical Perspective and Other Considerations, Including Senate 100. J. Products Liability 8 (1985): l-40.

[623] Alberto Cavaliere, Product Liability in the European Union: Compensation and Deterrence Issues, European Journal of Law and Economics, 18: 299–318, 307 (2004).

[624] Juries may be more easily influenced, and hence inclined to award damages, by the impact caused by having an injured victim before them, especially in cases where the defendant is a corporation. See William R. Darden, James B. DeConinck, Barry J. Babin and Mitch Griffin, The role of consumer sympathy in product liability suits. An experimental investigation of loose coupling, Journal of business research 22, 65 - 89 (1991).

[625] See Susan Narita, Product Liability Claims in Europe, Swiss Reinsurance Company, Zurich, 35 (1996) noting the effect on product liability claims of allowing mandatory discovery in U.S. product liability cases and banning it the different European product liability court rules of the different member states.

at trial.[626] Hence, U.S. plaintiffs can often obtain from manufacturers or sellers important evidence, in the form of documents, depositions and interrogatories.[627] The material requested must be necessary and admissible evidence,[628] and its production is facilitated through the threat of court sanctions.[629]

In contrast to the U.S. system most European civil procedure laws limit significantly or do not allow plaintiffs' discovery.[630] As a result, European plaintiffs face great difficulty in obtaining the necessary technical data upon which their cases are based.[631] It is for the party who alleges the facts of a case to prove them and this is generally done by the production of evidence in written documents.[632] Consequently, the limitation of discovery reduces the amount of information plaintiffs may have available regarding the circumstances of the product and hence the causes of the product accident, and makes it more difficult for the plaintiff to prove the prime facie elements of a product liability case -- defect, harm and a causal relationship between them.[633]

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[626] See Field, Richard H., Kaplan, Benjamin and Clemont, Kevin M., CIVIL PROCEDURE, MATERIALS FOR A BASIC COURSE, 8th ed., 70, Foundation Press Thomson Reuters (2003) noting that the main motive of pretrial discovery is avoiding the trial from being a "drama of surprises."

[627] Patrick Thieffry, Philip Van Doorn and Simon Lowe, Strict Product Liability in the EEC: Implementation, Practice and Impact on U.S. Manufacturers of Directive 85/374, 25 Tort & Insurance Law Journal 65, 88-89 (1989-1990). See also Erik Stenberg, Swiss Reinsurance, PL for US exports 01/99, 22. This article can be found in www.swissre.com

[628] See Field, Richard H., Kaplan, Benjamin and Clemont, Kevin M., CIVIL PROCEDURE, MATERIALS FOR A BASIC COURSE, 8th ed., 69-75, Foundation Press Thomson Reuters (2003).

[629] See Field, Richard H., Kaplan, Benjamin and Clemont, Kevin M., CIVIL PROCEDURE, MATERIALS FOR A BASIC COURSE, 8th ed., 69-75, Foundation Press Thomson Reuters (2003).

[630] Joan T. Schmit, Factors Likely to Influence Tort Litigation in the European Union, The Geneva Papers 31, 304–313, 310 (2006) and Sandra N. Hurd and Frances E. Zollers, Product Liability in the European Community: Implications for United States Business, 31 American Business Law Journal 245, 254 (1993).

[631] Alfred E. Mottur, The European Product Liability Directive: A Comparison With U.S. Law, An Analysis Of Its Impact On Trade, And A Recommendation For Reform So As To Accomplish Harmonization And Consumer Protection, 25 Law & Pol'y Int'l Bus. 983, 1005 (1994)

[632] Patrick Thieffry, Philip Van Doorn and Simon Lowe, Strict Product Liability in the EEC: Implementation, Practice and Impact on U.S. Manufacturers of Directive 85/374, 25 Tort & Insurance Law Journal 65, 88-89 (1989-1990).

[633] Sandra N. Hurd and Frances E. Zollers, Product Liability in the European Community: Implications for United States Business, 31 American Business Law Journal 245, 254 (1993).

As a result, European plaintiffs have are harder time meeting their burden of proof in product liability cases and, hence, they have lower incentives to pursue such claims to begin with.[634]

3.3 The attorney's compensation scheme: Contingency v. hourly fee attorney compensation

Access to justice for consumers in Europe and in the United States is also significantly different when it comes to representation.[635] One reason for this is that the compensation of attorneys in each system is governed by different rules: While in the United States, attorneys may be paid on a contingency fee basis; their European counterparts in most EU member states[636] are compensated by the hour.[637] Under contingency fees arrangements, lawyers are paid for their services only if the plaintiff is successful, and the amount due depends on the size of the award.[638] In contrast, under

[634] Lucille M. Ponte, Guilt By Association In United States Products Liability Cases: Are The European Community And Japan Likely To Develop Similar Cause-In-Fact Approaches To Defendant Identification?, 15 Loy. L.A. Int'l & Comp. L.J. 629, 657-658 (1993).
[635] Alfred E. Mottur, The European Product Liability Directive: A Comparison With U.S. Law, An Analysis Of Its Impact On Trade, And A Recommendation For Reform So As To Accomplish Harmonization And Consumer Protection, 25 Law & Pol'y Int'l Bus. 983, 1005 (1994) noting that contingency fees agreements are a great financial incentive for attorneys to pursue promising cases.
[636] Contingency fees have been permissible in Ireland and Scotland. See Christopher Hodges, Competition Enforcement, Regulation and civil justice: what is the case?, Common Market Law Review 43: 1381-1407, 1397 (2006).
[637] Joan T. Schmit, Factors Likely to Influence Tort Litigation in the European Union, The Geneva Papers 31, 304–313, 308 (2006) and Alfred E. Mottur, The European Product Liability Directive: A Comparison With U.S. Law, An Analysis Of Its Impact On Trade, And A Recommendation For Reform So As To Accomplish Harmonization And Consumer Protection, 25 Law & Pol'y Int'l Bus. 983, 1005 (1994) for an analysis of the impact of contingency fees agreements on product liability litigation in Europe. See also Susan Narita, Product Liability Claims in Europe, Swiss Reinsurance Company, Zurich, 35 (1996) noting that only the U.K allows "conditional fee arrangement" with solicitors.
[638] This kind of arrangement and the possibility for U.S. attorneys to advertise their services make it easier for consumers to have access to compensation though it can result in an excessive amount of litigation. N. Rickman, Contingent fees and litigation settlement, International Review of Law and Economics 19: 295–317 (1999). See also Joachim Zekoll, American Law in a Time of Global Interdependence: U.S. National Reports to the XVIth International Congress of Comparative Law: Section II Liability for Defective Products and Services, 50 Am. J. Comp. L. 121, 147 (2002).

per-hour compensation systems attorneys are compensated at an hourly rate regardless of the outcome of the lawsuit. Hence, a losing client must compensate the attorney for the job done under an hourly fee compensation system but not under a contingency fee structure (although the losing client paying contingency fees may still be responsible for paying the attorney's expenses).

The underlying economic justification of contingency fee compensation systems is that it provides an efficient means of financing litigation in many cases.[639] Its risk sharing component ensures that some cases that would not otherwise reach the courts are able to be litigated or settled.[640] Without such a tool, victims of product–related accidents bear all the risk involved in litigation and this may undermine the financial incentives for them to pursue their cases.

Both systems -- contingency fee or per-hour compensation -- present advantages and disadvantages, but the major effect of attorney compensation in Europe is on the amount of cases litigated, the number of lawsuits settled prior to trial, and the level of damages awarded.[641] Contingency fees may encourage victims to bring suits lacking merit, and may also encourage defendants to settle even in cases lacking merit.[642] Additionally, contingency fees give lawyers incentives to encourage victims to pursue claims as well as to negotiate favorable settlements given that they will receive a share of the settlement award. In contrast, the lack of contingency fees in Europe prevents both small firms and individuals with limited financial resources from bringing potentially

[639] Joachim Zekoll, American Law in a Time of Global Interdependence: U.S. National Reports To The XVIth International Congress Of Comparative Law: Section II Liability for Defective Products and Services, 50 Am. J. Comp. L. 121, 147 (2002).
[640] Given that the attorney's compensation is subject in certain degree to the success of the plaintiff's claim.
[641] Nuno Garoupa and Fernando Gomez-Pomar, Cashing by the hour: why large law firms prefer hourly fees over contingent fees (2006). This article is available at: http://works.bepress.com/nunogaroupa/2. See also N. Rickman, Contingent fees and litigation settlement, International Review of Law and Economics 19: 295–317 (1999).
[642] Sandra N. Hurd and Frances E. Zollers, Product Liability in the European Community: Implications for United States Business, 31 American Business Law Journal 245, 254 (1993) and Joachim Zekoll, American Law in a Time of Global Interdependence: U.S. National Reports To The XVIth International Congress Of Comparative Law: Section II Liability for Defective Products and Services, 50 Am. J. Comp. L. 121, 147 (2002).

strong product liability cases because of their impossibility of affording their per-hour lawyers' fees.[643] As a result, fewer product liability cases reach courts.

3.4 Availability of legal assistance

An additional aspect that impacts on the incentives and possibility of injured victims to bring their product liability claims is the availability of legal assistance.

Improving consumer access to justice and providing legal assistance enhances the performance of the tort system as a deterrent and compensation mechanism given that litigation would increase and hence product accidents would be optimally deterred and injured victims would be able to access to the compensation they would be entitled to.[644]

The cost of legal defense is significant such that for each Euro or dollar that a defendant pays in compensation, a significant amount is devoted to paying the legal services necessary for the process.[645] When the cost of legal services, the uncertainty about the outcome of the case and the amount of damages -- and hence compensation -- claimed are jointly considered, victims may not have incentives to pursue their legal

[643] Jean C. Buzby and Paul D. Frenzen, Food safety and product liability, 24 Food policy, 637-651, 647 (1999) and Sandra N. Hurd and Frances E. Zollers, Product Liability in the European Community: Implications for United States Business, 31 American Business Law Journal 245, 254 (1993).

[644] See the European Commission Green Paper: Access of consumers to justice and the settlement of consumer disputes in the Single market, COM/93/576FINAL, November 16, 1993, 56 (1993) available at http://europa.eu/legislation_summaries/other/l32023_en.htm, noting the need to facilitate consumers' access to justice in order to enhance deterrence of product-related accidents. See also Alberto Cavaliere, Product Liability in the European Union: Compensation and Deterrence Issues, European Journal of Law and Economics, 18: 299–318, 309 (2004).

[645] There are no studies in Europe regarding the proportion that legal costs represent with respect to the damage award. For the U.S., see TILLINGHAST-TOWERS PERRIN, U.S. TORT COSTS: 2003 UPDATE: TRENDS AND FINDINGS ON THE COSTS OF THE U.S. TORT SYSTEM 17 (2003) and TOWERS PERRIN, 2008 UPDATE ON U.S. TORT COST TRENDS (2008) finding that plaintiffs receive 46 cents for each dollar the defendant pays as victim's compensation. These studies have not been exempt from debate. See for Economic Policy Institute (EPI), responding and questioning the results of the Towers Perrin report on the costs of tort litigation during 2005. The document is available at http://www.cttriallawyers.org/_docs/public/EPI_FrivolousCaseTortLawChange_summary.pdf. See also http://www.epi.org/publications/entry/bp157/

claim. In such cases, the availability of legal aid is crucial to ensure the victim's access to justice[646]

3.5 The distribution of litigation costs between litigating parties: the American v. the British rule

Another aspect that might explain the different volume of product liability cases in the United States and Europe is the distribution of litigation costs among the parties involved in the litigation.[647]

Under the American rule, every party bears its litigation costs regardless of the outcome of the case. So under the American rule a plaintiff will not be liable for the defendant's legal costs in case of an unsuccessful claim.[648] In contrast, in most European countries, the litigation costs are allocated under the British rule -- also called the loser pays rule -- which provides that a successful plaintiff may recover all or at least part of the legal costs from the losing defendant.[649] Even though the British rule is in force in European member states, the final amount of costs charged to him may vary from country to country.[650]

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[646] The European Commission's interest in increasing the access justice has led member states to review their domestic laws regarding funding of litigation. See http://europa.eu.int/comm/consumers/redress/acc_just/indez_en.htm. See also Geraint Howells, COMPARATIVE PRODUCTS LIABILITY, 2 (Darmouth publishing Company Limited, 1993).

[647] Joan T. Schmit, Factors Likely to Influence Tort Litigation in the European Union, The Geneva Papers 31, 304–313, 307 (2006).

[648] See R. Revesz and Lewis A. Kornhauser, Multi-Defendant Settlements: The Impact of Joint and Several Liability, New York University C.V. Starr Center for Applied Economics Working Paper # 92-37 (1992).

[649] Hence, European plaintiffs face the risk of paying the legal fees of the other party in the lawsuit. See Lucille M. Ponte, Guilt By Association In United States Products Liability Cases: Are The European Community And Japan Likely To Develop Similar Cause-In-Fact Approaches To Defendant Identification?, 15 Loy. L.A. Int'l & Comp. L.J. 629, 658 (1993). See also Susan Narita, Product Liability Claims in Europe, Swiss Reinsurance Company, Zurich, 38 (1996).

[650] Alberto Cavaliere, Product Liability in the European Union: Compensation and Deterrence Issues, European Journal of Law and Economics, 18: 299-318, 308 (2004).

One of the arguments supporting the use of the British rule is the fact that the probability of having to bear the legal costs of the other party is an important deterrent element against frivolous lawsuits.[651] One of the downsides of the British rule is that it puts a strong burden on low income victims who may not be able to afford the expected litigation costs of both parties in case the claim is unsuccessful.[652] There is not much empirical literature on the impact of the different rules of distribution of litigation costs among parties on the litigation rate[653] but some tendencies can be expected.

In product liability cases, the impact of the British rule is very important in terms of deterring claims where injured victims do not have an important certainty of prevailing because some defendants, especially corporate defendants, might have the ability and resources to make litigation significantly expensive, especially when product information is relatively complex.[654] Further, some defendants in product liability cases are defendants in several cases and might have several product liability lawsuits for the same or different products while consumers are typically parties in a single lawsuit and therefore litigation becomes so risky that they will be interested in being certain they will win before filing the claim. Cost shifting rules such as the British rule are said to increase consumers' risk aversion concerning litigation.[655]

Consequently, under the British rule in force in most European member states, injured victims will have lower incentives for bringing product lawsuits and in contrast, under the American rule there might be a higher level of claims.[656] So the distribution of

[651] Steven Shavell, FOUNDATIONS OF ECONOMIC ANALYSIS OF LAW, Belknap Press of Harvard University Press, 389-415 (2004).
[652] Joan T. Schmit, Factors Likely to Influence Tort Litigation in the European Union, The Geneva Papers 31, 304–313, 307 (2006).
[653] Stephen B. Presser, How should the Law of Products Liability be Harmonized? What Americans Can Learn from Europeans, Center for Legal Policy at the Manhattan Institute (2002).
[654] Sandra N. Hurd and Frances E. Zollers, Product Liability in the European Community: Implications for United States Business, 31 American Business Law Journal 245, 254 (1993).
[655] Alberto Cavaliere, Product Liability in the European Union: Compensation and Deterrence Issues, European Journal of Law and Economics, 18: 299–318, 309 (2004).
[656] Steven Shavell, Suit and settlement v. trial: a theoretical analysis under alternative methods for the allocation of legal costs, 11 Journal of Legal Studies 1, 55-81 (1982).

the litigation costs might be an additional factor that explains the different trends in product liability litigation in Europe and the United States.

3.6 Damage awards

An additional factor that contributes to explain the lower level of product liability cases in Europe when compared with the United States is the level of damage awards.[657] Damage awards in Europe have been significantly lower than those in the United States.[658] This difference may be partially due to the generally lower salary levels and health care costs in Europe[659] as well as to use of judges rather than potentially more plaintiff-friendly juries.[660] But other factors affect the difference in damage awards as well.

Compensation for damages generally includes three different kinds of harms: economic harm, non-economic (personal or material) harm and punitive damages.[661] Economic damages are generally calculated in a similar way in Europe and in the United

[657] And might also be due to the low level of successful damage claims. But there is little empirical evidence available. See Christopher Hodges, Competition Enforcement, Regulation and civil justice: what is the case?, Common Market Law Review 43: 1381-1407, 1397 (2006).

[658] Patrick S. Atiyah, Tort law and the alternatives: some Anglo-American comparisons, 6 Duke Law Journal 1002–1044 (1987) for a comparison of the U.S. and the English legal systems. Atiyah found that U.S. plaintiffs were more likely to litigate, prevail in court and receive generous compensation. Given the higher expected value of the lawsuit in the U.S., victims have higher incentives to litigate and hence the aggregate level of litigation in tort -- and specifically in product liability cases -- is higher in the U.S. than in Europe.

[659] Sandra N. Hurd and Frances E. Zollers, Product Liability in the European Community: Implications for United States Business, 31 American Business Law Journal 245, 255 (1993) presenting the reasons that would explain that the adoption of a strict product liability rule in Europe would not change the different level of damage awards in Europe compared with the U.S.

[660] Lucille M. Ponte, Guilt By Association In United States Products Liability Cases: Are The European Community And Japan Likely To Develop Similar Cause-In-Fact Approaches To Defendant Identification?, 15 Loy. L.A. Int'l & Comp. L.J. 629, 658 (1993).

[661] See Joan T. Schmit, Factors Likely to Influence Tort Litigation in the European Union, The Geneva Papers 31, 304–313, 310 (2006). Punitive damages, as will be explained below, are not available in Europe.

States.[662] In Europe, however, they are typically limited to compensation for lost wages and medical expenses,[663] and the latter is less relevant than it is in the United States, given the European social welfare and health care systems.[664] Non-economic damages are sometimes not allowed in European legal systems[665] and when available, they often do not include the same damage categories that are included in the United States (for example pain and suffering[666]). Even when European systems include these non-economic damage categories, they are usually very low amounts[667] or are calculated according to a previously determined scale that does not necessarily reflect the exact amount of non-economic damages suffered by the injured victim.[668]

The last kind of damages, punitive damages is not available in most European legal systems.[669]

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[662] See 2000 Current Award Trends in Personal Injury, LRP Publications, Jury Verdict Research(R) Series 52 (2000) presenting results in damage awards in the U.S. and noting that the level of compensatory awards remained relatively stable between 1993 and 1997 and since then and until 2000 has more than tripled.

[663] Medical costs in the U.S. are mostly borne by private insurance companies. See Lucille M. Ponte, Guilt By Association In United States Products Liability Cases: Are The European Community And Japan Likely To Develop Similar Cause-In-Fact Approaches To Defendant Identification?, 15 Loy. L.A. Int'l & Comp. L.J. 629 (1993).

[664] Lucille M. Ponte, Guilt By Association In United States Products Liability Cases: Are The European Community And Japan Likely To Develop Similar Cause-In-Fact Approaches To Defendant Identification?, 15 Loy. L.A. Int'l & Comp. L.J. 629, 658 (1993).

[665] Sandra N. Hurd and Frances E. Zollers, Product Liability in the European Community: Implications for United States Business, 31 American Business Law Journal 245, 255 (1993)

[666] In some European countries recovery for pain and suffering is allowed but very limited. Alfred E. Mottur, The European Product Liability Directive: A Comparison With U.S. Law, An Analysis Of Its Impact On Trade, And A Recommendation For Reform So As To Accomplish Harmonization And Consumer Protection, 25 Law & Pol'y Int'l Bus. 983, 1005-1006 (1994).

[667] See Andrew C. Spacone, Strict Liability in the European Union - Not a United States Analog, 5 Roger Williams U. L. Rev. 341, 370 (2000) noting that the level of damages awarded in Europe often do not reflect the actual harm suffered by the victim and arguing that this factor deters injured victims from pursuing litigation. See also Sandra N. Hurd and Frances E. Zollers, Product Liability in the European Community: Implications for United States Business, 31 American Business Law Journal 245, 255 (1993) noting the main differences between the European and the U.S. product liability systems.

[668] See, for example, in Spain, the Real Decreto Legislativo 8/2004, de 29 de octubre, por el que se aprueba el texto refundido de la Ley sobre responsabilidad civil y seguro en la circulación de vehículos a motor (BOE núm. 267, de 5.11.2004)
available at http://www.boe.es/boe/dias/2004/11/05/pdfs/A36662-36695.pdf and see also Munich Re., Personal Inuuries and medical malpractice, available at http://www.munichre.com explaining the different compensation mechanisms for personal injuries in Europe.

[669] Up to today, Ireland is the only European member state that allows punitive damages in product cases. Some other member states are considering their introduction. See Stephen B. Presser, How should the Law of Products Liability be Harmonized? What Americans Can Learn from Europeans, Center for Legal Policy at the Manhattan Institute (2002). See also Geraint G. Howells, The relationship between product liability

Punitive damages are set not based on injury but on a calculation of the amount sufficient to punish the defendant for wrongful conduct and on deterring such conduct in the future.[670] Given that not all injured victims are compensated, but only those who are filing claims and prevailing in their legal process, economic theory often views punitive damages as contributing to covering the social cost of accidents.[671]

The use of punitive damages in product liability cases is not exempt from debate. Some view punitive damages as necessary whenever a defendant has been indifferent to public safety so that such behavior is punished and deterred.[672] Consumer protection is often considered an issue important enough to justify the harshness of punitive damages. Others, on the contrary, consider that the use of punitive damages is inappropriate in product liability cases unless the defendant has committed an intentional tort. Under this view, traditional tort instruments are sufficient to provide remedies to victims of accidents caused by defective products.[673]

This is not the place to discuss the adequacy of the use of punitive damages in product liability cases. However, what is important to note is that the unavailability of punitive damages and the use of compensatory damages alone has an effect on the incentives injured victims have to pursue their product liability claims.

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and product safety – understanding a necessary element in the European Product Liability through a comparison with the U.S. position, 39 Washburn L. J. 305, 307-308 (2000). See also J. Hersch, and W. Viscusi, Punitive damages: How judges and juries perform, Journal of Legal Studies 33: 1–36 (2004).

[670] See Meghan A. Crowley, From Punishment to Annihilation: Engle v. R.J. Reynolds Tobacco Co. – No More Butts – Punitive Damages Have Gone Too Far, 34 Loy. L.A. L. Rev. 1513, 1514 (2001) noting that punitive damages serve the same purpose as fines and penalties as well as have a specific deterrence factor of general deterrence.

[671] M. A. Polinsky & Steven Shavell, Punitive Damages: An Economic Analysis, 111 Harvard Law Review 4, 869-962 (1998).

[672] David Owen, Punitive Damages in Products Liability Litigation, 74 Mich. L. Rev. 1257, 1371 (1976) defending the use of punitive damages in product liability cases.

[673] John A. Fulton, Punitive Damages in Product liability Cases, 15 Forum 117, 132 (1979), against the use of punitive damages in product liability cases.

All of these factors result in lower damage awards in Europe than in the United States.[674] Because of the limitation on litigation and the level of damage awarded, producers' exposure to liability is more predictable[675] and significantly more limited in Europe than in the United States.[676]

3.7 Absence of class actions

Another factor that affects the individuals' incentives to bring a product liability lawsuit in Europe is the unavailability of class actions in most European legal systems.[677]

It is not uncommon that defective products cause relatively small damages to many different individuals. When considering the amount of damage suffered and the cost of brining a lawsuit, each victim individually often lacks an incentive to bring a lawsuit, but if it were possible for all of them to bring the lawsuit collectively, as in a class action, then it would become worth it in the aggregate as well as individually. Hence, in situations like the one described – small and broadly distributed damages – class actions would have an important role in protecting injured victims.[678]

Class actions, as characterized in the United States, do not exist in the different European member states and are still a recent discussion and a rather exceptional

[674] Hans Claudius Taschner, Harmonization of product liability in the European Community, 34 Tex. Int'l L. J. 21 (1999) arguing that the lower level of damage awards as well as its predictability are important for their insurability, that does not become a problem in Europe.
[675] Joan T. Schmit, Factors Likely to Influence Tort Litigation in the European Union, The Geneva Papers 31, 304–313, 310 (2006).
[676] Sandra N. Hurd and Frances E. Zollers, Product Liability in the European Community: Implications for United States Business, 31 American Business Law Journal 245, 255 (1993).
[677] Lucille M. Ponte, Guilt By Association In United States Products Liability Cases: Are The European Community And Japan Likely To Develop Similar Cause-In-Fact Approaches To Defendant Identification?, 15 Loy. L.A. Int'l & Comp. L.J. 629, 658 (1993).
[678] Jose Maria Lopez Jimenez, Las Acciones Colectivas como medio de proteccion de los derechos e intereses de los consumidores, La Ley, number 6851, January, 2, 4 (2008).

phenomenon.[679] In order to improve access to justice for injured victims in this kind of case, European authorities have discussed with member states whether class actions should be introduced.[680] The characterization of these class actions would be remarkably different than the class actions brought in the United States by an aggregate of individuals injured by a tortfeasor.[681] The introduction of class actions at the European level is essentially structured around the role of consumer representative bodies to defend consumer interests.[682]

In recent years some European member states such as the Netherlands, Portugal, England and Wales, Spain and Sweden have adopted laws on collective actions.[683]

Spain, for example, does not have a specific trial process when class actions are involved. When transposing the European directives on different issues regarding the protection of the interests of consumers and users,[684] the Spanish legislature considered

[679] Patrick Thieffry, Philip Van Doorn and Simon Lowe, Strict Product Liability in the EEC: Implementation, Practice and Impact on U.S. Manufacturers of Directive 85/374, 25 Tort & Insurance Law Journal 65, 90 (1989-1990) and Alberto Cavaliere, Product Liability in the European Union: Compensation and Deterrence Issues, European Journal of Law and Economics, 18: 299–318, 308 (2004).

[680] The first approximation of the European Commission to this issue was in 1984, in the Memorandum from the Commission: Consumer Redress COM(84) 692, 12.12.1984 where it concluded that in light of the diversity of regulation across the member states it was not possible to propose binding harmonization regulation of collective actions at the European level. The jurisdiction of European authorities over the regulation of collective actions is still today a debated issue. For a strong criticism of the evolution of European legal systems towards welcoming actions similar to class actions see Christopher Hodges, Multi-party actions: A European Approach, 11 Duke J. Comp. & Int' L. 321 (2001). See Christopher Hodges, Competition Enforcement, Regulation and civil justice: what is the case?, Common Market Law Review 43: 1381-1407, 1395-96 (2006) warning that the introduction of class actions might result in the American litigation crisis and arguing that facilitating private litigation and hence private enforcement might not respond to the interest in achieving justice and might result in the involvement of private intermediaries with their own commercial interests such as the maximization of the litigation market volume and the size of individual cases.

[681] European Union and member states authorities want to avoid what is considered to be serious problems of the U.S. class action system in terms of encouraging excessive litigation, blackmail settlements and become high costs for business. See Lessons from USA, Australia and the UK, (European Justice Forum, 2006). Conclusions may be found in www.europeanjusticeforum.org

[682] These collective actions would be limited to injunctive relief rather than monetary claims. See Background Report: OECD Workshop on Consumer Dispute Resolution and Redress in the Global Marketplace, 31, Washington, DC (2005).

[683] Similar laws are being considered in Finland, Denmark, Norway, Ireland, Italy, and France. See Christopher Hodges, Competition Enforcement, Regulation and civil justice: what is the case?, Common Market Law Review 43: 1381-1407 (2006).

[684] Ley 39/2002, de 28 de octubre, de transposición al ordenamiento jurídico español de diversas directivas comunitarias en materia de protección de los intereses de los consumidores y usuarios, BOE núm. 259, de 28-10-2002, pp. 37922-37933 (http://www.boe.es/boe/dias/2002/10/29/pdfs/A37922-37933.pdf). See also

necessary to facilitate access to justice of small claims that might not be filed because of the litigation costs involved and established special norms for certain consumer associations and other legal entities that could represent the interests of a class in a lawsuit whenever damages are spread.[685] The availability of these collective actions, though, does not preclude injured victims from bringing their product liability claims individually.[686] These actions are similar, but not equivalent, to the U.S. class actions:[687] for example, under Spanish law, the damage must be suffered by consumers or users and not by other parties; the parties with standing to bring these actions are listed specifically in the law[688] and injured victims cannot opt out and claim damages individually and are further bound by the judgment regardless of whether they file any claim at all.[689]

These collective actions, in the European states where available, have not been extensively used because very often the consumer organizations that could be in the position to bring such claims have not had enough financial resources to afford the legal costs involved in the process (including, in case of a loss in court, bearing the other party's legal costs).[690]

Jose Maria Lopez Jimenez, Las Acciones Colectivas como medio de proteccion de los derechos e intereses de los consumidores, La Ley, number 6851, January, 2, 2008 at 6.

[685] See Law 1/2000 of January 7 of civil procedure (LEC), BOE núm. 7, de 8 de enero del 2000, pp. 575-728 (http://www.boe.es/boe/dias/2000/01/08/pdfs/A00575-00728.pdf).

[686] Under article 78.4 of the LEC it is possible to cumulate these individual claims to the collective one.

[687] Miguel Pasquau Liaño, El Nuevo marco para la proteccion judicial de los intereses colectivos y difusos de los consumidores y usuarios, 119-120, Consejería de Gobernación de la Junta de Andalucía, Sevilla (2003).

[688] Article 11 of Law 1/2000 of January 7 of civil procedure (LEC), BOE núm. 7, de 8 de enero del 2000, pp. 575-728 (http://www.boe.es/boe/dias/2000/01/08/pdfs/A00575-00728.pdf) establishes three different parties with standing to bring these collective actions: first, associations of consumers and users; second, injured consumers or users that create a group that represents the majority of the injured individuals and finally, legal entities with the goal of protecting consumers and users. In contrast, in the U.S. it is the court who appreciates whether the individual bringing the lawsuit has standing or not. P. Gutiérrez de Cabiedes and Hidalgo de Cabiedes, Comentario al art. 11 LEC, in AAVV, Comentarios a la Ley de Enjuiciamiento Civil, vol 1, 144 Aranzadi, Madrid (2001).

[689] See Articles 11 and 222.3 of the LEC and Jose Maria Lopez Jimenez, Las Acciones Colectivas como medio de proteccion de los derechos e intereses de los consumidores, La Ley, number 6851, January, 2, at 8-9, 15 (2008).

[690] See the Commission's Green Paper: Access of Consumers to Justice and the Settlement of Consumer Disputes in the Single Market COM(93) 576, November 16, 1993, 64 (1993). Available at http://europa.eu/legislation_summaries/other/l32023_en.htm

The unavailability of an efficient instrument to bring these collective or class actions has very likely affected the level of product liability cases litigated in Europe.[691]

3.8 Cultural differences regarding the incentives to litigate

Procedural rules are crucial for victims' incentives to pursue product liability claims. However, procedural factors alone may not explain the level of product liability litigation in Europe and hence the little use and effect of the strict product laibiliy regime introduced by the product liability directive.[692]

Cultural attitudes may have also had a crucial effect on the plaintiffs' incentives to pursue product liability claims under the product liability Directive,[693] as the cultural approach to litigation in Europe and in the United States appears to be remarkably different.[694] Of course, explaining cultural differences is difficult generally, and explaining different cultural approaches to litigation is especially difficult given the lack of empirical evidence on the issue.[695]

However, when looking at the overall models of addressing legal issues, one should not neglect the fact that there is a fundamental difference in the approach to legal issues and social changes between Europe and the United States. European countries tend

[691] However, this tendency could be changing. See infra. Hein Kotz, Civil Justice Systems In Europe And The United States, 13 Duke J. Comp. & Int'l L. 61, 74 (2003).
[692] Mark Mildred, Litigation Rules and Culture: The European Perspective, 23 N.Y.U. Rev. L. & Soc. Change 433, 442 (1997).
[693] John G. Fleming, Mass Torts, 42 Am. J. Comp. L. 507, 519 (1994) noting the different reliance in the judicial process between Europeans and north-Americans. See also James Henderson Jr., Aaron D. Twerski, What Europe, Japan, And Other Countries Can Learn From The New American Restatement of Products Liability, 34 Tex Int.'l L. J. 1, 2 (1999).
[694] Andrew C. Spacone, Strict Liability in the European Union - Not a United States Analog, 5 Roger Williams U. L. Rev. 341, 372-373 (2000).
[695] See Mary J. Davis, Individual And Institutional Responsibility: A Vision For Comparative Fault In Products Liability, 39 Vill. L. Rev. 281, 337-338 (1994). See also See also Andrew C. Spacone, Strict Liability in the European Union - Not a United States Analog, 5 Roger Williams U. L. Rev. 341 (2000).

to rely on legislation more than on litigation to bring about social change.[696] Indeed, Europeans appear to have a general attitude against litigation.[697] In contrast, the U.S. social system heavily relies on individual participation through the court system to seek redress and eventually bring about legal and social change.[698]

Europe has developed in-depth product regulations that reflect a commitment to regulation rather than litigation in this field.[699] This is not the place to discuss whether one of the approaches is optimal or better than the other.[700] In fact, both models contain elements of the other and are not as structurally differentiated as one would imagine from a theoretical perspective. While the extended European product regulatory body interacts with some amount of litigation, U.S. tortfeasors do not only take into consideration the expected liability they are exposed to but also product safety regulations.[701]

A factor that is very significant in Europe and that does not seem to have the same influence in the United States regarding the individuals' decision in pursuing their legal claims and seeking redress -- especially economic redress -- is the role of social insurance or of the welfare state as a whole, under which the state becomes a safety net for citizens

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[696] Sandra N. Hurd and Frances E. Zollers, Product Liability in the European Community: Implications for United States Business, 31 American Business Law Journal 245, 254 (1993).

[697] See Alfred E. Mottur, The European Product Liability Directive: A Comparison With U.S. Law, An Analysis Of Its Impact On Trade, And A Recommendation For Reform So As To Accomplish Harmonization And Consumer Protection, 25 Law & Pol'y Int'l Bus. 983, 1007 (1994).

[698] The different approach is manifested both in the pre-marketing and post-marketing phase of the product. See in general Thomas Lundmark the Restatement of Torts (Third) and The European Product Liability Directive, 5 D.C.L. J. Int'l L. & Prac. 239 (1996).

[699] For a comparative analysis of both systems see Frances E. Zollers, Sandra N. Hurd, Peter Shears, Product Safety In The United States And The European Community: A Comparative Approach, 17 Md. J. Int'l L. & Trade 177 (1993). See also Geraint G. Howells, The relationship between product liability and product safety – understanding a necessary element in the European Product Liability through a comparison with the U.S. position, 39 Washburn L. J. 305, 344-345 (2000).

[700] Either system, under certain circumstances, could be more efficient than the other. For example, on one side regulators do not generally have perfect risk information leading to inefficient regulation. On the other side, incentives to adopt care may be diluted when considering that injurers, despite of being exposed to litigation, might have bought insurance; might not be sued or might be judgment proof. Steven Shavell, A model of the optimal use of liability and safety regulation, Rand Journal of economics 15(2), 271-280 (1984).

[701] See also James T. O'Reilly and Nancy C. Code, PRODUCTS LIABILITY RESOURCE MANUAL: AN ATTORNEY'S GUIDE TO ANALYZING ISSUES, DEVELOPING STRATEGIES, AND WINNING CASES, Chicago, Ill.: American Bar Association, General Practice Section, 291 (1993) for an analysis on U.S. Consumer Product Safety standards.

who suffer economic problems.[702] As it is developed in Chapter 7, health and social security systems of the different member states offset a large amount of the cost of injuries,[703] which clearly has an impact in shaping the attitude of Europeans towards litigation that often is considered unnecessary.[704] Litigation in the United States, in some way, is like a surrogate for the European welfare state while European injured victims do not only have tort law as a source of compensation for product-related injuries but also public benefits provided by the state.

Procedural rules as well as cultural attitudes towards litigation contribute to explain the evolution of product liability and the impact of the Directive on the matter in Europe. However, these elements are essential parts of the European and the U.S. legal systems and largely do not provide explanations for the different levels of litigation related to product accidents as well as for the different effects resulting from the introduction of strict product liability regime.

The product liability directive and its liability standard do not seem to have contributed to overcome the procedural barriers faced by injured victims when bringing product liability claims. The idea that the adoption and implementation of the Directive, without any amendment of the rules of procedure would facilitate the enforcement of its rights was quite optimistic. In light of the failure of the product liability directive as a self-help remedy for victims, some amendments in procedural rules are being considered. If victims' access to justice is facilitated, the Europeans' cultural perception of the role of litigation might change in the near future.

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[702] See generally Thomas Wilhelmsson and Samuli Hurri, FROM DISSONANCE TO SENSE: WELFARE STATE EXPECTATIONS, PRIVATISATION AND PRIVATE LAW, 307, Ashgate Publishing (1999).
[703] S. Mark Mitchell, A Manufacturer's Duty to Warn in a Modern Day Tower of Babel, 29 Ga. J. Int'l & Comp. L. 573, 581 (2001).
[704] Andrew C. Spacone, Strict Liability in the European Union - Not a United States Analog, 5 Roger Williams U. L. Rev. 341, 372-373 (2000).

The product liability directive intended to facilitate victims' compensation[705] but this goal does not seem to have been achieved when its low impact in terms of product liability cases is considered.[706] Additional elements, subject of the following chapters, have also contributed to the limited impact of the adoption of the product liability directive in Europe and of its introduction of strict product liability.

[705] Christopher Hodges, Competition Enforcement, Regulation and civil justice: what is the case?, Common Market Law Review 43: 1381-1407, 1406 (2006). See also David G. Owen, The moral foundations of products liability law: toward first principles, 68 Notre Dame L. Rev. 427, 434 (1992-1993).
[706] Anita Bernstein, L'harmonie Dissonante: Strict Products Liability Attempted In The European Community, 31 Va. J. Int'l L. 673, 689-690 (1991). See also Table 6.1 in Chapter 6 showing the amount and evolution of product liability judgements in Spain.

CHAPTER 4

ECHOES OF NEGLIGENCE IN EUROPEAN PRODUCTS LIABILITY

An additional significant factor that might further help explain the different functioning and role of product liability in the United States and in Europe is the structure and content of the product liability directive itself. In particular, it may be that the Directive does not create a system of liability as strict as is purporeted or intended. There may also be issues of different interpretrations by the member states.[707] The adoption of the Directive's strict liability regime was justified on three different grounds: protect product users against any threat to life, health and property,[708] facilitating victims' compensation,[709] and ensuring fair apportionment of risks among the parties involved in product accidents. The latter justification was made in light of strict liability's effect of transferring costs of victims' harm to manufacturers, who are considered to be better able to spread these costs.[710] Based in these justifications, strict product liability was considered more efficient than any other alternative.[711]

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[707] See Duncan Fairgrieve and Geraint Howells, Rethinking Product Liability: A Missing Element in the European Commission's Third Review of the European Product Liability Directive, The modern law review, 70(6) 962-978 (2007) arguing that the European Commission should adopt a more active role in defining the scope of the product liability directive and the content of its provisions.

[708] However, the empirical studies on product safety are not convincing in concluding either way. See Thomas Lundmark The Restatement Of Torts (Third) And The European Product Liability Directive, 5 D.C.L. J. Int'l L. & Prac. 239, (1996). For a different perspective, see Jorg Finsinger & Jurgen Simon, An Economic Assessment of the EC Product Liability Directive and the Product Liability Law of the Federal Republic of Germany, in ESSAYS IN LAW AND ECONOMICS: CORPORATIONS, ACCIDENT PREVENTION AND COMPENSATION FOR LOSSES 185, 202-05 (Michael Faure & Roger van den Bergh eds., 1989).

[709] Strict liability constitutes a compensation system whereby potential tortfeasors insure potential victims and they spread their expected losses through product prices In order to adequately perform, risks must be known and quantifiable so that potential tortfeasors can asses their exposure and buy insurance, if necessary. James A. Henderson, Why Negligence Dominates Tort, 50 U.C.L.A. L. Rev. 377, 392 (2002). See in contrast, Michael G. Faure, Product Liability and Product Safety in Europe: Harmonization or Differentiation?, Kylos, vol 53, 467-508, 488, 491 (2000) arguing that the introduction of strict product liability in Europe was due to the result of the industry rent seeking instead of an instrument to increase economic welfare.

[710] A producer is generally considered to be in a better position than a consumer to obtain insurance for product-related losses because he can either self-insure or purchase insurance coverage. See Thomas

Negligence and strict liability are not separated by a sharp distinction but instead exist along a continuum with many shades.[712] The fact that the product liability directive imposes "liability without fault on the producer,"[713] however, suggests that the Commission intended to adopt a system that falls squarely on the side of strict liability.[714]

As already noted, the product liability directive is not the only regulation on product liability in Europe. Instead, it exists alongside domestic legislation on tort and contract law that are often applicable to product-related accidents as well.[715] The interaction of the Directrive with this domestic legislation as it is interpreted and implemented by domestic courts attenuates the Directive's strict liability regime.[716] In addition, the Directive itself contains elements of negligence that affect its practical implementation and impact.[717]

1. The legal costs of defining a legal regime: Negligence elements in the product liability directive

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Lundmark, The Restatement of Torts (Third) And The European Product Liability Directive, 5 D.C.L. J. Int'l L. & Prac. 239, 265 (1996).

[711] W. Kip Viscusi, REGULATING CONSUMER PRODUCT SAFETY, American Enterprise Institute for Public Policy Research, 10 (1984).

[712] Bernanrd A. Koch and Helmut Koziol (eds.) UNIFICATION OF TORT LAW: STRICT LIABILITY, 101 (The Hague; London; New York: Kluwer Law International, 2002), and William Powers, Jr., A Modest Proposal to Abandon Strict Products Liability, 1991 U. Ill. L. Rev. 639 (1991) arguing that the determination on whether to impose liability should be made on a case-by-case basis.

[713] See the Preamble of the product liability directive.

[714] However, Anita Bernstein in L'Harmonie Dissonante: Strict Products Liability Attempted in the European Community, 31 Va. J Int'l L. 673 (1991) analyses the possibility that the Directive was promulgated only to show the European Commission's political power.

[715] Alberto Cavaliere, Product Liability in the European Union: Compensation and Deterrence Issues, European Journal of Law and Economics, 18: 299–318, 304 (2004).

[716] Alberto Cavaliere, Product Liability in the European Union: Compensation and Deterrence Issues, European Journal of Law and Economics, 18: 299–318 (2004).

[717] Geraint Howells, COMPARATIVE PRODUCT LIABILITY, 311-22, Darmouth publishing Company Limited, (1993)distinguishing between strict product liability and negligence based liability and considerations supporting each.

The product liability directive clearly aimed at introducing and establishing a strict product liability regime in Europe. However, it contains elements that involve analyses of care and hence move the regime in the direction of negligence.[718] These are essentially three elements: (1) the crucial concept of defect, (2) the optional provisions regarding damage caps and the development risk defense, and (3) the definition of the scope of potential tortfeasors subject to the Directive's regime.

1.1 The negligence music of the consumer expectations test

Among the cornerstones of a product liability regime are the criteria on which liability will be imposed. These involve questions of whether all kinds of products are subject to the same liability regime, whether there are different kinds of defects and finally, whether the different product defects entail the same or different defectiveness standards.

If the liability regime established by the product liabiltiy directive were truly strict, as indended, liability would be imposed based only on a finding of causation of harm but this is far from the practice in the U.S. -- when strict product liability was in place -- or European product liability cases. Under the product liability directive, liability is conditioned to the existence of a defect in the product that caused harm.[719] Hence, the

[718] See Mathias Reimann, Liability for Defective Products at the Beginning of the Twenty-First Century: Emergence of a Worldwide Standard?, 51 Am. J. Comp. L. 751, 776-777 (2003) and Paul Burrows, Consumer Safety under Products Liability and Duty to Disclose, International Review of Law and Economics 12, 457-478, 463 (1992).

[719] In not differentiating between product defects the product liability directive resembles the Restatement Second. See Jane Stapleton, Bugs in Anglo-American products liability, 53 S. C. L. Rev. 1225, 1243, 1232 (2002). Additionally, the definition of defect included in the Directive is remarkably broad. In this sense, some argue that there is no remarkable difference between a strict liability for the damage caused by a product and liability for defect in the product under the Directive. See EUROPEAN CENTRE OF TORT AND INSURANCE LAW, UNIFICATION OF TORT LAW: STRICT LIABILITY (B.A. Koch and H. Kaziol eds.) Kluwer Law International, 381 (2002).

injured victim must prove not only causation but also defect. This starts to sound similar to liability under negligence.[720]

The efficiency and performance of strict liability and negligence often depend on the circumstances such as the information available when defining the required level of care, whether care is observable or not and the circumstances of enforcement.[721] A unique and uniform product liability regime for all products and all product accidents with a uniform liability rule might generate inefficiencies.[722]

In addition to these contextual parameters, the extent to which product liability will function as a strict liability regime or a negligence system hinges on the definition of defect. When taking a close look to the concept of defect, which is one of the pivotal concepts of the Directive, it seems less clear how strict the Directive's regime is.[723] As explained earlier, the Directive defines defective product as one which does not provide the safety a reasonable consumer is entitled to expect, taking all circumstances into account.[724] Even though this test is applied in the context of strict product liability, spelling out the reasoning of the test implies considerations[725] that bring the standard closer to negligence than to strict liability.[726]

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[720] See William Powers, Jr., A modest proposal to abandon strict products liability, 1991 U. Ill. L. Rev. 639, 653 (1991) arguing that the structure of product liability cases is negligence-based.

[721] For example, evidentiary difficulties inherent to negligence -- in terms of determining the standard of care and observing whether the tortfeasor has adopted the required level of care --might justify introducing strict liability as a way of enforcing reasonable care. See Mark A. Geistfeld, PRINCIPLES OF PRODUCTS LIABILITY, 24, Foundation Press, New York (2006). See also Franceso Silva and Alberto Cavaliere, The Economic Impact of Product Liability: lessons from the US and the EU Experience, in: Giampaolo Galli and Jacques Pelkmans (eds.), Regulatory Reform and Competitiveness in Europe, I, Horizontal Issues. Cheltenham: Edward Elgar, 292–323 (2000).

[722] Depending on the context, strict liability or negligence might perform more efficiently and hence will be more adequate. See Michael G. Faure, Product Liability and Product Safety in Europe: Harmonization or Differentiation?, Kylos, vol 53, 467-508, 489 (2000).

[723] See THE BOUNDARIES OF STRICT LIABILITY IN EUROPEAN TORT LAW, Franz Werro and Vernon Valentine Palmer, (Eds.), 437, Durham, N.C.: Carolina Academic Press (2004).

[724] Despite the defect issue being within strict product liability, some argue that in adopting this definition the European Commission signaled that it was endorsing negligence standards for design and warning cases.

[725] Dan B. Dobbs, THE LAW OF TORTS § 358, 987 (2000).

[726] William Powers, Jr., A modest proposal to abandon strict products liability, 1991 U. Ill. L. Rev. 639, 653 (1991). Some consider that a true strict liability regime for product defects would exist if the concept of defectiveness was based on for example, the consumer assessment -- or misperception -- of product risks

The consumer expectations test included in the product liability directive does not provide an independent objective standard against which to judge a product.[727] Concepts such as average consumer,[728] that is, the reference and relevant consumer the expectations of whom will determine the expectations the consumer in the case is entitled to have, or the concept of reasonable expectations of safety, which is often vague and difficult to specify, can result in courts[729] applying negligence considerations when defining the level of safety a consumer is entitled to expect[730] or implying defect

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regardless of the actual product's level of safety. See THE BOUNDARIES OF STRICT LIABILITY IN EUROPEAN TORT LAW, Franz Werro and Vernon Valentine Palmer, (ed.), 56-57, Durham, N.C.: Carolina Academic Press, (2004). See also Paul Burrows, Consumer Safety under Products Liability and Duty to Disclose, International Review of Law and Economics 12, 457-478, 463 (1992).

[727] In fact, the broad definition of defect in article 6 of the product laibility directive could result in deeming the product defective just by the fact of having caused harm. European Centre of Tort and Insurance Law, Unification of Tort Law: Strict Liability, 381 (B.A. Koch and H. Kaziol eds.) Kluwer Law International (2002).

[728] In light of the consumers' perspective adopted by the consumers' expectation test, many consider that it represents a pro-defendant solution given that there are limitations inherent to its successful application. Geraint G. Howells & Mark Mildred, Is European Products Liability More Protective Than The Restatement (Third) Of Torts: Products Liability? 65 Tenn. L. Rev. 985, 1025 (1998).

[729] In light of the negligence elements of the defectiveness tests some anticipated problems for courts to define standards of product design, for example. See Mary J. Davis, Individual And Institutional Responsibility: A Vision For Comparative Fault In Products Liability, 39 Vill. L. Rev. 281, 352 n.2 (1994). Regarding the difficulty of applying a strict liability standard in warning defect cases see generally James A. Henderson, Jr. & Aaron D. Twerski, Doctrinal Collapse in Products Liability: The Empty Shell of Failure to Warn, 65 N.Y.U. L. Rev. 265 (1990) advocating for the use of a negligence standard in failure-to-warn cases to mitigate confusion stemming from a strict liability standard.

[730] See Arsenio R.V. v. Cunitor, S.A. e Hiperbebé, Roma 40-Bebés, Spanish Supreme Court 25.6.96 (RJ 1996\4853; MP: Alfonso Barcalá y Trillo-Figueroa) where the court understood that both the plaintiff and the defendant should have noticed the manufacturing defect of the crib before using it and causing an accident on the plaintiff's baby resulting in death; also Transportes Miguel Aranda, S.L. v. Automoción Ramos, S.A. y Firestone, Court of Appeals of Badajoz 13.7.2002 (AC 2003\303; MP: Francisco Rubio Sánchez) where the court held that the plaintiffs had proved the negligence of the manufacturer for not having adopted the " required level of care." Another example is the judgment in the case Pescados Montabán, S.L. v. Autodistribución Iliberis, S.A., SAFE de Neumáticos Michelín e Iveco-Pegaso, S.A., of the Court of Appeals of Granada, of 211.2000 (AC 2000\266; MP: Antonio Gallo Erena) where the court held that the plaintiff had met the burden of proof of the prima facie case and further proved the manufacturer's negligence based on the evidence showing a breach of the level of due care.

whenever causation is difficult to prove[731] through the application of *res ipsa loquitur* arguments that clearly hinge on negligence.[732]

Further, the flexible content of consumer expectations often allows manufacturers to defend themselves by putting the blame on the consumers' conduct and alleging that victims were contributorily negligent by ignoring warnings or that the product was used in a way that was not a foreseeable.[733] Again, this analysis rings negligence bells more than sounding like strict liability.

Together with the expectations of consumers, the product defect is to be established on the basis of the presentation of the product and its foreseeable uses.[734] These elements seem to imply that judges perform a global evaluation of the product risks and benefits, as it would be done under a negligence system, which may also include the product price as a parameter indicating the level of safety of the product.[735]

Finally, the use of a unique test for defect does not seem to take into account the different potential risks presented by products and the different investments in care that parties have incentives to adopt depending on the liability rule in force.[736] When analyzing the different kinds of product defects in practice, court are hard pressed to avoid using negligence considerations when they reach questions about the definition and determination of design defects or about warnings and instructions. This is particularly so

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[731] See Isabel v. Lidl Supermercados, S.A., Sevilla Court of Appeals, 13.11.06 (AC 2007\978; MP: Conrado Gallardo Correa) and Francisco Javier F.S. v. Dokasde, S.A., Compañía Vinícola del Norte de España, S.A., N.D de Comunicaciones, S.L. y Orbis Fabri, S.A.), Court of Appeals of Barcelona, 30.6.00 (JUR 2000\305476; MP: Pablo Díez Noval) where both court of appeals presumed the existence of defect in cases were the victim was not found contributorily negligent and further presumed negligence based on the inability of the defendant of proving diligence.

[732] See Comunidad de Propietarios v. Tecal Miguel Prieto, S.L. y Cahispa, S.A. de Seguros Generales, Court of Appeals of Salamanca, 12.2.2004 (AC 2004\426; MP: Ildefonso García del Pozo) where the court understood the plaintiff proved the causal relation between the defendant's negligence and the harm suffered by the victim.

[733] Eleonora Rajneri, Interaction Between the European Directive on Product Liability and the Former Liability Regime in Italy, Global Jurist Topics: Vol. 4 : Iss. 1, Article 3 (2004).

[734] Article 6.2 of the product liability directive.

[735] See THE BOUNDARIES OF STRICT LIABILITY IN EUROPEAN TORT LAW, Franz Werro and Vernon Valentine Palmer, (Eds.) Durham, N.C.: Carolina Academic Press, 443 (2004).

[736] Jane Stapleton, Bugs in Anglo-American products liability, 53 S. C. L. Rev. 1225, 1243 (2002).

when referring to reasonable alternative design, foreseeable risks or the reasonable amount and kind of information required in the instructions or warnings.[737]

The discussion of whether the different product defects considered in practice should be treated under different product liability rules has not arisen in Europe because product defects are uniformly treated in the product liability directive. However, in light of the jurisprudential practice differentiating between product defects -- at least in Spanish courts -- the discussion regarding whether different product defects should be subject to different liability regimes or different tests for defect seems important.

Additionally, when focusing on the consumer expectations test and particularly on the level of safety a consumer is entitled to expect, some argue that the test should be applied for all kinds of product defects -- manufacturing, design, and warnings and instructions -- given that consumers can reasonably expect that product manufacturers will take reasonable care when designing and manufacturing products as well as warning about product risks.[738] When reasonable care considerations are introduced in the application of the consumer expectations test negligence is present in the defectiveness standard.[739]

The different liability regimes available under tort to regulate product accidents – strict liability and negligence – represent different ways of balancing the interests of consumers and product manufacturers.[740] For example, the transition from the Second to the Third Restatement with the resulting change of liability from strict product liability to negligence triggerd a discussion of whether the Second Restatement represented a pro-victim approach, with victims insured by product manufactures, while the Third

[737] Owen, David A., PRODUCTS LIABILITY LAW, 411, Thomson/West (2005).
[738] Mark A. Geistfeld, PRINCIPLES OF PRODUCT LIABILITY, 23-26 (2006). See also Richard W. Wright, The principles of product liability, 26 Rev. Litig. 1067, 1122 (2007).
[739] David G. Owen, Rethinking the Policies of Strict Products Liability, 33 Vand. L. Rev. 681, 706-07 (1980).
[740] See Geraint Howells, COMPARATIVE PRODUCT LIABILITY, 311-2,2 Darmouth publishing Company Limited, (1993)distinguishing between strict product liability and negligence based liability and considerations supporting each.

Restatement represented the opposite, a pro-manufacturer approach, by imposing negligence as the liability system for design and warning defect cases (leaving aside manufacturing defect cases, which were still subject to a strict liability rule).[741] This discussion regarding the implications of product liability rules in the approach adopted by the product liability system has not been addressed in Europe. In light of the sometimes negligence-like application of the Directive's liability regime, it would be advisable to deal with these questions.

1.2 Optional provisions

Another parameter that impacts on the strict liability nature of the product liability directive and hence its practical application is the possibility for member states to introduce optional provisions in their domestic transposition laws.[742] The first defense is the threshold limit of 500 euros under which injured victims may not seek compensation under the Directive. The second is a development risks defense[743] and finally, the third is the possibility of limiting damages to 70 million euros and hence of introducing a damage cap.

The limit of 500 euros excludes compensation for injured victims who suffer minor damages caused by defective products. The Directive's strict liability is limited, then, to the minimum threshold damage. For these minor damages injured victims are the residual bearers of the harm they suffer.[744] If liability were purely strict, all damages

[741] See Abed Awad, The concept of defect in American and English products liability discourse: despite strict liability linguistics, negligence is back with a vengeance!, 10 Pace Int'l L. Rev. 275, 357 (1998) arguing that the Restatement Third introduces a pro-manufacturer ultra-negligence liability regime.
[742] Alberto Cavaliere, Product Liability in the European Union: Compensation and Deterrence Issues, European Journal of Law and Economics, 18: 299–318, 301 (2004).
[743] Article 7 of the product liability directive.
[744] See Steven Shavell, ECONOMIC ANALYSIS OF ACCIDENT LAW, Cambridge, Mass.: Harvard University Press, 47 (1987).

caused by defective products would be internalized by tortfeasors regardless of their amount.[745] The limitation of damages above a certain amount introduces a limitation on the internalization of harm and hence on how strict the product liability regime is.

The second optional provision available to member states is the development-risk defense layed out in article 7 of the Directive. The development risk defense is a negligence-based defense[746] under which defendants can escape liability in cases where they can show that the state of scientific and technical knowledge at the time when they put the product into circulation was not such as to enable the existence of the defect to be discovered.[747] The inclusion of this defense protects firms' incentives to introduce new products in the market because if they cannot discover product defects in light of the state of scientific and technological knowledge, they will not be liable for the harm caused by their defective products that in these cases may be unpredictable.[748]

But the introduction of the development risk defense can also be seen as weakening the goal of strict liability.[749] By allowing the defense, the Directive tries to "square a circle," as Stapleton puts it,[750] because while using strict liability language, it provides protection to business for unforeseeable risks.[751] If the strict liability principles of risk spreading and of loss distribution are accepted, the inclusion of a development

[745] See Steven Shavell, ECONOMIC ANALYSIS OF ACCIDENT LAW, 47 , Harvard University Press, Cambridge (MA) (1987) and William Landes and Richard Posner, THE ECONOMIC STRUCTURE OF TORT LAW, 273-280, Harvard University Press, Cambridge (MA) (1987).
[746] Geraint Howells, COMPARATIVE PRODUCTS LIABILITY, 35, Darmouth publishing Company Limited, (1993).
[747] See European Commission v. United Kingdom, C-300/95 (1997) ECR I-2649, para 29. However, it is still not clear if the knowledge refers to the general existence of the defect or to the finding of the defect in particular products. See also THE BOUNDARIES OF STRICT LIABILITY IN EUROPEAN TORT LAW, Franz Werro and Vernon Valentine Palmer, (Eds.) Durham, N.C.: Carolina Academic Press, 43 (2004).
[748] Thomas Lundmark, The Restatement Of Torts (Third) And The European Product Liability Directive, 5 D.C.L. J. Int'l L. & Prac. 239, 255 (1996). See also Geraint G. Howells & Mark Mildred, Is European Products Liability More Protective Than The Restatement (Third) Of Torts: Products Liability?, 65 Tenn. L. Rev. 985, 986 (1998).
[749] By allowing product manufacturers to claims such defense the product liability directive went beyond the U.S. Restatements that do not include such defense. See Jane Stapleton, Bugs in Anglo-American products liability, 53 S. C. L. Rev. 1225, 1243, 1232 (2002).
[750] Jane Stapleton, Bugs in Anglo-American products liability, 53 S. C. L. Rev. 1225, 1231 (2002).
[751] This was a compromise demanded by the English Government of Margaret Thatcher. See Jane Stapleton, Bugs in Anglo-American products liability, 53 S. C. L. Rev. 1225, 1231 (2002).

risks defense is difficult to defend[752] given that it allows European courts to use a negligence-based risk utility test for design defects.[753] If this defense were applicable not only in design defect cases but also in manufacturing defects, the strict product liability alluded to in the Directive's preamble would be reduced largely to mere rhetoric.[754]

The importance of the negligence component of this defense depends on how it is interpreted.[755] If the defense is interpreted shield producers in cases where the defect was not reasonably foreseeable, it would result in a negligence-based regime. If, instead, the product manufacturer is liable for damages caused by defective products unless the defect was absolutely undiscoverable, the liability regime would be someplace in between a purely strict and a negligence based regime. In light of the Directive's failure to include guidance as to how the content of this defense is to be established, it is left for domestic courts to determine the state of scientific and technical knowledge available at the time the product was put into circulation.[756]

The interpretation, scope, and content of this defense is important to the question of how the Directive impacts on consumers' rights. It could either strengthen them through a strict liability regime or leave them largely as they were prior to the adoption of the Directive by introducing only elements of strict liability while leaving in place

[752] Geraint G. Howells & Mark Mildred, Is European Products Liability More Protective Than The Restatement (Third) Of Torts: Products Liability?, 65 Tenn. L. Rev. 985, 1030 (1998).
[753] See Thomas Lundmark The Restatement Of Torts (Third) And The European Product Liability Directive, 5 D.C.L. J. Int'l L. & Prac. 239, 255 (1996). See also Paul Burrows, Consumer Safety under Products Liability and Duty to Disclose, International Review of Law and Economics 12, 457-478, 464 (1992).
[754] Or could even be rendered meaningless. See Lawrence C. Mann and Peter R. Rodrigues, The European Directive on PL: the promise or progress?, 18 Ga. J. Int'l & Comp. L. 391, 423 (1988).
[755] Jane Stapleton, Products Liability In The United Kingdom: The Myths Of Reform, 34 Tex. Int'l L. J. 45, 56 (1999).
[756] In contract see the U.S. Supreme Court in Daubert v. Merrell Dow Pharmaceuticals. Inc. 509 U.S. 579 (1993) which refined the concept of state of scientific knowledge in particular by insisting that the material relied upon by expert witnesses in their evaluation of scientific controversies should be subject to careful review. See Jane Stapleton, Products Liability in the United Kingdom: The Myths of Reform, 34 Tex. Int'l L.J. 45, 56 (1999).

negligence as the regime in force in most member states (as was the case before the product liability Directive entered into force).[757]

The third optional provision that affects the strict liability nature of the Directive is the damage cap of 70 million euro on liability resulting from death or personal injury caused by a defective product.[758] As with the damage threshold discussed earlier, this provision limits the tortfeasor's internalization of expected damages and hence impacts its incentives to invest in care. Consequently, this provision diminishes the effectiveness of the strict product liability regime.

1.3 Potential tortfeasors subject to the product liability directive

All members of the chain of distribution, including product manufacturers, have a duty to warn of product risks when they know, or should know, that a product without warnings is likely to be dangerous when used for its intended purpose.[759] The scope of this duty, however, is not uniform for all members of the chain. Manufacturers are held to a higher standard than product retailers, for example, because they are presumed to have higher knowledge of the product and the risks it imposes on others.[760] The duty element is clearly a negligence concept.

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[757] Lawrence C. Mann and Peter R. Rodrigues, The European Directive on PL: the promise or progress?, 18 Ga. J. Int'l & Comp. L. 391, 422 (1988) arguing that the introduction of the development risk defense as a different defense to the concept of state of the art sends a confusing signal that undermines the effectiveness of the strict product liability regime aimed by the Directive.

[758] Article 16.1 of the product liability directive.

[759] Article 3 of the product liability directive. See also Paula Giliker, Strict Liability for Defective Products: The Ongoing Debate, 24 Business Law Review 4, 87-90, 89 (2003).

[760] S. Mark Mitchell, A Manufacturer's Duty to Warn in a Modern Day Tower of Babel, 29 Ga. J. Int'l & Comp. L. 573, 575 (2001). See also Mathias Reimann, Liability for Defective Products at the Beginning of the Twenty-First Century: Emergence of a Worldwide Standard?, 51 Am. J. Comp. L. 751, 776-777 (2003).

2 Strict product liability or a negligence regime with a reversal of the burden of proof?

Despite the negligence elements present in the product liability directive and explained above, it should not be concluded that the strict product liability regime becomes a fault liability system just because of the fact that it contains certain elements based on fault.[761]

The initial enthusiasm for the strict liability laid down by the Directive is quite diluted by these fault-based considerations.[762] But the negligence-based aspects of the product liability directive do not turn the liability regime into a fully negligence-based one. The Directive does not simply maintain the negligence regime in force in most member states before its adoption[763] because it does not include duty elements and hence lacks the core element of any negligence regime.[764] The introduction of negligence-based elements does not change its strict liability nature, even though they may have an impact regarding the burden of proof among the parties. The burden of proof is generally defined on two different levels: first, which of the parties must provide the evidence required -- called the burden of proof -- and second, what is the level of confidence required by the

[761] Bernanrd A. Koch and Helmut Koziol (eds.) UNIFICATION OF TORT LAW: STRICT LIABILITY (the Hague; London; New York: Kluwer Law International, 101 (2002).
[762] See Jane Stapleton, Products Liability In The United Kingdom: The Myths Of Reform, 34 Tex. Int'l L. J. 45, 67 (1999) arguing that despite the product liability directive's intent to impose liability without fault on the producer, in practice only some areas such liability regime was introduced while the core of the liability in some other areas was negligence-based.
[763] See Michael R. Will, Liability for failure to warn in the European Community, 6 B.U. Int'l L. J. 125, 133 (1988) arguing that the product liability directive is not a negligence-based liability system and did not just replace the negligence product liability systems in force before the product liability directive was adopted but put a new clothing on them.
[764] See Alan Calnan, Perpetuating Negligence Principles in Strict Products Liability: The Use of State of the Art Concepts in Design Cases, 36 Syracuse L. Rev. 797 (1985) and Kathleen D. Wilkinson, Admissibility of State of the Art Defense - Manufacturer's Expertise May No Longer Be Allowed in the Courtroom, Pennsylvania Bar Association Quarterly, 205 (1988).

adjudicator in order to understand that the evidence supports the legal claim – called standard of proof.[765]

Under a pure strict liability regime, the injured victim bears the burden of proving the harm, the defect and the causal relation between them.[766] However, with the introduction of optional provisions and the adoption of the consumer expectations test, strict liability may function as a rebuttable presumption of liability that can be overcome by the defendant alleging and proving any of the available defenses.[767]

There is a remarkable divergence between common-law and civil law standards of proof in civil cases. In England and the U.S., the standard of proof is probabilistic, and civil claims must be proved by a preponderance of the evidence.[768] In contrast, in civil-law countries the standard is that a civil claimant must in effect convince the trier of fact that the claimant's assertions are true.[769] If we assume that the standards of proof have a practical impact, this difference between common-law and civil law rules are of great practical importance.

The difference between the common law and civil law systems shows basic differences in attitudes toward the process of trial. For example, there is very little interest shown in civil law countries regarding standards of proof or the study of the differences between civil law and common law standards of proof.

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[765] Fernando Gómez, Burden of Proof and strict liability: an economic analysis of a misconception, Indret 01/2001.

[766] See James A. Henderson Jr., Richard N. Pearson, John A. Siliciano, THE TORTS PROCESS, Aspen 413-435 (6th ed.) (2003). The two different liability regimes have a direct impact on the manufacturer's decision regarding product design, manufacturing and pricing. See Andrew F. Daughety, Jennifer F. Reinganum, Product Safety: liability, R&D and signaling, the American Economic Review, vol. 85 no. 5, 1187-1206. 1188 (1995).

[767] For an explanation on the effect of exceptions on the content of rules see Robert C. Casad, Kevin M. Clermont, RES JUDICATA: A HANDBOOK ON ITS THEORY, DOCTRINE, AND PRACTICE, Durham, NC: Carolina Academic Press, 39-44 (2001).

[768] Kevin M. Clermont & Emily Sherwin, A Comparative View of Standards of Proof, 50 Am. J. Comp. L. 243, 243 (2002).

[769] Kevin M. Clermont & Emily Sherwin, A Comparative View of Standards of Proof, 50 Am. J. Comp. L. 243, 243 (2002).

In civil-law systems, the legal proof's requirement of "full proof" avoided the necessity of formulating or even contemplating expressly different standards of proof for criminal and civil cases. So, continental scholars have not paid much attention to standards of proof because of the lack of probabilistic determinations.

Another parameter that may explain the little concern about burden of proof and standards of proof shown by civil law systems may be the absence of the jury institution. Under an adversarial system of litigation such as the one in the United States, the court does not conduct an independent investigation of its own but instead distributes between the litigants the burdens of provinig facts.[770] Whether one or the other of the parties has met the burden of proof is for the judge to decide and there is no occasion for the jury to hear anything about it. But it is for the jury to decide, when a case is submitted to it, whether the party with the burden of proof on a particular issue of fact has sustained it. In such case, the judge must explain to the jury the charge and the degree of persuasion to which the jurors must be convinced.[771]

The modern institution of the civil jury appears to have been especially effective in introducing the common law's progress toward probabilistic standards of proof. At least, the correlation between the existence of the civil jury and the development of the preponderance standard seems to be working in the sense of introducing probabilistic considerations in the decision-making process.[772]

Some scholars argue that from a theoretical perspective, the allocation of the burden of proof between the parties should not be relevant for the outcome of the case because given the information about the case, parties would start from opposite sides but

[770] For an analysis of the burden of proof in U.S. products liability see James T. O'Reilly and Nancy C. Code, PRODUCTS LIABILITY RESOURCE MANUAL: AN ATTORNEY'S GUIDE TO ANALYZING ISSUES, DEVELOPING STRATEGIES, AND WINNING CASES, Chicago, Ill.: American Bar Association, General Practice Section, 135 (1993).
[771] Richard H. Field, Benjamin Kaplan, Kevin M. Clermont, MATERIALS FOR A BASIC COURSE IN CIVIL PROCEDURE, New York, N.Y.: Foundation Press; [St. Paul, MN]: Thomson/West, 1245 (2003).
[772] Barbara J. Shapiro, "BEYOND REASONABLE DOUBT" AND "PROBABLE CAUSE": HISTORICAL PERSPECTIVES ON THE ANGLO-AMERICAN LAW OF EVIDENCE, Berkeley: University of California Press, 253-55 (1991).

ultimately converge in persuading the jury and the judge.[773] In contrast, other scholars understand that rules are a way of allocating power among individuals[774] and therefore defend that the allocation of the burden of proof has an impact on the outcome of the case given the differences in the costs of the information for the parties when obtaining the necessary evidence.[775] In this sense, shifting the burden of proof upon the defendant in tort cases may be justified on efficiency grounds in light of the defendant's lower costs of presenting evidence of diligence or lack of fault.

Coming back to the product liability discussion, some of the negligence elements included in the Directive result in the application of a negligence rule with a reversal of the burden of proof, requiring defendants to prove diligence in order to avoid being held liable. But whenever strict liability is in force, fault considerations should be irrelevant. The choice between a strict liability regime or a regime of negligence with a reversal of the burden of proof has a significant practical impact on the outcome of product liability cases in light of the different access to information that directly affects the parties' positions in the process and their probability of prevailing. Consumers may have difficulties in proving claims due to a lack of legal or other resources needed to investigate, or due to an inability to obtain essential information from the other party. Such problems are particularly severe in relation to technical products, or where the alleged injuries are of complicated nature. Producers and insurers, on the other hand, have a real concern that any relaxation of the rules relating to the burden of proof would encourage "frivolous claims."[776]

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[773] See Kevin M. Clermont & Emily Sherwin, A Comparative View of Standards of Proof, 50 Am. J. Comp. L. 243, 243, 2002 and Robert C. Casad, Kevin M. Clermont, RES JUDICATA: A HANDBOOK ON ITS THEORY, DOCTRINE, AND PRACTICE, Durham, NC: Carolina Academic Press, 39-44 (2001).

[774] Frederick Schauer, PLAYING BY THE RULES: A PHILOSOPHICAL EXAMINATION OF RULE-BASED DECISION-MAKING IN LAW AND IN LIFE, Oxford University Press (Clarendon Press), 1991) (paperback edition 1992) P 158- 162 See also Frederick Schauer, Neutrality and Judicial Review, Law and Philosophy, 23, 217-240 (2003) arguing that rules have an underlying objective of achieving moral goals. Therefore, Professor Schauer in this article defends that neither rules nor their interpretation is neutral.

[775] See Fernando Gómez, Burden of Proof and strict liability: an economic analysis of a misconception, Indret 01/2001, www.indret.com.

[776] See generally Manfred Wandt, German Approaches to Product Liability, 34 Tex. Int'l L.J. 71 (1999).

If information was perfect, the liability rule in force -- or the absence of liability -- and the allocation of the burden of proof between the parties would be irrelevant given that consumers and producers would have the same information regarding product risks and hence on the expected liability and such information would be reflected in the prices of products.[777] Consequently, both parties, consumers and producers, would have access to the relevant information for meeting the burden of proof of the liability rule in force. But in cases with imperfect information the efficiency of liability rules and of the allocation of the burden of proof between parties significantly depends on who has access to the relevant information.[778]

Thus, the allocation of the burden of proof often hides the real question of who should bear the consequences of damages resulting from unavoidable defects -- manufacturers, the victim, society at large, or the relatively small group of product users, one of whom has used a defective product. Consequently, the introduction of these negligence-based elements and burden of proof issues is important.

3 Are the negligence-based elements of the product liability directive distortive enough of the liability regime?

The presence of negligence elements in the product liability directive is not necessarily a problem for the product liability regime,[779] but may raise concerns at two

[777] This result is consistent with the Coase theorem. See Ronald H. Coase, The Problem of Social Cost, 3 Journal Law Econ. 1 (1960). See also Dennis Epple and Artur Raviv, Product Safety: Liability Rules, Market Structure, and Imperfect Information, 68 American Economic Review, 80 (1978) and Michael Spence, Consumer Misperception, Product Failure, and Producer Liability, 44 Review of Economic Studies, 561 (1977).

[778] See Steven Shavell, ECONOMIC ANALYSIS OF ACCIDENT LAW, 52-53, Harvard University Press, Cambridge (MA) (1987); William Landes and Richard Posner, THE ECONOMIC STRUCTURE OF TORT LAW, 275-280, Harvard University Press, Cambridge (MA) (1987).

[779] Some suggest abandoning strict product liability and defend negligence in product liability cases -- with a special rule for manufacturing defects – based on the idea that product cases are not a distinct group of

different levels: (1) the internalization of damages caused by defective products and (2) the protection and compensation of injured victims, both goals of the Directive.

Regarding the internalization of damages, strict product liability aims at creating incentives for care on the part of tortfeasors, who will try to minimize the expected costs of the liability to which they are exposed.[780] But the negligence elements included in the product liability directive, such as the damage threshold or the damage caps, reduce the expected costs of liability and, therefore, impact the incentives' torfeasors have to adopt care.

Regarding the consumer protection goal of the product liability directive, the aim was to allow victims to bring their product liability claims without having to prove fault. But the Directive's purported advantages to consumers are questionable in light of the limitations of their claims, both in terms of amount – excluding claims below 500 euros or above 70 million – and in terms of fault.[781] The presence of the development risk defense introduces fault considerations based on sophisticated knowledge – scientific knowledge – that is often difficult to challenge or obtain for injured victims. Consequently, from this perspective the product liability directive does not seem to have enhanced consumer protection as it intended.

The combination of a strict product liability regime with negligence elements should not necessarily be problematic from a theoretical or practical perspective.[782] Even though the strict nature of the product liability regime introduced by the Directive should be affirmed, the lack of definition of the negligence elements it contains and of their

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tort cases that could perform better under strict liability than under negligence. See William Powers, Jr., A modest proposal to abandon strict products liability, 1991 U. Ill. L. Rev. 639, 640, 642 (1991).

[780] See Steven Shavell, ECONOMIC ANALYSIS OF ACCIDENT LAW, 52-53, Harvard University Press, Cambridge (MA) (1987); William Landes and Richard Posner, THE ECONOMIC STRUCTURE OF TORT LAW, 275-280, Harvard University Press, Cambridge (MA) (1987).

[781] Eleonora Rajneri, Interaction Between the European Directive on Product Liability and the Former Liability Regime in Italy, Global Jurist Topics: Vol. 4 : Iss. 1, Article 3 (2004).

[782] From a practical perspective, strict liability may present lower evidence requirements for injured victims to receive compensation. See Mark A. Geistfeld, PRINCIPLES OF PRODUCTS LIABILITY, Foundation Press, New York, 23-26 (2006). .

practical implementation would require some guidance in order to preserve the Directive's strict liability spirit.

CHAPTER 5

EX ANTE PRODUCT REGULATION: EUROPEAN PRODUCT SAFETY LAW

1. Structure of product safety law in Europe

Understanding product safety law in Europe is not an easy task. It can be difficult even to sort out the general structure of this body of law -- what instruments are in force, their hierarchy, and the major differences between them -- let alone the law's actual impact on products. This chapter aims to clarify the picture and to place it in the broader context of product regulation, which covers not just issues of liability but also those of safety.[783] Whereas product liability law is a form of ex post regulation, product safety law operates ex ante. Chapter 6 will discuss the interaction of ex post liability rules with ex ante safety rules when they operate together in the same legal system.

[783] Up to today, most of the literature on European product safety often evaluates the performance of certain Directives, their potential improvements and interactions with safety standards but do not generally provide a global analysis of the European product safety regulation, its nature and performance. Further, there is little literature including the recent developments and regulation adopted on this issue. Examples of literature once the first General Product Safety Directive (1992) was adopted are Geraint Howells, CONSUMER PRODUCT SAFETY, Dartmouth (1998); Peter Cartwright, Product Safety and Consumer Protection, 58 The Modern Law Review 2, 222-231 (1995); Christopher J.S. Hodges, A new EC Directive on the Safety of Consumer Products, Eur. Buss. Law Review, vol. 12, num. 11-12, 274-280 (2001), Giandomenico Majone, REGULATING EUROPE, Routledge (1996) and J. Pelkmans, the New Approach to Technical Harmonization and Standardization, 25 J. Comm. Mkt. Stud. 249, 252-3 (1987). Examples of more recent literature that include analysis of the new General Product Safety Directive (2004) and New Approach Directives are in Christopher Hodges, EUROPEAN REGULATION OF CONSUMER PRODUCT SAFETY, Part II : Procedural Mechanisms for safety (Chapters 7-15), Oxford University Press (2005).

Table 5.1 - General Structure of European Product Safety Regulation

			PRE-MARKETING REQUIREMENTS		MARKETED PRODUCT		POST-MARKETING OBLIGATIONS
HARMONIZED PRODUCT SAFETY STANDARDS (CEN, CENELEC, ETSI)	PRODUCT-SPECIFIC REGULATION	**NEW APPROACH WITH CE MARKING**	Essential safety requirements	Conformity assessment	Notified bodies	CE marking	RAPEX (under GPSD)
		NEW APPROACH / GLOBAL APPROACH WITHOUT CE MARKING	Essential safety requirements	Conformity assessment	Notified bodies	No CE marking	
		DIRECTIVES BASED ON PRINCIPLES OF NEW APPROACH OR GLOBAL APPROACH	Product standards	Presumption of compliance	CE marking		RAPEX
	NO PRODUCT-SPECIFIC REGULATION	**GENERAL PRODUCT SAFETY DIRECTIVE (GPSD)**	General Safety Clause (Obligation to place safe products in the market)	Compliance with Product standards if available			RAPEX + Information about product risks to the European Commission and other member states
				Risk-utility assessment			

European product safety law is based on a system of product safety standards, notifications and enforcement mechanisms. The legislation through which the system is layed out can be categorized according to a number of different criteria, which are summarized in Table 5.1. Instruments may be categorized based on the extent to which they contain their own express safety standards or merely incorporate external standards -- called essential safety requirements. They may also be categorized according to whether they regulate specific products or apply generally. Finally, they may be categorized according to their use of "CE" markings and the obligations they impose during the pre- and post-marketing phases.

At one extreme are a set of directives known as New Approach Directives, which include their own specific standards -- essential safety requirements -- and apply to specific products. At the other extreme is the General Product Safety Directive (GPSD),[784] which applies generally and does not include safety standards but give effects to compliance with safety standards. (In this sense, the GPSD is often referred to as a standard-receptive directive.) In between are two categories of instruments that apply to specific products but rely on a combination of standards they they expressly lay out and ones that they incorporate by reference. These last two categories are known as New Approach/Global Approach Directives, which follow New Approach principles except for providing for CE marking, and directives based on New Approach/Global Approach principles, which refer to harmonized standards instead of including essential safety requirements.

New Approach Directives[785] generally include essential safety requirements that are applied together with general safety standards products must comply with. These

[784] Council Directive 2001/95/EC of December 3, 2001 on General Product Safety O.J. (L 11) (January 15, 2002), hereinafter, the GPSD.
[785] See http://www.newapproach.org

directives also include notification and risk monitoring procedures for the products they apply to.

At the same time, the European Commission established a general principle of safety under which there is an obligation to place only safe products in the market. This obligation is included in the GPSD,[786] which is applicable whenever there is no specific legislation applicable to a certain consumer product. The obligation includes notification and enforcement mechanisms for member states as well as for European authorities. Notification measures entail the obligation of member state authorities to notify European authorities of the existence of unsafe products. Enforcement mechanisms refer to the measures European or member states authorities must adopt after an unsafe product has been detected in a certain market.

The following sections follow the structure of Table 5.1 in presenting and discussing the role of standards and the standardization process in Europe, and then looking at these questions in the context of New Approach Directives and GPSD.

2. The standardization process

One of the pillars of the European product safety regime consists of product safety standards.[787] Since the mid-1980s, the European Community has made increasing use of standards in support of its policies. Today, there are around five thousand standards

[786] Council Directive 92/59/EEC of June 29, 1992 on General Product Safety, O.J. L228 24 (Aug. 11, 1992) amended by the Council Directive 2001/95/EC of December 3, 2001 on General Product Safety O.J. (L 11) (January 15, 2002).

[787] Product safety standards have been increasingly used and harmonized around the world given that it is often not possible to design one product where standards from different countries are technically different. See Mark R. Barron, Creating consumer confidence or confusion? The role of product certification marks in the market today, 11 Marq. Intell. Prop. L. Rev. 413, 437 (2007).

implemented in Europe, many of which are consumer product safety standards.[788] Some standards are included in product-specific regulations like the New Approach Directives,[789] while others are applied without any product-specific legislation.

There are two major types of standards in Europe.[790] On one side, there are "harmonized standards," which are designed by independent standard bodies acting at the domestic, European and international levels.[791] At the European level, these bodies are the European Committee for Standardization (*Comité Européen de Normalization*, CEN),[792] the European Committee for Electrotechnical Standardisation (*Comité Européen de Normalization Electrotechnique*, CENELEC),[793] which deals with electrotechnical matters, and the European Telecommunications Standards Institute (ETSI),[794] which covers the telecommunications field and other areas of broadcasting and office information technology. These institutions adopt standards whenever the European Commission mandates it, after consultation with the member states.

On the other side, there are standards of the type included in New Approach Directives.[795] New Approach Directives are characterized as including a comprehensive regulation of the products to which they apply, from the safety standards applicable to these products, called essential safety requirements, to the conformity assessment and notification procedures manufacturers must follow in the pre- and post-marketing phases. The New Approach technique has not been used often because the standards elaborated

[788] It should be noted that there are also non-consumer product safety standards. This information can be found at : http://europa.eu.int/comm/enterprise/standards_policy/index_en.htm and http://europa.eu.int/comm/enterprise/standards_policy/european/flyer/index.htm
[789] See http://www.newapproach.org
[790] These two types of standards have three dimensions concerning their nature, scope and level of applicability. See W. Kip Viscusi, REGULATING CONSUMER PRODUCT SAFETY, American Enterprise Institute for Public Policy Research, 24 (1984).
[791] In the U.S., there are over 400 public organizations that write standards that are adopted by the manufacturers within an industry. These standards are generally voluntary. See Sheila L. Birnbaum, Legislative reform or retreat? A response to the product liability crisis, 14 Forum 251, 278 (1978-1979).
[792] For further information See www.cenorm.be
[793] For additional information see www.cenelec.be
[794] For more information see www.etsi.org
[795] See infra.

on this basis have raised substantial debate about their completeness and appropriateness.[796] In addition to the essential safety requirements included in New Approach Directives, harmonized product standards are also applied to the products regulated by these Directives.

Hence, the major body of European product safety standards consists of the harmonized standards adopted by the three European standardization organizations: CEN, CENELEC and ETSI.

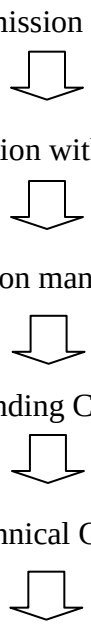
2.1 Standardization organizations

This section will present the functioning of the European standardization process, focusing in the first type of standards: "harmonized standards." The standardization process begins with the initiative of the European Commission, which consults with the member states regarding the need for adopting a product safety standard and the approach that should be used to design the standard. Once there is an agreement, the Commission issues a mandate to the European standardization bodies to draft the product safety standard. The process followed by CEN, CENELEC and ETSI is based on the principles of consensus, voluntary compliance and transparency.[797] The importance of participation and consensus is essential in order to minimize the pressure from private interests -- whether economic operators or pressure groups -- or public or political forces seeking to influence or to capture the regulator when drafting the safety standard.[798] For that reason, before the standard is adopted all parties affected by it are given an opportunity to raise

[796] So far, the field in which the New Approach technique has been used the most is for environmental design of products, regulated by the Packaging and Packaging Waste Directive 94/62/EC on Packaging and Packaging Waste, as amended by Directive 2004/12/EC (consolidated text).
[797] Council Resolution of 28 October 1999 on the role of standardisation in Europe, Official Journal C 141 of 19.05.2000.
[798] Anthony Ogus, REGULATION: LEGAL FORM AND ECONOMIC THEORY, 171, Oxford University Press (1994).

objections and present their views to the standardization body at the member state level,[799] and all comments submitted are considered. By emphasizing consensus, European authorities believed that parties would be less inclined to lobby for standards most beneficial to their interests.[800] Once standards are designed, they are published in the Official Journal of the European Communities and after that they must be transposed into domestic regulation, so that they become then domestic standards.[801]

FIGURE 5.1 - THE STANDARDIZATION PROCESS - roughly summarizes this process:



[799] The European standardization bodies have delegations in the different member states. These are domestic bodies that are responsible to collect the comments, objections and inputs provided by all parties participating to the drafting of the product safety standard at the domestic level. Once all this information is collected, these domestic standardization bodies transfer it to the European standardization bodies.
[800] The clash between domestic and European standards also takes place in the U.S. between Congress and state governments. Some authors claim that the Congress should establish national product safety standards that would preempt state safety regulation. See Alan Schwartz, Statutory Interpretation, Capture, and Tort Law: the regulatory compliance defense, American Law and Economics Review 2(1) (2000).
[801] See Vademecum on European standardization http://europa.eu.int/comm/enterprise/standards_policy/vademecum/

A voluntary standard is issued

When drafting the safety standard, the European standardization bodies have the task of including the technical specifications that reflect the "state of the art" in the matter.[802] The technical information included in the standards also has an additional function: establishing the meaning of "safe" for Directives that include general references to safety.[803]

Compliance with harmonized standards adopted by these institutions is voluntary, which means that manufacturers are free to choose the technical solution they believe is best to comply with the requirements established by the Directives applicable to the products they manufacture.[804] However, compliance is quite attractive because it provides significant benefits for the manufacturer such as the presumption of conformity included in some directives, especially in the New Approach Directives, and the possibility of attaching the CE marking to their products, which represents a passport for their products to the whole European market.[805] Because of these incentives, industry *de facto* complies with the standards.[806] But whenever the Commission considers either on

[802] See Commission Communication on the Development of European Standardization, 1991 O.J. C20/1 which states that standards must be effective and therefore must be kept up to date and reviewed in order to include new technological developments.
[803] Geraint G. Howells, The relationship between product liability and product safety – understanding a necessary element in the European Product Liability through a comparison with the U.S. position, 39 Washburn L. J. 305, 315 (2000).
[804] The use of voluntary standards is not exclusive from the European Union. In the United States, the Consumer Product Safety Commission also establishes, together with the industry being regulated, voluntary standards of product safety. Once the voluntary standards are designed, the Consumer Product Safety Commission does not impose a mandatory regulation for the same product risk. Such standardization scheme was not except from debate. See W. Kip Viscusi, REGULATING CONSUMER PRODUCT SAFETY, 64, American Enterprise Institute (1984).
[805] See section 3.5 of this chapter on CE marking.
[806] Given that complicate with voluntary harmonized standards raises a presumption of conformity to the essential safety requirements included in New Approach Directives product manufacturers have great incentives to comply with such standards. See Mark R. Barron, Creating consumer confidence or confusion? The role of product certification marks in the market today, 11 Marq. Intell. Prop. L. Rev. 413, 430 (2007).

its own initiative or upon request of member states that a standard presents shortcomings, the Commission can decide to withdraw the publication of the reference of the standard in the Official Journal. Only in those cases, compliance with harmonized standards will not provide a presumption of conformity.

2.2 The process of design and adoption of standards

European standards are adopted on the basis of a mandate from the European Commission to the European standardization bodies, which is like a contract between the Commission and CEN for drafting standards.[807] Once the Commission proposes a Directive and negotiations between member states begin, the Commission and CEN also start to negotiate the content of the standards to be drafted.[808]

As mentioned above, the process within the standardization bodies is intended to be open to all interested economic agents. The interested parties and European bodies collaborate in drafting a proposal for a safety standard,[809] and upon completing it they send it to the European Standing Committee for approval.[810] Once this Committee approves the proposed standard, the Commission asks CEN for its opinion on it and CEN

[807] The contract is signed with CEN given that it is the standardization body that deals with more kinds of products generally. See Vademecum on European standardization http://europa.eu.int/comm/enterprise/standards_policy/vademecum/

[808] See Vademecum on European standardization http://ec.europa.eu/enterprise/standards_policy/vademecum/index.htm

[809] Consumers are also encouraged to participate in this process. However, in order to ensure that their participation is effective, they are generally represented by technical experts given that in general consumer movement is not quite organized and lacks the expertise to decide in this process and to have some impact and influence on producers. For this reason, the consumer representation in the European standardization process is done since 1985 through the ANEC (European Association for the Co-ordination of Consumer Representation in Standardization", also referred as "The European consumer voice in standardization"). See www.anec.org for further information on ANEC. See also Geraint G. Howells, The relationship between product liability and product safety – understanding a necessary element in the European Product Liability through a comparison with the U.S. position, 39 Washburn L. J. 305, 326-28 (2000).

[810] The Standing Committee is set up under the Technical Standard Directive. Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998. Official Journal L 204, 21/07/1998 P. 0037-0048.

responds with a detailed specification of the number of standards that will be necessary depending on the scope of regulation of the safety Directive, how long it will take to the different technical committees to have them prepared and what the cost of designing such standards will be. After financial negotiations the Commission and CEN sign a contract.

At this stage of the process, the responsibility lies with a Technical Board,[811] which has different procedures depending on the issue being regulated and on whether there is already an existing safety standard.[812] A first procedure is used whenever the standard to be issued is a new standard. Under this procedure the proposed standard is sent to a Technical Committee. Once a standard is drafted, it is open to public participation for six months. After that, there are discussions regarding the comments of the public and an ultimate version of the standard is done. A second procedure is used in cases where there is already a reference document such as a domestic standard, a European trade specification or a standard of an international organization. In these cases there is no need for a Technical Committee to allow public participation and the standard can be directly adopted. Nevertheless, there are still six months for replies in case anyone has something to say about the standard. A third procedure is the one established by the "Vienna Agreement,"[813] under which CEN is allowed to transfer the work for the design of European Standards to the International Standards Organization (ISO).[814]

After allowing public participation through one of these three mechanisms,[815] member states take a vote on the final draft. Given that compliance with standards is

[811] The technical board of standardization is an organization that controls the process of drafting a product safety standard as well as promotes its fast execution. See also http://europa.eu/legislation_summaries/internal_market/single_market_for_goods/technical_harmonisation/index_en.htm on Technical harmonization.
[812] Geraint G. Howells, The relationship between product liability and product safety – understanding a necessary element in the European Product Liability through a comparison with the U.S. position, 39 Washburn L. J. 305, 319 (2000).
[813] The agreement on technical cooperation between ISO and CEN is called the Vienna Agreement.
[814] See www.iso.org. See generally Suzanne Laplante, The European Union's General Product Safety Directive: another call for US exporters to comply with the ISO 9000 series, 22 Syracuse J. int'l L. & Com. 155 (1996).
[815] Note that, differently to the process used by the Consumer Product Safety Commission in the United States, the industry only participates in the final draft of the standard and its participation does not limit the

voluntary, maximum consensus is key for the success of a standard since the higher the level of acceptance by all parties the more they will be willing to comply.[816]

This process imposes obligations at both the European and the domestic levels. At the European level, the Technical Standards Directive[817] requires that standardization bodies send draft standards upon request of the European Commission[818] and keep the Commission informed of any action taken regarding the drafts. At the domestic level, member states must ensure that their own different standardization bodies communicate necessary information for the design of a standard and publish their domestic standards so that parties in other member states can comment on them.[819]

This process is essentially the same for standards developed under the New Approach, although in this latter case compliance is required, because compliance with the essential requirements included in New Approach Directives is mandatory.[820]

2.3 Are standards harmonized?

The European Community's goal with respect to product safety standards is to achieve Europe-wide harmonization wherever possible.[821] However, it is difficult to

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scope of decision of the European standardization bodies. See Anthony Scascia, Safe or sorry: how the precautionary principle is changing Europe's consumer safety regulation regime and how the United States' Consumer Product Safety Commission must take notice, 58 Admin. L. Rev. 689, 694-694 (2006) describing the role of the industry in the design of product safety standards, that could delay the implementation of such safety measures.

[816] CEN, STANDARDS FOR ACCESS TO THE EUROPEAN MARKET, 13 (2d ed. 1995). See Also Jacques Pelkmans & Dr. Michelle Egan, Fixing European Standards: Moving Beyond The Green Paper, 14-15, CEPS Working Document No. 65, Brussels (1992).

[817] Technical Standard Directive, 98/34/EC of the European Parliament and of the Council of 22 June 1998. Official Journal L 204, 21/07/1998 P. 0037-0048. See http://europa.eu/scadplus/leg/en/s06011.htm for technical harmonization.

[818] Article 3 Technical Standard Directive, 98/34/EC of the European Parliament and of the Council of 22 June 1998. Official Journal L 204, 21/07/1998 P. 0037-0048.

[819] Article 4 Technical Standards Directive, 98/34/EC of the European Parliament and of the Council of 22 June 1998. Official Journal L 204, 21/07/1998 P. 0037-0048.

[820] Council Resolution on a New Approach to technical harmonization and standardization, Council Resolution of 7 May 1985 OJ C 136, 4.06.1985.

assess the degree of harmonization in the implementation of the standards because these harmonized standards are implemented at the domestic level either by transposing European standards into domestic law, or by withdrawing domestic laws that conflict with the European standards. At the same time, the existence of harmonized standards does not preclude member states from maintaining or adopting domestic standards dealing with subjects that are within the scope of a harmonized standard,[822] as long as the domestic provisions refer to technical requirements and do not conflict with European provisions. [823]

The European Commission is especially interested in ensuring that European standards are transposed and applied uniformly by the member states to avoid having certain products meet the standards in one state and not in another, which would jeopardize the free circulation of goods and the proper functioning of the internal market.[824] In order to achieve this goal, the Commission has introduced procedures to monitor the member states' activities and thereby minimize, as much as possible, the differences between the domestic rules of the member states.

3 New Approach Directives[825]

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[821] Christopher Hodges, EUROPEAN REGULATION OF CONSUMER PROTECTION SAFETY, 68, Oxford University Press (2005).
[822] These harmonization documents refer to the harmonized standards issued by the standardization bodies.
[823] www.british-europeanstandards.org/en-standards.htm and see also Geraint Howells and Stephen Weatherill, CONSUMER PROTECTION LAW, 99, Ashgate Publishing Company (2005).
[824] The European Commission's goal is similar to the discussion taking place in the U.S. regarding whether the Federal government could adopt minimum national standards or, because of the possibility of Congress being captured by the interests of the industry, it is better that states are responsible for product safety regulation. See §4 of the Restatement (Third) of Torts: Products Liability (1998). See also Ashley W. Warren, Compliance with governmental regulatory standards: is it enough to immunize a defendant from liability?, 49 Baylor Law Review 763 (1997) defending the desirability of non biased agencies not subject to lobbyists' activities.
[825] For additional information on New Approach regulation in Europe see www.newapproach.org

3.1 Origin of the New Approach

A crucial element of the single internal market was ensuring that the technical harmonization governing products addressed the diversity of domestic technical standards and regulations within the European Community.[826]

The Community New Approach originated in a European Council Resolution of May 1985[827] with the goal of improving the performance of the internal market[828] and simplifying and speeding the creation of harmonized regulations. The hope was that the regulations would evolve from the detailed product-specific technical requirements included in safety standards to regulations that would only include the essential requirements for certain types of products.[829] The New Approach Directives lay down essential safety requirements but also rely on European standards to develop details of

[826] See Commission Guide to the Implementation of Directives Based on the New Approach and the Global Approach, 7-8 (2000) describing the goal of creating a single internal market by Dec. 31, 1992. This document is available at http:// europa.eu.int/comm/enterprise/newapproach/legislation/guide/document/1999_1282_ en.pdf

[827] On 7 May 1985, the Council adopted a Resolution on A New Approach to technical harmonization and standards, Council Resolution of 7 May 1985, 1985 O.J. (C 136). The New Approach responded to the European Court of Justice's Cassis de Dijon jurisprudence. Case Rewe-Zentral AG v Bundesmonopolverwaltung für Branntwein, C-120/78 (known as Cassis de Dijon), (1979) E.C.R. 649, 662, (1979) C.M.L.R. 494 (1979). See also Communication from the Commission Concerning the Consequences of the Judgment Given by the Court of Justice on 20 February 1979 in Case 120/78 (Cassis de Dijon), Official Journal of the European Communities C 256/2 (March 10, 1980). In this communication, the Commission interpreted Cassis de Dijon to require that barriers to trade resulting from regulatory differences (i) necessary, that is appropriate and not excessive, (ii) satisfy mandatory requirements including public health, protection of consumers or the environment, (iii) and must be the means which are the most appropriate and least hinder trade. See also Jacques Pelkmans, The New Approach to Technical Harmonization and Standardization, 25 J. Comm. Mkt. Stud. 249 (1987).

[828] The Agreement on the European Economic Area extends the Internal Market to Iceland, Liechtenstein and Norway despite their non-membership to the European Union. Consequently, all New Approach Directives apply in these countries as they do in EU member states.

[829]New Approach Directives are based on article 95 of the Treaty of the European Community and are adopted according to the co-decision procedure provided for in article 251 of the same treaty. See European Commission, Guide to the implementation of Directives Based on the New Approach and the Global Approach (Brussels, 2005), http://europa,eu.int/comm/enterprise/newapproach/newapproach.htm. The New Approach has been considered of fundamental importance for the internal market. See Günter Verheugen, Exchange of views of Vice-President Verheugen with the Internal Market and Consumer protection Committee (IMCO) European Parliament, Internal Market and Consumer Protection Committee European Parliament (2006). This speech is available at http://europa.eu/rapid/pressReleasesAction.do?reference=SPEECH/06/500&format=HTML&aged=0&language=EN&guiLanguage=en

certain product safety issues. The essential element of product safety in Europe, though, is still the standardization process.[830]

The essential safety requirements are different from product safety standards. Essential technical requirements included in New Approach Directives are based on the principle of protecting health and safety of product users[831] either by requiring safety measures regarding specific product hazards or by requiring certain product characteristics in terms of manufacture or design.[832] They are, thus, mandatory. In contrast, harmonized standards consist of detailed technical specifications for ensuring the safety of specific products.[833] And further, they are voluntary.

New Approach Directives have a two-fold purpose: on one side, assuring compliance with harmonization technical requirements of certain product sectors, and on the other side, guaranteeing a "high level of protection" of the public interest by preventing member states from adopting technical barriers to trade without notifying the other member states.

Given that compliance with essential safety requirements is mandatory, the European Commission introduced transparent and harmonized conformity assessment procedures. Products that conform to the requirements are allowed to bear a "CE" mark that shows such compliance and are given access to the European market. Conformity assessment procedures were introduced by the New Approach Directives and then further

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[830] Despite the obligation to comply with mandatory essential safety requirements, standards are an essential element of product safety given that compliance with them raises a presumption of conformity with the essential safety requirements. See the Commission Green Paper on the Development of European Standardization: Action for Faster Technological Integration in Europe, COM (90) 456 final, 8 October 1990. This paper is available at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:1996:0013:FIN:EN:PDF

[831] European Commission, Guide to the implementation of Directives Based on the New Approach and the Global Approach, 7 (Brussels, 2005), http://europa,eu.int/comm/enterprise/newapproach/newapproach.htm.

[832] European Commission, Guide to the implementation of Directives Based on the New Approach and the Global Approach, 27 (Brussels, 2005), http://europa,eu.int/comm/enterprise/newapproach/newapproach.htm.

[833] European Commission, Guide to the implementation of Directives Based on the New Approach and the Global Approach, 28 (Brussels, 2005), http://europa,eu.int/comm/enterprise/newapproach/newapproach.htm.

developed by what is known as the Global Approach.[834] The Global Approach subdivided conformity assessment procedures into a number of different operations -- called modules -- which have different content depending on the stage of the development of the product and the type of assessment involved.[835] Conformity assessment procedures sought to harmonize conformity assessment so that member states could have confidence that all products claimed to conform to European standards actually complied with them.

The New Approach and the Global Approach[836] are aimed at (1) achieving technical harmonization limited to compliance with the essential requirements,[837] (2) assuring that only products fulfilling the essential requirements are placed in the market and put into service; (3) leaving compliance with harmonized standards or other technical specifications voluntary so that manufacturers may choose the technical solution that is best for complying with the essential safety requirements; (4) creating a presumption that harmonized standards conform to the corresponding essential requirements; and (5) allowing manufacturers to choose among the different conformity assessment procedures provided for in the applicable directives.[838]

[834] See the Council Resolution of 21 December 1989 on a global approach to conformity assessment, O.J. C 010. This Resolution is available at http://eur-lex.europa.eu/Notice.do?val=163035:cs&lang=en&list=163035:cs,&pos=1&page=1&nbl=1&pgs=10&hwords=&checktexte=checkbox&visu=#texte.

[835] See Council Resolution on a Global Approach to Conformity Assessment 90/683/EEC, 1990 O.J. C 10, which led to the Council Decision 93/465/EEC, Concerning the Modules for the Various Phases of the Conformity Assessment Procedures and the Rules for the Affixing and Use of the CE Conformity Marking, Which are Intended to be Used in the Technical Harmonization Directives, 1993 O.J. (L 220). These decisions laid down general guidelines and detailed procedures for conformity assessment to be used in New Approach directives.

[836] European Commission, Guide to the Implementation of Directives Based on New Approach and Global Approach, Introduction 7 (2005). This document can be found at http://ec.europa.eu/enterprise/newapproach/legislation/guide/index.htm

[837] Council Resolution of 07.05.1985 on the "New Approach to technical harmonization and standards"

[838] See the Council Resolution of 21 December 1989 on a global approach to conformity assessment, O.J. C 010 and Council Decision 93/465/EEC of 22 July 1993 concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the CE conformity mark.

Not all the directives included in what is called the New Approach are uniform.[839] Some New Approach Directives include essential safety requirements and provide for CE marking. Others are based on the ideas of the New Approach and the Global Approach but do not provide for CE marking. Still others are just based merely on New Approach and Global Approach principles. New Approach Directives cover a large number of product sectors[840] even though the rules contained in these Directives may vary.[841] Since the adoption of the New Approach technique, twenty-one New Approach Directives have been adopted and came into force,[842] four Directives that do not provide for CE marking have been adopted,[843] and four additional Directives based on the principles of the New and Global approach have been adopted.[844]

3.2 Elements of the New Approach

This legislative technique of the New Approach presented some innovation such as the inclusion of mandatory essential requirements, setting up conformity assessment

[839] Communication from the Commission to the Council and the European Parliament, Enhancing the Implementation of the New Approach Directives, 7.5.2003, COM(2003) 240 final. For example, the Toys Directive includes a notification procedure, not included in the Low Voltage Directive 73/23/EEC that includes a safeguard clause.

[840] It is estimated that the trade of products covered only by the major sectors regulated by the New Approach directives largely exceeds the volume of € 1500 billion per year. Communication from the Commission to the Council and the European Parliament, Enhancing the Implementation of the New Approach Directives, 7.5.2003, COM(2003) 240 final. Page 4 annex II, table 1b. Examples of products regulated by New Approach Directives range from the Directive on Toy safety: 88/378/EEC, OJ 1988 L 187/1; Machinery: 89/392/EEC, OJ 1989 L 198/16 amended by the Directive 91/3689/EEC, OJ 1991 L 198/16; pressure vessels: 87/404/EEC, OJ 1987 L 220/48; Construction products: 89/106/EEC, OJ 1988 L 40/12; Personal protective equipment: 89/686/EEC, OJ 1989 L 399/18; Implantable medical devices: 90/385/EEC, OJ 1990 L 189/17; Gas burning appliances: 90/396/EEC, OJ 1990 L 196/15; Medical devices: 93/42/EEC, OJ 1993 L 169/1.

[841] For example, while the Toys directive is very clear and precise, other directives include vague objectives and refer to the need to minimize risks or reduce them as far as possible.

[842] For a directive's list see http://ec.europa.eu/enterprise/newapproach/legislation/directives/table1.htm

[843] For a list of the Directive's, see http://ec.europa.eu/enterprise/newapproach/legislation/directives/table2.htm

[844] See http://ec.europa.eu/enterprise/newapproach/legislation/directives/table3.htm

procedures and introducing the CE mark.[845] The product control system designed by New Approach directives covers both the pre-market product phase through the required conformity assessment procedures, and the post-market phase, by imposing market surveillance obligations.

The essential requirements aim to ensure a high level of protection to the public.[846] For that reason, they are mandatory. The essential requirements are defined in a way that makes it possible for member states to enforce them uniformly.

Even though New Approach Directives set down essential safety requirements, they leave the method of compliance in the hands of the manufacturer, who can decide either to comply with standards[847] or to comply with essential safety requirements and obtain some kind of conformity for the product design. Hence, despite being subject to a New Approach Directive, manufacturers also take into consideration the content of safety standards when adopting their safety decisions. This regulation places on manufacturers and, more generally, on economic operators the responsibility of ensuring regulatory compliance through the means they choose,[848] without having authorities involved in the pre-marketing phase of the product.[849]

This approach is also made possible by the vertical nature of New Approach Directives that contrasts with horizontal Directives -- like the GPSD -- that cover consumer products but place emphasis on post-marketing mechanisms.[850] Even though

[845] Council Resolution on a New Approach to technical harmonization and standardization, Council Resolution of 7 May 1985 OJ C 136, 4.06.1985. New Approach Directives are based on three pillars, which are the Council Resolution of 07.05.1985, the Council Resolution of 21.12.1989 on a Global Approach to certification and testing and the Council Decision 93/465/EEC.
[846] See Anthony I. Ogus, REGULATION: LEGAL FORM AND ECONOMIC THEORY, 150 (Oxford 1994).
[847] If a manufacturer complies with harmonized standards published by the Official Journal of the European Communities, they are presumed to comply with the corresponding essential requirements.
[848] Communication from the Commission to the Council of the European Parliament Enhancing the Implementation of the New Approach Directives, COM (2003) 240, 7.5.2003.
[849] Christopher Hodges, EUROPEAN REGULATION OF CONSUMER PROTECTION SAFETY, 61, Oxford University Press (2005).
[850] The main difference between vertical and horizontal directives is against whom the rights included in them can be asserted. Under vertical directives it is necessary to invoke such rights before a public authority or the state while horizontal directives include rights that may be invoked and enforced by private

these two approaches share some features in common, they are significantly different given that horizontal directives do not involve pre-marketing assessment of a product and merely require manufacturers to produce a declaration stating that a product conforms to the legal standards. Sometimes such a declaration is approved by an independent technical organization though this is not strictly necessary. Once a declaration is issued, the other member states are required to recognize it and allow the product to be marketed.[851]

In contrast, New Approach Directives include conformity assessment procedures that product manufacturers must choose from in order to assure that their products conform to the essential technical requirements. Conformity assessment procedures allowed under New Approach Directives are quite flexible and may be adjusted to the specific type of product risk involved. In some cases, these procedures require the intervention of third parties, namely notified bodies that will certify compliance after evaluating whether a product conforms to essential requirements.

Finally, New Approach Directives include a CE marking, which is a mark attached to the product that declares that a manufacturer has verified that a product conforms to all the harmonization provisions that apply to it and that the product has been subjected to the applicable conformity assessment procedures.

This New Approach technique is intended to prevent the creation of domestic product safety mechanisms that could represent barriers to trade. Under certain strict circumstances, however, member states can nonetheless restrict the free moment or the marketing of specific products lawfully manufactured or marketed in another member state as long as the Commission is notified in advance.[852]

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individuals against other privates. See Sacha Prechal, DIRECTIVES IN EC LAW, Oxford Law Library, 255 (2nd Ed. 2005).

[851] Case 120/78, Cassis de Dijon, [1979] E.C.R. 649, 662, [1979] C.M.L.R. 494 (1979).

[852] See Decision 3052/95/EC of the European Parliament and of the Council of 13 December 1995 establishing a procedure for the exchange of information on national measures derogating from the principle of the free movement of goods within the Community, OJ L 321 (1995). A report on the first years of application of the Decision was published by the Commission on 7 April 2000 - COM(2000) 194

3.3 Conformity assessment

The process of showing that a product complies with applicable requirements is known as conformity assessment.[853] The Global Approach introduced conformity assessment procedures to be used in New Approach Directives.[854] Through these conformity assessment procedures,[855] public authorities can ensure that products placed in the market conform to the requirements included in the directives applicable to them while at the same time manufacturers can prove that their products comply with the safety requirements included in New Approach Directives and obtain the declaration of conformity.[856]

There are different ways in which the determination of conformity can be done. All the conformity assessment procedures are based on modules[857] that vary depending on whether they are applied to the manufacturing phase of the product, the design phase, or both.[858] These modules describe the elements that a manufacturer must use in order to

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final. All this information is available at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31995D3052:EN:NOT

[853] The formal definition of conformity assessment procedures by the ANSI is the "demonstration that specified requirements relating to a product, process, system, person or body are fulfilled." See ANSI: Understanding the Benefits of Accreditation, http:// www.ansi.org/conformity_assessment/accreditation_programs/benefits.aspx? menuid=4.

[854] See Council Decision on a Global Approach to Conformity Assessment 90/683/EEC, 1990 O.J. (C 10), which was amended by the Council Decision 93/465/EEC of 22 July 1993 concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the CE conformity marking, which are intended to be used in the technical harmonization Directives.

[855] Christopher Hodges, EUROPEAN REGULATION OF CONSUMER PROTECTION SAFETY, 31, 87, Oxford University Press (2005).

[856] Modules for conformity assessment are defined in the Council Decision of 22 July 1993 (93/465/EEC). See also Christopher Hodges, EUROPEAN REGULATION OF CONSUMER PROTECTION SAFETY, 62, appendix 5, Oxford University Press (2005). For a discussion of the relationship between mandatory and voluntary regulations in European consumer protection see Geraint G. Howells, The Relationship between product liability and product safety –understanding a necessary element in European Product Liability through a Comparison with the U.S. position, 39 Washburn L. J. 305 (2000).

[857] The modules applicable to a certain produce vary depending on the product and the risks involved in it. Generally, the higher risks the product presents, the more complex the conformity assessment process is. See Council Decision 93/465 (1993) concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the CE conformity marking, which are intended to be used in the technical harmonization directives.

[858] If a manufacturer would subcontract the product design or production, he would still remain responsible for the execution of conformity assessment for both phases. See Mark R. Barron, Creating consumer

show that the product complies with the safety requirements included in the applicable directive.[859]

The conformity assessment procedures are based on the intervention of either the manufacturer or a third independent party, called a notified body, which must ensure in its assessment, approval and surveillance that the product complies with the applicable product regulation.[860] Through the first conformity assessment method, product manufacturers issue a self-declaration of compliance with the safety requirements included in the directives applicable to the product. Given that no third party is involved in this quality assessment process, the manufacturer must provide all the documentation required by the conformity assessment procedure regarding the design, manufacture and operation of the product and include a declaration of conformity.[861] It is also generally required that the manufacturer keeps all the technical documentation for a period of ten years after the product has been manufactured so that domestic authorities can check whether the self-declaration is adequate.

The other method for a manufacturer to obtain a declaration of conformity involves the manufacturer filing an application with the third party notified body. The application must be supported by all the technical documentation and include a product sample in order to obtain the body's conformity assessment.[862] The notified body examines the quality of the manufacturer's product in order to ensure its conformity with

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confidence or confusion? The role of product certification marks in the market today, 11 Marq. Intell. Prop. L. Rev. 413, 427 (2007).

[859] See http://ec.europa.eu/enterprise/policies/single-market-goods/files/blue-guide/guidepublic_en.pdf at 31-33. For a comprehensive list and explanation of the different modules see Christopher Hodges, EUROPEAN REGULATION OF CONSUMER PRODUCT SAFETY, 292-296, Oxford University Press (2005).

[860] See the Guide to the Implementation of Directives Based on New Approach and Global Approach, Chapter 5 on Conformity assessment procedure available at http://ec.europa.eu/enterprise/policies/single-market-goods/files/blue-guide/guidepublic_en.pdf

[861] Some authors consider that the fact that CE marking can often be obtained by the manufacturers' self-declaration should be a matter of concern. Geraint G. Howells, The relationship between product liability and product safety – understanding a necessary element in the European Product Liability through a comparison with the U.S. position, 39 Washburn L. J. 305, 345 (2000).

[862] H-W. Micklitz, PRINCIPLES OF JUSTICE IN PRIVATE LAW WITHIN THE EUROPEAN UNION, IN PRINCIPLES OF JUSTICE AND THE LAW AT THE EUROPEAN UNION, 8, E. Paasivirta and K. Rissanen (eds.), Institute of International Economic Law, University of Helsinki (1995).

the applicable directives; if the product complies, the body attaches its identification number on the approved product and issues a certificate of conformity.[863]

Regardless of the method followed, the responsibility lies with the manufacturer to apply the appropriate conformity assessment procedure, and either issue a self-declaration of conformity or seek a declaration of conformity from the third party notified body.[864]

The amount and type of documentation that the manufacturer must keep under the self-declaration procedure or under the third party conformity assessment procedure depends on the nature of the product and the regulation applicable to it. In either case, the retained documentation must be such as to enable authorities to determine whether the product complies either with the essential safety requirements included in the applicable New Approach Directive or with the applicable harmonized standards set by the standardization bodies.[865]

These conformity assessment procedures are strongly based on the role of member state authorities in encouraging manufacturers to test their products and seek certification from the notification bodies or to issue self-declarations.[866] These procedures are not free from implementation problems at the procedural and structural levels. Procedural problems arise because of the lack of a common conformity assessment procedure in all directives. This variance causes problems for manufacturers, whose

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[863] However, the two most important approaches to conformity assessment are based either on an approved total quality management system named ISO 9000 series standard or on individual product assessment. See Suzanne Laplante, The European Union's General Product Safety Directive: another call for US exporters to comply with the ISO 9000 series, 22 Syracuse J. int'l L. & Com. 155, 162 (1996).

[864] Even though the three procedures are available to manufacturers, most of the New Approach directives require the intervention of a third party conformity assessment body called notified body. Geraint G. Howells, CONSUMER PRODUCT SAFETY, 110-14 (Dartmouth) (1998).

[865] See the Guide to the Implementation of Directives Based on New Approach and Global Approach, Chapter 5 on Conformity assessment procedure available at http://ec.europa.eu/enterprise/policies/single-market-goods/files/blue-guide/guidepublic_en.pdf at 34-35.

[866] The Commission has had an active role in making such symmetric enforcement possible and has passed some resolutions in this respect. See the Conformity Assessment and CE Marking Decision 1993 O.J. L 200/23 and the European organization for Testing and Certification (EOTC), established on April 25, 1990 on the basis of the memoranda of understanding between the Commission, EFTA and CEN.

products may be covered by more than one directive and thus may be subject to different conformity assessment procedures. At the same time, it is not uncommon for member states to have more than one notification body, which can result in confusion (for both manufacturers and public authorities) over which of these bodies is the proper one to turn to for a given declaration of conformity.

Structural difficulties arise from the fact that these procedures are designed at the European level but implemented at the domestic level.[867] Member states may have the temptation to be benevolent to their own manufacturers and facilitate declarations of compliance for them. The European Commission, being aware of this potential problem, has included as part of the New Approach, an automatic recognition and acceptance clause under which member states must recognize and accept each others' testing and certification procedures.[868] On the basis of this harmonization, conformity assessment procedures result in the CE marking, which is a common product mark that signals the approval of that product to access the entire Union's internal market.[869]

3.4 Notified bodies

[867] The European commission developed the Global Approach to Certification and Testing (OJ 1989 C 267/3) which lead to the Council Resolution on a Global Approach to Conformity Assessment of December 21 1989 (OJ 1990 C 10/1). The outcomes of this global approach included the Conformity Assessment and CE Marking Decision (OJ 1993 L 220/23) and the establishment of the European Organization for Testing and Certification (EOTC).

[868] This mutual recognition is automatic in the case of products coming from a European member state. However, there is also mutual recognition for products coming from third countries of the European Economic Area and EFTA states whenever there is a Mutual Recognition Agreement (MRA) signed between the European Union and that country. See Guide to the Implementation of Directives Based on New Approach and Global Approach, Chapter 9 on External Aspects, 63. This document can be found at: http://ec.europa.eu/enterprise/newapproach/legislation/guide/document/chap09.pdf

[869] See the proposal for a Council Decision regarding the modules for the various phases of the conformity assessment procedures which are intended to be used in the technical harmonization directives, O.J. C231/3, COM (89) 209 (1989). For a critical perspective on this issue see H. Micklitz, Inquiry on EC and current national certification schemes for particular consumer goods, SECO, 1990.

New Approach Directives include a mandate for the creation of notified bodies, privately or publicly owned, the function of which is to provide independent verification that certain aspects of the product design, manufacture or quality system have been satisfactorily carried out by the manufacturer.[870] Once the product passes this evaluation, the notified body issues the conformity assessment declaration according to the requirements established by the applicable directives. [871]

Member States have the responsibility to ensure that these notified bodies meet certain requirements that are included in the annexes of the applicable directives.[872] Each directive provides the legal basis for notification and for the legally binding criteria that member states must apply to the bodies in question.[873]

Up to today, notified bodies have developed different procedures and criteria that may result in diverse notification systems in the different bodies of the member states under the same directive. For that reason, the Commission has recently proposed consolidating the requirements that notified bodies will have to fulfill.[874]

Once a notified body has been created, member states are responsible to inform the Commission and the other member states that this body will conduct conformity assessment procedures under the applicable directive. States are also responsible for

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[870] The exact function of each body is determined in each Directive but is generally different from the pre-marketing conformity assessment functions, which are under the manufacturers' responsibility.

[871] Approximately 1000 bodies had been notified to the Commission by the end of 2002. See Communication from the Commission to the Council and the European Parliament, Enhancing the Implementation of the New Approach Directives, 7.5.2003, COM(2003) 240 final, Tables 1a and 1b in annex II. This document may be found at http://eur-lex.europa.eu/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=COMfinal&an_doc=2003&nu_doc=240

[872] For a list of the notified bodies by country, product or directive. See NANDO-IS, that is a web site that links directly to the database of Notified Bodies (NANDO). http://europa.eu.int/comm/enterprise/nando-is/home/index.cfm.

[873] Council Decision 93/465/EEC of 22 July 1993 concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the CE conformity marking.

[874] Communication from the Commission to the Council of the European Parliament; Enhancing the Implementation of the New Approach Directives, COM (2003) 240, 7.5.2003. See additionally Christopher Hodges, EUROPEAN REGULATION OF CONSUMER PROTECTION SAFETY, 66, Oxford University Press (2005) discussing the role of the European Commission.

informing the Commission and other member states if they wish to remove a notified body.[875]

These procedures are not always fully observed and sometimes governments fail to send the notification to all other member states,[876] which causes problems for the recognition of notified bodies or for the certificates of conformity they issue. This can ultimately result in restrictions on the free movement of goods.[877] Since New Approach Directives were implemented, there has not been a systematic exchange of information between member states regarding the criteria and procedures applied by notified bodies.[878] This lack of uniformity and supervision at the European level may be significantly undermining states' confidence in the mutual recognition principle and creating problems both in the level of product safety and in the functioning of the internal market. Transparency regarding the implementation of the requirements concerning notified bodies is one of the key elements for the success of the system created by New Approach Directives.

Whenever a member state informs the European Commission and other member states of the creation of a notified body, that body is to enjoy mutual recognition by the notified bodies of the other member states.[879] Consequently, once such a notified body

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[875] Christopher Hodges, EUROPEAN REGULATION OF CONSUMER PROTECTION SAFETY, 186, Oxford University Press (2005).

[876] Communication from the Commission to the Council and the European Parliament, Enhancing the Implementation of the New Approach Directives, 7.5.2003, COM(2003) 240 final, page 7. The text of this Communication is available at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2003:0240:FIN:EN:PDF

[877] See Mark R. Barron, Creating consumer confidence or confusion? The role of product certification marks in the market today, 11 Marq. Intell. Prop. L. Rev. 413, 439 (2007) noting that the recognition of notified bodies as well as of the certifications they issue has taken place within the European Union but also between different states, through entering into mutual recognition agreements of their conformity assessment bodies in order to facilitate and promote trade.

[878] Communication from the Commission to the Council and the European Parliament, Enhancing the Implementation of the New Approach Directives, 7.5.2003, COM(2003) 240 final. Page 7. The text of this Communication is available at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2003:0240:FIN:EN:PDF

[879] See Guide to the Implementation of Directives Based on New Approach and Global Approach, Chapter 9 on External Aspects, 63. This document can be found at: http://ec.europa.eu/enterprise/newapproach/legislation/guide/document/chap09.pdf

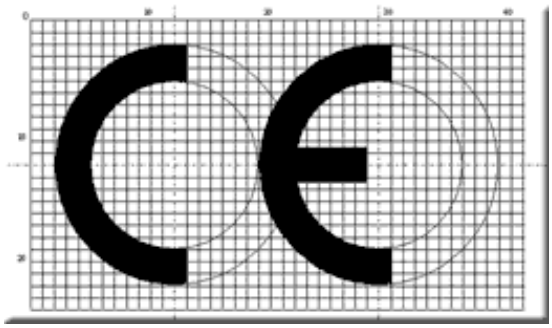
issues a conformity certificate, the product must be allowed to be marketed in all of the European Union member states.[880] For that reason, some New Approach Directives require notified bodies to have an active exchange of information so that notice on denials and withdrawal of certificates are widely and quickly known. This is especially important to prevent non-complying products from being marketed in a member state different from its state of origin and to prevent products from being submitted for certification several times. The information transmitted by notified bodies to other notified bodies needs only to refer to the type of product and to the reasons for denial or withdrawal; thus, confidential information about a product provided by the manufacturer is protected.[881]

3.5 CE marking

The Global Approach also established and called for the use of the CE marking.[882] The CE marking is the result of the conformity assessment procedures regarding compliance with the applicable directives. Once it is determined that a product complies with the established requirements and a conformity declaration is issued, a CE marking sign or a sticker is attached to the product.[883] This shows that the product conforms to all the obligations and all requirements included in the directives applicable to it -- compliance with essential requirements included in the applicable New Approach

[880] However, authorities do not always have the tools to assess and control the activities of the notified bodies they have designated, but which operate in countries outside their jurisdiction. This may impede authorities from taking appropriate measures if the bodies' activities do not conform to the applicable legal requirements set out in the directives.
[881] Guide to the Implementation of Directives Based on New Approach and Global Approach, Chapter 6 on Notified Bodies, 39. This document can be found at:
http://ec.europa.eu/enterprise/newapproach/legislation/guide/document/chap07.pdf
[882] Council Decision 90/683, Global Approach Resolution, Council Decision 93/465, 1993 O.J. (L 220) 23.
[883] The CE mark is covered by Council Decision 93/465/EC that harmonizes the rules for affixing and using the CE marking. Annex B(d) gives these guidelines for the CE marking regarding its size, the place where it should be affixed on the product and the requirements regarding its visibility.

directives and with conformity assessment procedures as governed by the modules established by Global Approach -- and can therefore freely circulate within the European Union market.[884] Failure to comply with the directives applicable to the product can affect the manufacturer's rights regarding the product or its brand.[885]



The CE marking is not a commercial quality mark but it is equivalent to a declaration by the manufacturer (or his authorized representative) -- whether established inside or outside the Community -- stating that the product conforms to all applicable provisions.[886] The flexibility introduced by the New Approach in offering free circulation of products throughout the European Union market entailed an increased responsibility on the manufacturer for the conformity of the product with the safety provisions of the directives applicable to it and for the affixing of the CE marking.[887]

The CE marking, required by the Global Approach on most products in order to allow free circulation in the European Union market, coexists with different domestic

[884] See Guide to the Implementation of Directives Based on New Approach and Global Approach, Chapter 5 on CE Marking. This document can be found at:
http://ec.europa.eu/enterprise/newapproach/legislation/guide/document/chap07.pdf
See also Mark R. Barron, Creating consumer confidence or confusion? The role of product certification marks in the market today, 11 Marq. Intell. Prop. L. Rev. 413, 428 (2007).
[885] Mark R. Barron, Creating consumer confidence or confusion? The role of product certification marks in the market today, 11 Marq. Intell. Prop. L. Rev. 413, 424 (2007).
[886] See http://www.cemarking.net/ce-mark. See also Geraint G. Howells, CONSUMER PRODUCT SAFETY, 45-46 (Dartmouth) (1998) and Christopher Hodges, EUROPEAN REGULATION OF CONSUMER PROTECTION SAFETY, 57, Oxford University Press (2005).
[887] See Commission Guide to the Implementation of Directives Based on the New Approach and the Global Approach, 7-8 (2000). This document is available at http://
europa.eu.int/comm/enterprise/newapproach/legislation/guide/document/1999_1282_ en.pdf

certification marks of different member states.[888] During the last 20 years, certification marks -- as well as conformity assessment procedures -- have increased in number and kind in different countries. The impact of this increase in certification marks -- local or national -- on the performance of the CE marking remains unclear so it is still not possible to conclude whether multiple certification marks on a product may result in consumer or market confusion. Nevertheless, in light of the importance of certification marks for the functioning of the internal market and the high level of consumer protection pursued by the European Commission, the increase in the amount and variety of certification marks should closely be observed so that CE marking does not lose the purpose it aimed at achieving.[889]

3.6 Product withdrawal

While member states must recognize the product safety certifications issued by their own domestic notified bodies and the notified bodies of the other member states they can also take steps to block or withdraw a product from the market when it is found that the product may endanger the safety of individuals, domestic animals or property.

Monitoring the products about to be introduced or already introduced in the domestic market is the responsibility of domestic market surveillance authorities, whose role is crucial to ensure a successful implementation of New Approach Directives and to achieve the desired high degree of consumer protection at which these directives are

[888] Local marks that coexist with CE marking are for example VDE in Germany or BSI in the United Kingdom.

[889] See Commission Guide to the Implementation of Directives Based on the New Approach and the Global Approach, 7-8 (2000). The document is available at http://europa.eu.int/comm/enterprise/newapproach/legislation/guide/document/1999_1282_ en.pdf Noting that conformity assessment procedures in the European Union have significantly changed in the last 20 years and have impacted the use of certification marks.

aimed.[890] If a product is deemed unsafe, the competent market surveillance authority of a member state has the power to withdraw it from the market under what is often called the "safeguard clause" included in New Approach Directives.[891] Such actions may be taken at any of the different stages of the product's life: before it is marketed or once it is already in the market.[892]

Given the economic consequences that a product withdrawal may have for product manufacturers, this procedure involves not just domestic authorities but also the European Commission, and it includes numerous guarantees in order to ensure that there are enough grounds in support of the product withdrawal.[893]

Before adopting any withdrawal action, the authorities of the member states must inform the European Commission that they are considering adopting such a measure so that all member states can coordinate their subsequent actions. Once the Commission is notified, it decides whether the measure is justified.[894] If it deems the measure justified, the Commission will then inform the other states that they should also prevent the product from being marketed.[895]

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[890] However, there is no evidence that these enforcement mechanisms are uniform throughout the different European member states.

[891] Member States are obliged to take restrictive measures against products that are found to be unsafe. The safeguard clause procedure provided for in New Approach Directives allows the European Commission to check the grounds for national measures that aim to restrict the free movement of goods bearing the CE marking. See Communication from the Commission to the Council and the European Parliament, Enhancing the Implementation of the New Approach Directives, 7.5.2003, 15 COM(2003) 240 final.

[892] Allowing the European Commission to take actions against a certain product places the consumer safety's interests before those of the manufacturer. See Anthony Scascia, Safe or sorry: how the precautionary principle is changing Europe's consumer safety regulation regime and how the United States' Consumer Product Safety Commission must take notice, 58 Admin. L. Rev. 689, 706 (2006).

[893] Any non-compliance does not justify the adoption of restrictive measures. The product must present significant risks and must be considered unsafe. See European Commission "Guide to the Implementation of Directives Based on New Approach and Global Approach", Chapter 8 on Market Surveillance, at 57. This document is available at http://ec.europa.eu/enterprise/newapproach/legislation/guide/document/chap08.pdf

[894] See Guide to the Implementation of Directives Based on New Approach and Global Approach, Chapter 8 on Market Surveillance, at 60. This document is available at http://ec.europa.eu/enterprise/newapproach/legislation/guide/document/chap08.pdf

[895] If the product manufacturer would consider that such measure was not justified, it could subsequently challenge it in court. See Anthony Scascia, Safe or sorry: how the precautionary principle is changing Europe's consumer safety regulation regime and how the United States' Consumer Product Safety Commission must take notice, 58 Admin. L. Rev. 689, 706 (2006).

In addition to withdrawal from Europe-wide circulation, domestic authorities may also consider that a product should be withdrawn simply from its own market because of non-compliance with domestic standards. This could occur when the product complies with European-level safety requirements but not the stricter requirements that a member state may impose.[896] In these cases, the European Commission, which has priority in harmonizing safety standards in the union's internal market, adopts even more precautions before withdrawing the product from the market and refers the case to the Standing Committee for a determination as to whether the domestic standard in question conflicts with European safety standards.[897] After studying the action, the Commission will notify the member state whether the domestic standard needs to be withdrawn and, if so, the consequences of this withdrawal on the product's continued circulation.

4 Standard-Receptive Directives (General Product Safety Directive)

The other major body of European product safety regulation, together with New Approach Directives, is structured around the General Product Safety Directive,[898] which will be the focus of this section.

The General Product Safety Directive (GPSD)[899], in effect since January 15, 2004,[900] aims to protect consumer health and safety by imposing an obligation on

[896] The European Commission has tried to overcome this problem by promoting the participation of the national delegations of the different member states in order to harmonize as much as possible the standardization process and avoid a diverse application of product standards. See Article 2(b) of the GPSD. See also Geraint G. Howells, The Relationship Between Product Liability and Product Safety -- Understanding a Necessary Element in European Product Liability Through a Comparison with the U.S. Position, 39 Washburn L.J. 305, 328 (2000).

[897] See the Commission Green Paper on the Development of European Standardization: Action for Faster Technological Integration in Europe, COM (90) 456 final, 8 October 1990. This paper is available at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:1996:0013:FIN:EN:PDF

[898] Council Directive 92/59/EEC of June 29, 1992 on General Product Safety, O.J. L228 24 (Aug. 11, 1992) amended by the Council Directive 2001/95/EC of December 3, 2001 on General Product Safety O.J. (L 11) (January 15, 2002).

member states to ensure that only safe consumer products are placed in the European market[901] while ensuring that the functioning of the internal market is protected and enhanced.[902] Unlike New Approach Directives with their essential safety requirements, the GPSD is a standard-receptive directive.[903] This means that the GPSD provides for a general obligation of placing safe products in the market but does not include the safety standards products must comply with. So products must comply with safety standards *not* included in the GPSD itself.

The GPSD was originally adopted in 1992[904] and was revised in 2001.[905] Its 2001 revision entered into force in 2004. The 1992 version of the GPSD introduced into the European Union the concept of a "general product safety obligation" in order to ensure a

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[899] GPSD, Council Directive 2001/95/EC of December 3, 2001 on General Product Safety O.J. (L 11) (January 15, 2002).

[900] The GPSD 2001/95/EC came into force when it was published in the Official Journal of the European Communities (OJEC L 11) on 1-15-2001 and overruled the former product safety directive 92/59/EEC. However, the new GPSD did not have any effect until January 15th 2004 that was the deadline of member states to transpose the directive into domestic law. See also Norbert Reich, Christopher Goddard And Ksenija Vasiljeva, UNDERSTANDING EU LAW, OBJECTIVES, PRINCIPLES AND METHODS OF COMMUNITY LAW, 213-215 (Interscentia 2003).

[901] Art 1(1) of the GPSD. However, even though European product safety is harmonized, differences between consumers regarding attitudes towards risk may significantly vary. Geraint G. Howells, The Relationship Between Product Liability and Product Safety -- Understanding a Necessary Element in European Product Liability Through a Comparison with the U.S. Position, 39 Washburn L.J. 305, 328 (2000).

[902] See Council Directive 2001/95, 2001 O.J. (L11) 4 (EC) including a goal of ensuring the importance of protecting consumer health and safety while ensuring a proper functioning of the European internal market based on the precautionary principle. See also Frances E. Zollers, Sandra N. Hurd, Peter Shears, Product Safety in the United States and the European Community: a comparative approach, 17 Md. J. Int'l L. & Trade 177, 179 (1993).

[903] Examples of this type of Directives are the Council Directive 86/594/EEC on Airborne noise emitted by household appliances; the Council Directive 97/67/EC Community postal services, Amended by 2002/39/EC; the Council Directive 76/769/EEC on Restrictions on marketing and use of certain dangerous substances and preparations and the Council Directive 2002/96/EC on Waste electrical and electronic equipment (WEEE) amended by the Council Directive 2003/108/EC.

[904] Council Directive 92/59/EEC of June 29, 1992 on General Product Safety, O.J. L228 24 (Aug. 11, 1992). This directive was the first general directive on consumer safety and introduced the concept of a general safety directive.

[905] Council Directive 2001/95/EC of December 3, 2001 on General Product Safety O.J. (L 11) (January 15, 2002).

high and uniform level of safety of consumer products throughout the European Union. However, it did not have much impact.[906]

The 2001 revision of the GPSD maintained the requirements of the original 1992 GPSD but added and reinforced provisions regarding the directive's scope of application, required producers to provide information to consumers about product risks and product recall, emphasized the application of standards in order to ensure that only safe products could be marketed, reinforced the powers of authorities for market surveillance, established a framework for sharing information regarding product risks and for facilitating the collaboration between authorities of the different member states, and finally, aimed to ensure that unsafe products were withdrawn from the market through rapid intervention measures.[907]

The GPSD is based on the precautionary principle,[908] which aims at establishing a coherent level of consumer protection for all consumer products in the internal market without interfering or overlapping with sector-specific legislation.[909] For that reason, the GPSD declares a right of consumers throughout the European Union to a minimum level

[906] Some practitioners argued that the GPSD '92 did not have much impact because it did not go far enough in terms of enforcement measures and was too vague regarding some important provisions. See The International Comparative Legal Guide to: Product Liability 2007, Chapter 3. Product Safety: The New EU Regime. This document is available at http://www.iclg.co.uk/khadmin/Publications/pdf/1486.pdf

[907] See generally Council Directive 2001/95/EC of December 3, 2001 on General Product Safety O.J. (L 11) (January 15, 2002).

[908] The precautionary principle is based on the premise that the government should regulate potential risks before they become certain. The European Commission has stated repeatedly that the precautionary principle should be taken into account when analyzing and quantifying risks. The Commission has structured risk analysis in three different elements: risk assessment, risk management and risk communication and has noted that the precautionary principle is particularly associated with risk management. See Communication from the Commission on the Precautionary Principle COM (2000) 1 final, 1-2 (2000) emphasizing the importance of the precautionary principle for the European Commission.

[909] Guidance Document on the Relationship Between the General Product Safety Directive (GPSD) and Certain Sector Directives with Provisions on Product Safety, Directorate General Health and Consumer Protection, (DG SANCO) November 2003 at 39. This document is available at http://ec.europa.eu/consumers/cons_safe/prod_safe/gpsd/guidance_gpsd_en.pdf

of product safety and establishes that non-compliance will result in sanctions by governmental authorities responsible for the enforcement and punishment.[910]

The GPSD complements specific product safety legislation as well as operates on its own when no such legislation exists. In general, specific directives have priority over general provisions of the GPSD, but the GPSD nonetheless applies to products covered by specific legislation, governing those areas that the specific legislation does not address.[911] In cases when there is no applicable specific legislation,[912] the GPSD applies fully.

The GPSD can be divided into three different parts. First, articles 3 and 4 establish a general safety obligation that is applicable whenever sector directives do not cover the category of risk involved. Second, articles 5-18 apply as long as the issue considered is not regulated by a specific provision in a sector directive.[913] Finally, the GPSD includes notification requirements[914] applicable to all sector directives for products with CE markings.[915] The GPSD requires member states to notify the European Commission whenever a consumer product presents serious risks. Such notification is done through a notification procedure called the European Rapid Alert System for non-

[910] Frances E. Zollers, Sandra N. Hurd, Peter Shears, Product Safety in the United States and the European Community: a comparative approach, 17 Md. J. Int'l L. & Trade 177, 178 1993. See also Geraint G. Howells, The relationship between product liability and product safety – understanding a necessary element in the European Product Liability through a comparison with the U.S. position, 39 Washburn L. J. 305, 335 - 336 (2000).

[911] Guide to the implementation of Directives based on the New Approach and the Global Approach. See http://europa.eu.int/comm/enterprise/newapproach/legislation/guide/legislation.htm. See also Geraint G. Howells, The relationship between product liability and product safety – understanding a necessary element in the European Product Liability through a comparison with the U.S. position, 39 Washburn L. J. 305, 335-336 (2000).

[912] Suzanne Laplante, The European Union's General Product Safety Directive: another call for US exporters to comply with the ISO 9000 series, 22 Syracuse J. int'l L. & Com. 155, 162 (1996).

[913] Guidance Document on the Relationship Between the General Product Safety Directive (GPSD) and Certain Sector Directives with Provisions on Product Safety, Directorate General Health and Consumer Protection, (DG SANCO), 39 November 2003.

[914] Article 12 GPSD. Guidance Document on the Relationship Between the General Product Safety Directive (GPSD) and Certain Sector Directives with Provisions on Product Safety, Directorate General Health and Consumer Protection, (DG SANCO), 40 November 2003.

[915] These sector Directives would be New Approach Directives that regulate specific kinds of products and provide for CE marking. See http://ec.europa.eu/enterprise/newapproach/legislation/directives/table1.htm.

food consumer products (RAPEX). With respect to products covered under sector directives, in addition to the RAPEX notification, there are other notification processes established and designed by the specific sector directive. In cases where notification is not required under safeguard clauses of New Approach Directives or under the RAPEX system of the GPSD,[916] the GPSD requires member states to give notification to European authorities of any domestic measure adopted.[917]

4.1 The relationship between the GPSD and New Approach Directives

The GPSD, as adopted in 1992,[918] was not a New Approach Directive because it did not include essential safety requirements and did not provide for CE marking. The new GPSD[919] of 2001 is still not a New Approach Directive even though it shares some of the New Approach characteristics and has important implications for consumer products covered by New Approach legislation.

As mentioned above, New Approach Directives regulate all aspects of safety and risk regarding the products to which they apply. In this context, the GPSD is a horizontal directive that complements the specific vertical New Approach Directives (and related directives) and applies to consumer products not covered by specific EU regulation.[920] When a product is regulated by a New Approach Directive and complies with the

[916] Article 12, of the GPSD refers to the RAPEX procedure.
[917] Article 11 of the GPSD.
[918] Council Directive 92/59/EEC of June 29, 1992 on General Product Safety, O.J. L228 24 (Aug. 11, 1992).
[919] Council Directive 2001/95/EC of December 3, 2001 on General Product Safety O.J. (L 11) (January 15, 2002).
[920] See Sacha Prechal, DIRECTIVES IN EC LAW, Oxford Law Library, 255 (2nd Ed. 2005) for the difference between vertical and horizontal directives.

essential safety requirements, the product is deemed to comply with the GPSD as well.[921] In this sense, the GPSD functions as a safety net.

Hence, the safety requirement included in the GPSD applies to consumer products only when the specific regulation applicable to them does not contain provisions on safety and risks. New Approach Directives include these essential safety requirements but that does not imply that the GPSD does not affect products covered by them: New Approach Directives do not include provisions regarding enforcement mechanisms and it is the GPSD that provides them.[922]

4.2 The safety net: the general safety obligation in the GPSD

In 1989, the European Council adopted a resolution on future directions for the European Community consumer protection policy[923] in which it stated the importance of promoting a high level of safety and established the need for better information about products and services in order to improve the confidence of consumers in the functioning of the European internal market.

The European Council recognized the difficulty of relying on horizontal regulations alone to set Community-wide standards that would ensure the high level of consumer safety and health protection sought. For that reason, it created in the GPSD a

[921] Compliance with harmonized standards raises a presumption of conformity with the essential requirements included in New Approach directives. See the Commission Green Paper on the Development of European Standardization: Action for Faster Technological Integration in Europe, COM (90) 456 final, 8 October 1990. This paper is available at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:1996:0013:FIN:EN:PDF

[922] See infra for an explanation of these enforcement mechanisms but among these enforcement mechanisms, the GPSD includes the requirement for member states to define the organization and tasks of surveillance authorities, the RAPEX procedure and the imposition of the obligation to manufacturers to order the recall of dangerous products.

[923] Council Resolution 89/ C 294 of November 9th 1989 on future priorities for relaunching consumer protection policy, 1989 OJ (C 294) 1

general duty of safety,[924] which interacts with the product-specific safety rules that are tailored to the particular characteristics of the products they regulate. The general duty included in the GPSD takes the form of a safeguard clause that imposes a general safety obligation on all product manufacturers for all products they place in the market.[925]

The GPSD requires all consumer products to conform to applicable safety standards or, in the absence of a standard, to conform to "the degree of safety that consumers and users in general can reasonably expect."[926] Through this general safety duty, the GPSD becomes the basis of authority for proceeding against any and all consumer products that pose a danger[927] and for imposing liability on producers for marketing unsafe products even without causing any injury to an end-user.[928] This general duty of product safety represents a consumer-oriented bias when determining whether a product may be deemed unsafe.[929]

The general safety obligation can be considered part of the pre-marketing product control mechanisms because even though it does not impose any specific control on the product manufacturer, it is intended to influence the manufacturer's decisions regarding

[924] Article 3(2) of the GPSD. See also A. Ogus, REGULATION: LEGAL FORM AND ECONOMIC THEORY, 150, 170 (Oxford 1994) who considers that such general obligation provides regulators with a discretion that impedes public scrutiny and leaves economic operators uncertain as to what is required to them.
[925] Article 1(2) of the GPSD. Such duty does not apply to products covered by "specific rules of Community law of the total harmonization type." See Recital 7 of the GPSD. See also Suzanne Laplante, The European Union's General Product Safety Directive: another call for US exporters to comply with the ISO 9000 series, 22 Syracuse J. int'l L. & Com. 155, 162 (1996).
[926] Recital 16 of the GPSD. In practice, the Directive is only relevant for non-food products given that food safety is regulated by specific food safety regulation. See Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, O.J. L 031 (2002), applicable to food products.
[927] Article 2(b) of the GPSD. See also Frances E. Zollers, Sandra N. Hurd, Peter Shears, Product Safety in the United States and the European Community: a comparative approach, 17 Md. J. Int'l L. & Trade 177, 190 (1993).
[928] Suzanne Laplante, The European Union's General Product Safety Directive: another call for US exporters to comply with the ISO 9000 series, 22 Syracuse J. int'l L. & Com. 155, 165-166 (1996).
[929] See Anthony Scascia, Safe or sorry: how the precautionary principle is changing Europe's consumer safety regulation regime and how the United States' Consumer Product Safety Commission must take notice, 58 Admin. L. Rev. 689, 691 (2006) considering the general obligation of safety preferable to a cost benefit approach when determining whether a product may be qualified as unsafe because it allows focusing only on the safety of all consumers instead on cost-benefit considerations.

the level of safety to adopt.[930] These safety incentives are created through the imposition of penalties for marketing an unsafe product regardless of whether the product has injured a consumer or product user.[931]

This general duty provides two important benefits. On one side, it creates an incentive for manufacturers to factor in product safety as a priority when designing, manufacturing and distributing products. On the other, it provides guidance as to the consumer expectation standard that is used in subsequent liability procedures.[932] Such safety requirement represents a balancing approach to regulation because it requires removing only those risks that are justified by the benefits or use derived from the product.[933]

The duty is made concrete by requiring member states to adopt adequate measures to ensure that only safe products are marketed and to take action when an unsafe product is placed on the market. In this way, the general safety obligation directly affects member states in that it requires them to adopt laws, regulations or administrative provisions and to create enforcement authorities to enforce such duty.[934]

The GPSD does not specify the content of the general duty and the safety clause functions as an abstract obligation subject to the interpretation of the surveillance authorities of each member state.[935] Despite the uncertainty created by this abstractness, a

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[930] Geraint Howells and Stephen Weatherill, CONSUMER PROTECTION LAW, 10, Ashgate Publishing Company (2005).
[931] Article 3(2) of the GPSD. Suzanne Laplante, The European Union's General Product Safety Directive: another call for US exporters to comply with the ISO 9000 series, 22 Syracuse J. int'l L. & Com. 155, 165-166 (1996).
[932] See article 6 of the product liability directive that established the consumers' expectations test as the defectiveness test. Frances E. Zollers, Sandra N. Hurd, Peter Shears, Product Safety in the United States and the European Community: a comparative approach, 17 Md. J. Int'l L. & Trade 177, 191, 1993
[933] See Geraint Howells and Stephen Weatherill, CONSUMER PROTECTION LAW, 110, Ashgate Publishing Company (2005).
[934] Article 5 of the GPSD.
[935] France, for example, does not provide a sanction for breach of such general safety obligation. French Consumer Code, articles 221-225. Some have suggested attempting to define the safety expectations consumers are entitled to have. See H-W. Micklitz, PRINCIPLES OF JUSTICE IN PRIVATE LAW WITHIN THE EUROPEAN UNION" IN PRINCIPLES OF JUSTICE AND THE LAW AT THE EUROPEAN UNION, 284-286, E. Paasivirta and K. Rissanen (eds.), Institute of International Economic Law, University of Helsinki (1995).

significant proportion of consumer products are governed by specific legislation -- particularly when it comes to the imposition of standards. This specific legislation often makes it possible to easily assess whether a product complies with the general duty of safety of the GPSD because compliance with the specific standards will mean compliance with the general duty.[936]

Although the general duty of safety is most frequently viewed in the context of a product's pre-marketing phase, it also affects the marketing and post-marketing phases as well. When an unsafe product reaches the market in spite of the GPSD's general safety clause and any applicable specific safety legislation, the general duty of safety may still be invoked in the post-market control phase to impose a fine on the manufacturer.[937] This would be done at the member state level, however, as the GPSD does not itself lay out enforcement or remedial measures, but instead leaves it to member state authorities to ensure that marketed products comply with general safety duty.[938]

The existence of a European Union standard and regulatory framework does not imply that manufacturers are subject to a harmonized concept of safety or safety standards: On the contrary, consistent with the European Union's goal of high consumer protection, member states may adopt stricter safety standards, extend the scope of individuals with product safety responsibilities, and even make distributors (as well as producers) liable for unsafe products.[939] The limit on such measures is simply that they

[936] Article 3(2) and article 3(3) of the GPSD includes a list of factors to consider such as voluntary national standards giving effect to European standards, the community technical specifications; standards drawn up in the member states in which the product is in circulation; codes of good practice in respect of health and safety in the sector concerned and the state of the art.
[937] Geraint Howells and Stephen Weatherill, CONSUMER PROTECTION LAW, 128-129, Ashgate Publishing Company (2005).
[938] Article 3(1) of the GPSD. Even though the general duty of safety is created at the Community level, member states are the responsible for its enforcement. In this sense, local particularities are preserved and taken into account. Frances E. Zollers, Sandra N. Hurd, Peter Shears, Product Safety in the United States and the European Community: a comparative approach, 17 Md. J. Int'l L. & Trade 177, 189 (1993).
[939] Article 3(2) of the GPSD.

cannot be imposed if they would create trade barriers.[940] Assuming a member state's stricter safety measures pass this test, these measures may be enforced and will be complementary to Europe-level measures.[941]

4.3 Safe product under the GPSD

The GPSD applies only to consumer products, which are defined as "any product intended for consumers or likely (…) to be used by consumers"[942] supplied in the course of a commercial activity whether new, used or reconditioned.[943] In order to ensure a high level of consumer protection, these consumer products are required to be safe.[944] Under the GPSD this means that they (i) do not present any risk or (ii) present the minimum risks compatible with the product's use.[945] However, other aspects should also be taken into account. These include: the categories of consumers at risk when using the product, especially children and the elderly; the characteristics of the product, including composition, packaging, instruction for assembly or for installation and maintenance; the product's effect on other products; the presentation of the product, including labeling, warnings, instructions for use and disposal, and any other indications or information

[940] Articles 30-36 of the Treaty of Rome established the free circulation of goods, labor and services within the European internal market. See http://ec.europa.eu/economy_finance/emu_history/documents/treaties/rometreaty2.pdf

[941] See Suzanne Laplante, The European Union's General Product Safety Directive: another call for US exporters to comply with the ISO 9000 series, 22 Syracuse J. int'l L. & Com. 155, 159 (1996).

[942] Article 2(a) of the GPSD. The GPSD is only applicable for non-food products as food safety is regulated by Regulation 178/2002/EC of 28 January 2002 – 2002 O.J. L 31. However, there is no equivalent directive for non consumer products.

[943] Article 2(a) of the GPSD defines products. Second-hand products identified by the supplied as antiques or reconditioned products are not included in the definition as long as the supplier informs the person to whom he supplies the product..

[944] Article 2(b). In fact, European regulation regarding consumer protection is structured around the concept of safe product, which is crucial, for example, in the Product Safety and Product Liability Directives.

[945] Article 2(b) of the GPSD '01.

regarding the product.[946] These other aspects are important to assessing safety under the GPSD.

The Directive uses the risk-utility test to define a safe product.[947] This test does not require a zero risk level for consumer products but requires removing risks when a safe alternative exists and removing those risks that are not outweighed by the benefits derived from the product use.[948] Thus, a safe product will have to pass the risk-utility test, which means that it must reach the highest level of safety compatible with its use.

The determination of the level of safety required for a given product is done according to specific product standards considering the product's "fitness for use" and providing the required "safety for the user."[949] The GPSD does not explicitly state the safety requirements for each kind of consumer product but provides a list of factors, related to the product's nature and use, that should be taken into account when evaluating the risks presented by a product:[950] the categories of consumers at risk when using the product; the characteristics of the product; the product's composition; the instructions for assembly and maintenance of the product; the product's effect on other products; and the product's presentation and disposal.[951] The GPSD specifically states that the feasibility of obtaining higher levels of safety or the availability of other products presenting a lesser degree of risk do not necessarily constitute grounds for considering a product "unsafe" or "dangerous."[952]

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[946] Article 2(b) of the GPSD '01.
[947] Article 2(b) of the GPSD clearly states a risk-utility analysis by stating that a product is safe when it does present "only the minimum risks compatible with the product's use." Note that the defectiveness test used by the Council Directive 85/374 of 25 July 1985 Concerning Liability for Defective Products, 1985 O.J. (L 210) 29 is the consumer's expectations test. See Chapter 2 of this dissertation.
[948] Reducing accidents risks to achieve a zero risk level would not be efficient. Accidents should be reduced until the cost of investing in a marginal unit of care is lower or equal to the marginal cost of the accident prevented. See Richard A. Posner, ECONOMIC ANALYSIS OF LAW 167-213, Aspen eds., 6th ed. (2003). See also Thomas J. Miceli, ECONOMICS OF THE LAW, 15, Oxford University Press (1997).
[949] Article 2(b) of the GPSD.
[950] Article 2(b) of the GPSD.
[951] Article 2(b) GPSD.
[952] Article 2(b) last paragraph GPSD. See also Suzanne Laplante, The European Union's General Product Safety Directive: another call for US exporters to comply with the ISO 9000 series, 22 Syracuse J. int'l L. & Com. 155, 158-159 (1996).

The GPSD not only defines safe products with respect to the product characteristics, but it also refers to a product's compliance with safety rules at both the European and the domestic levels.[953] In this sense, a product is deemed safe if it conforms with the specific European safety legislation applicable to it.[954] In the absence of specific European safety legislation, a product is deemed safe if it complies with the specific domestic safety rules in the member state in which the product is marketed.[955]

Whenever there is neither a specific European nor a specific domestic safety provision applicable to the product, compliance with the GPSD's general safety duty is determined based on the state of the art and technological knowledge, analogous domestic standards of the member states where the product is marketed, and reasonable consumer expectations concerning safety.[956]

4.4 The actors of this directive: producers and distributors

Article 3 of the GPSD introduces responsibilities for producers and distributors. It requires these actors to comply with product-specific directives and more generally, with the general safety obligation included in the GPSD. Producers and distributors are not the only actors upon which obligations are imposed. Member states are also required to create a framework where such compliance will be possible and where enforcement mechanisms will ensure that producers and distributors adopt safety standards and comply with the general safety obligation.[957]

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[953] See Article 3(2) and article 3(3) of the GPSD.
[954] Article 3(2) of the GPSD. It should be noted that member states still have an active role in the definition of product safety and therefore can pass regulation establishing higher safety requirements. See also Suzanne Laplante, The European Union's General Product Safety Directive: another call for US exporters to comply with the ISO 9000 series, 22 Syracuse J. int'l L. & Com. 155, 159 (1996).
[955] Article 3(2) of the GPSD.
[956] Article 3(3) of the GPSD.
[957] Christopher Hodges, EUROPEAN REGULATION OF CONSUMER PROTECTION SAFETY, 87-112, 155-190, Oxford University Press (2005).

4.4.1 Primary actors: Producers

Consistent with the goal of minimizing the amount of dangerous products that reach the market, the GPSD embraces in its applicable scope a broad range of agents involved in the manufacturing process so that all of these agents have incentives to seek information regarding the risks of the products they supply and adopt appropriate measures to prevent these risks and to stop dangerous/unsafe products from reaching consumers.

Under the GPSD, producers, as defined in article 2 (e) of the GPSD, include the manufacturer of the product itself, as well as the manufacturer's representatives or importers (in cases where there is no representative in the European Union) and any entity that presents itself as the product manufacturer by affixing its name, trademark or other mark on the product.[958] Additionally, the GPSD also applies to other entities in the supply chain that may affect the safety properties of a product placed on the market.[959]

The GPSD imposes two major duties on producers[960] that are adjusted to the "limits of their respective activities."[961] A first duty, which is mandatory, is to comply with the general safety obligation under which manufacturers must ensure that the products they market are safe.[962] This duty mostly affects the pre-marketing product phase. The second duty, which is voluntary,[963] is to inform consumers of product risks

[958] Article 2 (e) GPSD. See also Christopher Hodges, EUROPEAN REGULATION OF CONSUMER PROTECTION SAFETY, 93, Oxford University Press (2005).
[959] Article 2(e) of the GPSD.
[960] Article 3(1) and Article 5 (1) of the GPSD.
[961] Article 5(1) of the GPSD. However, there is no guidance to determine how this adjustment is going to be made. Christopher Hodges, EUROPEAN REGULATION OF CONSUMER PROTECTION SAFETY, 93, Oxford University Press (2005).
[962] Article 3(1) of the GPSD. See also Geraint G. Howells, The relationship between product liability and product safety – understanding a necessary element in the European Product Liability through a comparison with the U.S. position, 39 Washburn L. J. 305, 339 (2000).
[963] Article 5(1) of the GPSD establishes that among "other obligations" of producers and distributors,

> "Producers *shall* provide consumers with the relevant information to enable them to assess the risks inherent in a product throughout the normal or reasonably foreseeable period of its use, where such risks are not immediately obvious without adequate warnings, and to take precautions against those risks."

and monitor the products they place in the market.[964] This includes creating systems to continuously provide consumers with information about product risks and establishing mechanisms to react to them, including, if necessary, withdrawing products from the market. These informational obligations, that mostly take place at the post marketing product phase, are not uniform across producers given that they adjust to the diverse size, nature and capacities of the different product manufacturers.

The main goal of the informational duty is to provide consumers with information during the foreseeable period of product use about product risks that are not obvious without the product manufacturer's warning.[965] This may be done by marking products for identification purposes, sample testing products, investigating complaints, and keeping distributors informed of the results of monitoring activities.[966] The information provided must be such that the risk is identified in a way that will enable the potential user or consumer to make his or her own risk assessment.[967] Warnings should not be false or misleading and must take into account the perception and knowledge that can reasonably be expected from the potential user or consumer.[968] In light of the existing linguistic differences between the European member states, there is a general agreement between European and domestic legislators[969] that any safety information offered to

[964] Article 3(2) of the GPSD.
[965] Article 5(1) of the GPSD.
[966] Article 5(1) fourth section, GPSD.
[967] Article 5(1) of the GPSD. See also Suzanne Laplante, The European Union's General Product Safety Directive: another call for US exporters to comply with the ISO 9000 series, 22 Syracuse J. Int'l L. & Com. 155, 1996 at 159-160.
[968] The Commission has also approved regulation prohibiting misleading advertising. Article 2.2 Directive 98/8/EEC.
[969] See Council Resolution of 17 December 1998 on Operating Instructions for Technical Consumer Goods, 98C/411/01, OJ C411/1, 31.12.98.

consumers must be provided in the local language or languages of each member state[970] so that consumers are informed of the product risks in an effective manner.[971]

Of course, regardless of the informational duty, a manufacturer that learns of product risks that qualify the product as unsafe or dangerous must take action and, if necessary, withdraw the product from the market.[972]

4.4.2 Secondary actors: product distributors

Distributors also have duties under the GPSD, although such duties are framed under due care and negligence parameters.[973] Distributors are required to act with due care to help ensure compliance with specific safety requirements and with the general safety obligation of the GPSD.[974] In particular, they must collect information on product risks, keep and provide documentation necessary for tracing the origin of products, and cooperate in actions taken by manufacturers and government agencies to avoid risks.

At the same time, distributors should not supply products that they know, or should know, pose risks not compatible with the general safety requirement.[975] As with

[970] Using the words of the European Commission, "information should be presented in a way adapted to local needs and concerns, and be available in all official languages if the Union is not to exclude a vast proportion of its population (…) a challenge which will become more acuter in the context of enlargement." European Commission, European Governance: A White Paper, COM (2001) 428, 25.7.2001.
[971] Christopher Hodges, EUROPEAN REGULATION OF CONSUMER PROTECTION SAFETY, 124, Oxford University Press (2005).
[972] Article 3(2) of the GPSD.
[973] Distributors are defined in article 2(f) of the GPSD as "*any professionals in the supply chain whose activity does not affect the safety properties of a product*."
[974] Article 5(2) and 5(3)of the GPSD.
[975] Article 5(3) of the GPSD. The Directive includes a system for rapid exchange of information between Member States and the Commission on products causing serious risks that allows saving resources while maximizing consumer protection. This information system is called the RAPEX-system by the General product Safety Directive. See section 4.7 of this Chapter.

producers, distributors' duties hinge on the limits and capacities of their respective activities.[976]

The burdens placed on producers and distributors are different, however, in that producers[977] are subject to a higher safety standard than the one placed on distributors.[978] While producers are compelled to place only safe products in the market,[979] distributors are required to help comply with safety obligations and such help is evaluated under negligence parameters.[980] In this sense, distributors are given a subsidiary role to that of producers.

4.4.3 Member States

As mentioned above, producers and distributors are not the only agents that have responsibilities under the GPSD. They are joined by member states, which are required to adopt laws, regulations, and administrative provisions to compel producers and distributors to comply with the obligation of placing only safe products in the European Union market.[981]

Member states must be active parties in two different areas that are crucial for successful implementation of the GPSD: market monitoring and enforcement. Member

[976] Article 5(2) of the GPSD. This difference may be due to the intention of the GPSD of being sensitive to the diverse resources distributors have and the variety of activities they perform. Christopher Hodges, EUROPEAN REGULATION OF CONSUMER PROTECTION SAFETY, 138-140, Oxford University Press (2005).
[977] Producers are defined in art. 2(d) and its obligations are established in article 3. 3(1) includes the obligation to place only safe products on the market while art 3(2) outlines two supporting information obligations: informing consumers of products risks and keeping informed of the risks of the product in order to react to them. Producers are strictly liable for the harm caused as a result of the failure to comply with these obligations.
[978] Article 2(f) of the GPSD. Distributors are subject to a negligence liability regime under which they must exercise due care in order to help ensure compliance with the general safety standard.
[979] Article 3(1) of the GPSD.
[980] Article 5(2) of the GPSD.
[981] Article 6 of the GPSD. See also Suzanne Laplante, The European Union's General Product Safety Directive: another call for US exporters to comply with the ISO 9000 series, 22 Syracuse J. int'l L. & Com. 155, 160-161 (1996).

states must establish and appoint authorities to monitor the compliance of all the producers' duties under the GPSD, allow these domestic authorities to require all necessary information from the parties involved, and make arrangements to ensure that persons who may be exposed to a risk are informed of that risk in a timely and suitable manner.[982] The RAPEX system requires member states to inform the European Commission of serious risks so that it can alert the other member states. At the same time, these domestic authorities may also impose penalties if a producer or distributor fails to comply with the obligations under the GPSD and they may temporarily prohibit marketing of certain products while carrying out inspections, or permanently prohibit marketing if the products have already proved to be dangerous.[983]

4.5 Reporting to authorities: a special obligation under the GPSD

The GSPD is the only directive that explicitly requires producers and distributors to notify authorities when a consumer product is dangerous.[984] Such notification must be provided when the producer or distributor knows or should know that the product is unsafe, based on the information in its possession.[985]

This obligation is two-fold: on one side, it is intended to encourage producers to comply with their post-marketing obligation to monitor product risks, while enabling authorities to control and monitor such compliance. On the other side, it is intended to make sure that the final determination of whether a product is dangerous is done by a public authority so that there are no other commercial interests involved.

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[982] Article 6(2) of the GPSD. Christopher Hodges, EUROPEAN REGULATION OF CONSUMER PRODUCT SAFETY, 155-190, Oxford University Press (2005).
[983] Article 7 of the GPSD.
[984] Article 5.3 of the GPSD. See also Christopher Hodges, EUROPEAN REGULATION OF CONSUMER PRODUCT SAFETY, 143, 145, Oxford University Press (2005).
[985] Article 5.3 of the GPSD.

The practical implementation of this reporting process is quite complicated and does not appear to be very effective because there are no coordination mechanisms[986] between the public authorities who receive the manufacturers' or distributors' notifications regarding product risks and who must decide what action should be adopted.[987] This lack of Europe-wide coordination may undermine the functioning of the internal market and jeopardize the success of the safety obligations under the GPSD.

4.6 Notification procedures under the GPSD

Once producers and distributors have reported to public authorities, member states must notify the European Commission of the actions they decide to adopt. The GPSD includes two kinds of notification procedures: non-emergency and emergency procedures.[988] The former are used most frequently, while the latter are rarely used.

These notification procedures are aimed at producing a coordinated response to cross-border problems that could arise with the application of different standards and different obligations for product manufacturers and distributors. The structure and language of the GPSD is designed to prevent member states from creating trade barriers by taking different measures with respect to the same product. Member states need to define the rule and penalties applicable in case there is a breach of obligations by any of the agents affected by the GPSD and to notify to the Commission.[989] Such procedures are

[986] The GPSD is silent regarding whether there is a reporting obligation to report to an authority of one state when the event has occurred in another member state. See Christopher Hodges, EUROPEAN REGULATION OF CONSUMER PROTECTION SAFETY, 146, Oxford University Press (2005).
[987] Christopher Hodges, EUROPEAN REGULATION OF CONSUMER PROTECTION SAFETY, 144, Oxford University Press (2005).
[988] Directorate General Health and Consumer Protection (DG SANCO), Guidance Document on the Relationship Between the General Product Safety Directive (GPSD) and Certain Sector Directives with Provisions on Product Safety, 12 (2003). This document is available at http://ec.europa.eu/consumers/cons_safe/prod_safe/gpsd/guidance_gpsd_en.pdf
[989] Article 7 of the GPSD.

meant to: (i) supervise the adequacy of the actions of the member states, (ii) inform other member states, and (iii) take community action, where adequate. However, the actual implementation of these procedures takes place at the domestic level and evidence suggests that domestic authorities do not give their European obligations a high priority.[990]

Under the non-emergency procedures, whenever authorities of the member states are notified of product risks, they must adopt measures[991] proportional to the seriousness of the risk and based on the precautionary principle.[992] Once any of these measures have been adopted, the European Commission must be notified.[993] If the European Commission determines that the measure is justified, it informs all other member states. If it concludes that the measures were not justified, the Commission informs the member state that initiated the action.[994]

The GPSD also includes emergency procedures that are applied whenever there is a serious or immediate product risk to the health and safety of consumers in one or some member states.[995] Every time a member state initiates an emergency procedure, it must inform the Commission of any emergency measures taken to prevent or restrict product marketing or use in order to prevent an expansion of the risk of harm beyond the member state's boundaries. It should be noted that whenever there is an immediate risk of harm to consumers in more than one member state, the European Commission is involved in the decision regarding the measures that should be adopted so that there is a Community-

[990] Geraint Howells and Stephen Weatherill, CONSUMER PROTECTION LAW, 144, Ashgate Publishing Company (2005).
[991] Article 8(1) of the GPSD. These measures include restricting the marketing of a product or requiring its withdrawal.
[992] Article 8(2) of the GPSD.
[993] Article 11 of the GPSD.
[994] Article 11(2) of the GPSD.
[995] Article 13 of the GPSD.

wide solution not subject to the sometimes long and difficult discussion among the authorities of the different member states involved.[996]

4.7 RAPEX

RAPEX is a system that allows market surveillance authorities in the different European member states and the European Commission to efficiently share information about dangerous products found in the European market and to further inform consumers about potential risks to their health and safety.[997]

The RAPEX system aims to ensure that information about dangerous products can be quickly circulated among domestic authorities and passed to the European Commission. It also aims to ensure evaluation of the effectiveness of product safety regulation on the basis of product notifications made by European member states to European authorities and the measures adopted.

Information should generally flow between member states regarding product safety but RAPEX is especially relevant in cases where a member state restricts the marketing of a product or requires that a product be withdrawn from the market.[998]

The RAPEX procedure requires notification of measures taken against a product or a class of products that presents a serious and immediate risk to the health and safety of consumers.[999] This notification procedure is established by the GPSD, but it is also one of the areas in which the GPSD and New Approach Directives interact. RAPEX is

[996] When determining the actions that should be adopted the European Commission is assisted by Scientific Committee formed by representatives of the member states. Articles 13 of the GPSD.
[997] See European Commission, Keeping European Consumers Safe, 2009 Annual report on the operation of the Rapid Alert System for non-food consumer products, RAPEX. This document is available at http://ec.europa.eu/consumers/safety/rapex/docs/2009_rapex_report_en.pdf
[998] In fact RAPEX is two parallel systems, one for food products and the other for non-food products. Council Decision 84/133/EEC, OJ 1984 L 70/16. it was subsequently replaced by the Decision 89/45/EEC: OJ L 17/51 as amended by the Decision 90/352/EE, OJ L 173/49.
[999] Article 12 of the GPSD.

applicable to consumer products covered only by the GPSD as well as to products covered by New Approach Directives,[1000] whenever these product-specific directives do not include their own notification procedure.[1001]

When a consumer product falls within the scope of RAPEX[1002] and a serious and immediate risk is detected,[1003] measures, based on information about the product and the nature of the risk provided by the producer or the distributor, may be adopted. Each of the 30 countries participating in this system[1004] appoints a RAPEX contact point.[1005] The contact point submits to the Commission detailed information about the risks presented by dangerous products found in that country's market and the measures domestic authorities are considering adopting in order to prevent those risks from causing accidents. The information received and validated by the Commission is rapidly

[1000] Some New Approach Directives include notification procedures known as "Safeguard Clause," that aims to check the grounds for domestic measures which seek to restrict the free movement of products. However, this mechanism is different from the goals aimed by the RAPEX system, which intends to create the framework for a rapid exchange of information on dangerous products in order to protect the consumers' health and safety. See the European Commission Guidelines for the management of the Community Rapid Information System (RAPEX) and for notifications presented in accordance with Article 11 of Directive 2001/95/EC, 24. This document is available at http://ec.europa.eu/consumers/cons_safe/prod_safe/gpsd/rapex_guid_en.pdf

[1001] Examples of sectoral New Approach Directives that do not include a notification procedure and where therefore the RAPEX system is applicable are: Toys Directive 88/378/EEC, Low Voltage Directive 2006/95/EC (amending Council Directive 73/23/EEC of 19 February 1973 on the harmonization of the laws of Member States relating to electrical equipment designed for use within certain voltage limits, OJ L 77, 26.3.1973, p. 29–33), Machinery Directive 98/37/EC, Cosmetics Directive 76/768/EEC, Motor Vehicles Directive 70/156/EEC, Personal Protective Equipment Directive 89/686/EEC.

[1002] As mentioned above, RAPEX is applicable to dangerous consumer products which can be used by professionals and consumers (such as toys or lamps) with the exception of pharmaceutical and medical devices and food products that have specific mechanisms – for example, food product have the RASFF alert system. See European Commission, Keeping European Consumers Safe, 2009 Annual report on the operation of the Rapid Alert System for non-food consumer products, RAPEX. This document is available at http://ec.europa.eu/consumers/safety/rapex/docs/2009_rapex_report_en.pdf

[1003] The European Commission requires objective evidence of the danger, suspicion is not enough. Article 3(4) of the GPSD.

[1004] The participation countries are all European Union member states plus three EEA countries: Iceland, Liechtenstein and Norway. See European Commission, Keeping European Consumers Safe, 2007 Annual report on the operation of the Rapid Alert System for non-food consumer products, RAPEX, 9. This document is available at http://ec.europa.eu/consumers/safety/rapex/docs/rapex_annualreport2008_en.pdf

[1005] A list of Contract Points of the different member states can be found at http://ec.europa.eu/consumers/safety/rapex/contact_points.pdf

circulated to the national contact points in all countries participating in the system.[1006] These contact points then ensure that their respective domestic authorities check whether the product in question is present in their market and take appropriate action. The results of these market surveillance activities, including additional information relevant for other national authorities, are then reported back to the Commission through the RAPEX system.

When there is a need for immediate action by a member state, it must first inform the European Commission.[1007] The duty to inform under the RAPEX system arises when the decision to adopt measures has been taken (even if they have not been adopted yet). Member states must provide the Commission with detailed information of any restrictive measures they decide to adopt in response to identified risks as well as any preventive measures that producers and distributors might have adopted voluntarily.[1008]

It is important to note that a safety notification is not equivalent to deeming the product unsafe or dangerous and thus the number of RAPEX notifications is not equivalent to the number of safety measures adopted either by domestic or European authorities. In order to take a safety measure under European safety law, notification is required but not all notifications result in a subsequent measure. So the number of measures adopted in response to RAPEX notifications is significantly smaller than the number of notifications reported to European authorities, either because they are not necessary or because the notification has not been performed as required. Hence, while

[1006] The European Commission publishes on the internet every week an overview of dangerous products and the measures adopted to eliminate the risks. See http://ec.europa.eu/consumers/dyna/rapex/rapex_archives_en.cfm

[1007] Article 12(1) and Annex II, paragraph 4 of the GPSD establishing the steps a state must follow whenever there is a danger of a serious and immediate risk and a member state seeks to prevent, restrict or impose specific conditions on the possible marketing or use of the product within its own territory.

[1008] Of the 1355 notifications for products presenting serious risks, 643 were measures concerned by domestic authorities (47%), 669 were adopted voluntarily by manufacturers and distributors (50%) and in 43 cases, measures adopted by domestic authorities were complemented by actions adopted by private market operators (3%). See European Commission, Keeping European Consumers Safe, 2007 Annual report on the operation of the Rapid Alert System for non-food consumer products, RAPEX, 22. This document is available at http://ec.europa.eu/consumers/safety/rapex/docs/rapex_annualreport2008_en.pdf

RAPEX statistics can suggest inferences about the number of measures taken or, more broadly, the number of unsafe markets on the European market, these are only inferences subject to possible error, not direct measurements.[1009]

Further, even assuming that all safety notifications were to result in a measure adopted, the enforcement activities of the Member States are mostly based on post-marketing monitoring that may result in product recalls or withdrawals but such activities do not catch all the dangerous products on the market. The RAPEX system, thus, includes all safety notifications validated by the European Commission during the period between January 1st to December 31st of years 2001 to 2009,[1010] regardless from the date such notifications were transmitted by the National Contact Points, the date of publication by the Commission and whether they subsequently resulted in a safety measure adopted.

Hence, the RAPEX system does not allow to determine which products have been notified, by whom, and whether a subsequent measure – compulsory or voluntary – was adopted for that specific product. The latter type of information would be ideal for assessing which are the riskier products in the market and the effectiveness of the European product safety mechanisms regarding the adoption of pre-market and post-market controls in order to ensure that safe products reach the market. Unfortunately, however, this type of information is not available, and inferences must instead be drawn from the RAPEX notifications.

Despite these important limitations, the safety notifications collected by the RAPEX system through the information provided by the domestic authorities allow for an assessment and an evaluation of changes in time of the amount of potentially unsafe products, the risk involved in them, the activity of domestic authorities regarding notifying potentially unsafe products and which product categories are the most

[1009] See European Commission, Keeping European Consumers Safe, 2005 Annual report on the operation of the Rapid Alert System for non-food consumer products, RAPEX, 3-4. This document is available at http://ec.europa.eu/consumers/reports/report_rapex_05_en.pdf

[1010] However, annual RAPEX reports are only available for the period ranging from 2004 to 2009. See http://ec.europa.eu/consumers/dyna/rapex/rapex_archives_en.cfm

frequently notified as potentially unsafe, as well as whether notifications have resulted in an increase in care adopted by producers and therefore in a subsequent reduction of safety notifications of that product category.

It should be noted that in order to be able to accurately assess the effectiveness of the European product safety regulation, it would be necessary to know the exposure of products to the safety regulation. That is, the total number of products marketed in a given European member state – regardless of their origin of manufacture – and evaluate whether the amount of notifications evolves in parallel to the products marketed and subject to the European product safety regime.

Under RAPEX, safety notifications are classified by product category. Table 5.2 comprises all the safety notifications collected by the RAPEX mechanism as classified by European authorities between 2004 and 2009. As it can be seen, safety notifications have increased their variety as the RAPEX system was developing. At the same time, some product categories have been aggregated together in light of the difficulty differentiating between often similar concepts.[1011]

Table 5.2 - Categories of product notified under RAPEX

PRODUCT CATEGORY	2004	2005	2006	2007	2008	2009
Chemical products	1	1	9	19	21	44
Childcare machines/articles	4	0		30	89	67
Children's equipment	30	2	41	59		
Clothing	9	13	33	54	140	395
Communication equipment				1	8	10
Computer hardware	4	0	4			
Construction	0	2	0	1		
Cosmetics and hygiene	23	22	48	81	56	86
Decorative articles	0	24	23	20	21	14
Electronic appliances	105	238	174	156	169	138

[1011] An example of this grouping is childcare machines, articles and children's equipment that since 2008 are grouped into a single category that collects their safety notifications. Before 2008, these categories were differentiated.

Fashion items				1		
Firearms				1		
Food-imitating products				23	55	40
Furniture	8	7	20	8	12	17
Gadgets	6	1		3	4	6
Garden machines/furniture	4	10		1		
Gas and heating appliances			6	7	12	15
Hand tools				2		2
Hobby/sports equipment	9	7	30	24	27	49
Household appliances	12	38	24	25		
Jewelry			5	3	13	7
Kitchen/cooking access.	8	1		10	10	14
Laser pointers	3	15		20	5	8
Lighters	16	21	22	18	37	30
Lighting chains				17	44	39
Lighting equipment			98	84	81	52
Machinery and tools			19	29	25	7
Motor vehicles	25	63	126	197	160	
Motor vehicles parts				1		146
Others	18	16	11	2	8	19
Percussion caps	2	0				
Personal protective equipment			6	12	22	12
Pet accessories				1		
Pyrotechnical products				1		
Recreational crafts				6	8	5
Stationary	0	6	4	3	20	5
Toys	101	171	221	417	498	472
Vehicles				8		

As it can be seen from the table 5.2, the categories of products which are most often notified under RAPEX are articles intended for children (toys and children's equipment) and electrical products (domestic appliances and lighting equipment). These categories account for over 50% of all RAPEX notifications.

The origins of the products that generate safety notifications under RAPEX is very diverse. During 2009, 60% of all notification sent through RAPEX referred to products with China – including Hong Kong – as their country of origin. Additionally, 337 notifications – 20% of the notifications sent through RAPEX during 2009 – concerned products originated from the 27 European Union member states and 3

EFTA/EEA countries.[1012] These figures are similar for previous years as well, with notifications of EU and EFTA/EEA products accounting for 20% of all notifications in 2008, 22% in 2007 and 21% in 2006.[1013]

Given the significantly high proportion of RAPEX notifications relating to products of Chinese origin and the remarkable proportion of these products subsequently deemed dangerous, the European Commission has sought cooperation from China and its authorities. In 2006, the Directorate General for Health and Consumer Safety of the European Commission (DG SANCO)[1014] and the Chinese General Administration for Quality Supervision Inspection and Quarantine (AQSIQ) signed a Memorandum of Understanding (MoU) on general product safety. This memorandum provided for the support of Chinese authorities in the effort to ensure product safety, especially for consumer goods subsequently exported to the European Union market. The system laid out in the memorandum is known as the "RAPEX-CHINA"[1015] and it is an on-line information exchange system between European and Chinese authorities, who may follow up directly on notifications regarding unsafe products coming from their country.[1016] The European Commission committed to report on the effectiveness of this system every three months.[1017]

Another important RAPEX classification is the nature of the danger under the GPSD. The GPSD differentiates between article 12 and article 11 measures; depending on how serious the danger is (with higher levels of danger falling under article 12).

[1012] See European Commission, Keeping European Consumers Safe, 2009 Annual report on the operation of the Rapid Alert System for non-food consumer products, RAPEX. This document is available at http://ec.europa.eu/consumers/safety/rapex/docs/2009_rapex_report_en.pdf

[1013] See in general http://ec.europa.eu/consumers/dyna/rapex/rapex_archives_en.cfm

[1014] For more information on the DG SANCO see http://ec.europa.eu/dgs/health_consumer/index_en.htm

[1015] See http://ec.europa.eu/consumers/safety/int_coop/docs/rapex_china_summary_analysis.pdf

[1016] Some European countries also have online systems of exchange of information of product risks. For example, the Spanish website where producers and distributors may report information on product risks is: http://www.consumo-inc.es/Seguridad/formularioNotificacion.jsp

[1017] See http://ec.europa.eu/consumers/safety/rapex/index_en.htm for a brief analysis of the quarterly reports.

As table 5.3 shows, the categories of dangers have also increased as the RAPEX system has developed while some dangers, such as fire risks or suffocation, for example, have remained present and quite stable.

Table 5.3 – Nature of the danger under article 12 of the GPSD

DANGER	2004	2005	2006	2007	2008	2009
Allergy			2	3		
Bacteriological				8		
Burns				71	103	90
Cancer	20	0	7	14		
Chemical	5	69	95	212	341	493
Choking/suffocation[1018]	80	96	157	317	285	261
Cuts	1	0	5	24	26	18
Damage to hearing			2	20	39	32
Damage to sight			8	38	11	19
Drowning			4	5	5	12
Electrical shock	110	249	270	246	282	214
Explosion	2	0	8	8		
Fire risk/burns[1019]	64	114	194	216	185	124
Health	5	27	44	11	14	2
Microbiological risk			11	6	12	11
Other	22	1	2			
Poisoning			10	50		
Risk of injury	115[1020]	227	274	376	366	405
Skin lesion/irritation	4	0	2	4		
Release of metals				6		
Suffocation					166	35

[1018] Since 2007 choking and suffocation are separated as different kinds of dangers. See European Commission, Keeping European Consumers Safe, 2007 Annual report on the operation of the Rapid Alert System for non-food consumer products, RAPEX. This document is available at http://ec.europa.eu/consumers/safety/rapex/docs/rapex_annualreport2008_en.pdf

[1019] Since 2007 burns are a different danger category than fire risks. See European Commission, Keeping European Consumers Safe, 2007, Annual report on the operation of the Rapid Alert System for non-food consumer products, RAPEX. This document is available at http://ec.europa.eu/consumers/safety/rapex/docs/rapex_annualreport2008_en.pdf

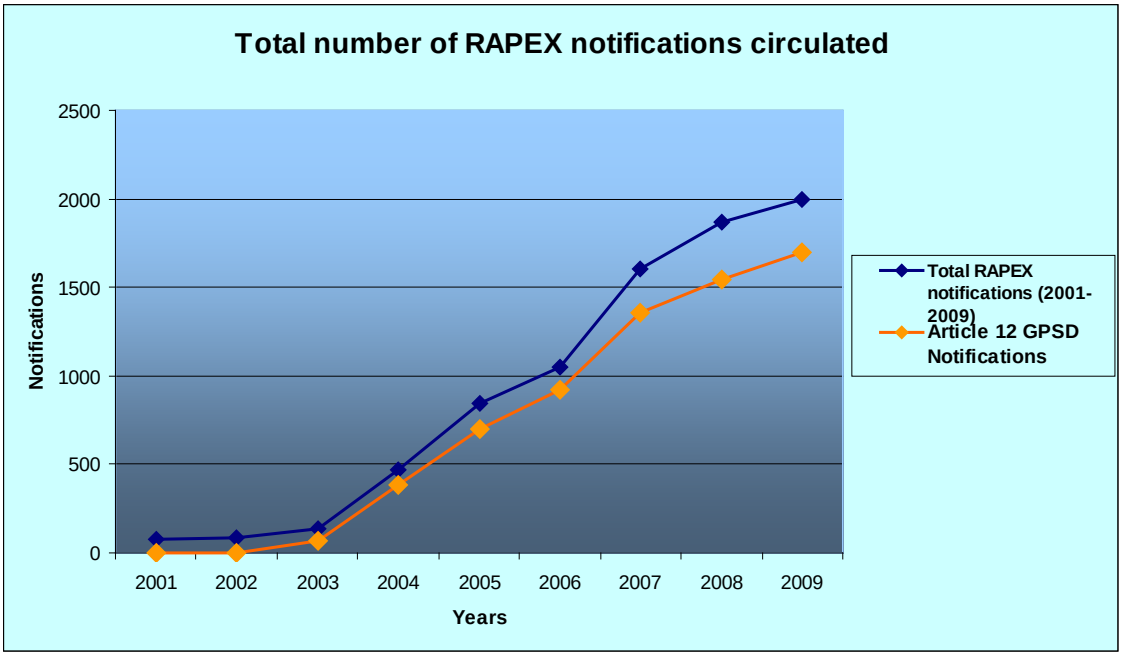
[1020] It should be noted that risk of injury appears in the 2005 report referring to 2004 data but such information is not included in the 2004 report. See European Commission, Keeping European Consumers Safe, 2005 Annual report on the operation of the Rapid Alert System for non-food consumer products, RAPEX. This document is available at http://ec.europa.eu/consumers/reports/report_rapex_05_en.pdf

Strangulation					**36**	**182**

As the table above shows, the most common risks observed have been the risk of injury, choking and electrical shock as well as burns, fire, suffocation and chemical risks.

The RAPEX alert system has evolved in such a way that domestic authorities, through their contact points, have increasingly notified authorities of the presence of dangerous products in the market.[1021]

Figure 5.2 – Number of RAPEX notifications circulated



As figure 5.2 shows, the number of RAPEX notifications circulated by the different member states has increased significantly every year the RAPEX system was in force.[1022]

[1021] This information can be found at European Commission, Keeping European Consumers Safe, 2008, Annual report on the operation of the Rapid Alert System for non-food consumer products, RAPEX, 15-16. This document is available at http://ec.europa.eu/consumers/safety/rapex/docs/rapex_annualreport2009_en.pdf. Table 5.4 - Total Number of RAPEX Notifications Circulated 2001-2009 summarizes the results.

These results might be attributed to an increased effectiveness of product safety enforcement by national authorities, increased awareness by businesses of their responsibilities, the European Union enlargement in 2004 and 2007,[1023] as well as to several network-building actions coordinated by the Commission.[1024] The European Commission is clearly optimistic about the implementation and effectiveness of this system and has interpreted that the increasing awareness of obligations by producers and distributors and of member state authorities and the enhanced cooperation with third countries has been the key to the increased effectiveness of the RAPEX system.[1025]

The different member states participating in the RAPEX system are not equally active. During 2009, the member states that were most active in the RAPEX system and that accounted for 47% of the total number of notifications were Spain (220 notifications, 13% of the total), Germany (187 notifications, 11% of the total), Greece (154 notifications, 9% of the total), Bulgaria (122 notifications, 7% of the total), and Hungary (119 notifications, 7% of the total).[1026] Other countries are increasingly participating in RAPEX as well: during 2009, half of the countries increased their activities in the RAPEX system and notified authorities of more dangerous products than during 2008 given that the total share of the five most notifying countries decreased from 50% in 2008 to 47% in 2009. Similarly, the 44% of notifications accounted for by the top 5

[1022] See European Commission, Keeping European Consumers Safe, 2004-2009 Reports. RAPEX reports are available at http://ec.europa.eu/consumers/safety/rapex/stats_reports_en.htm

[1023] In 2004, Czech Republic, Estonia, Cyprus, Latvia, Lithuania, Hungary, Malta, Poland, Slovakia and Slovenia joined the European Union. On 1 January 2007 Romania and Bulgaria also joined, becoming the current 27 Union member states. For further information on the different phases of European enlargements see http://europa.eu/abc/history/index_en.htm.

[1024] See European Commission, Keeping European Consumers Safe, 2006, Annual report on the operation of the Rapid Alert System for non-food consumer products, RAPEX. This document is available at http://ec.europa.eu/consumers/safety/rapex/stats_reports_en.htm

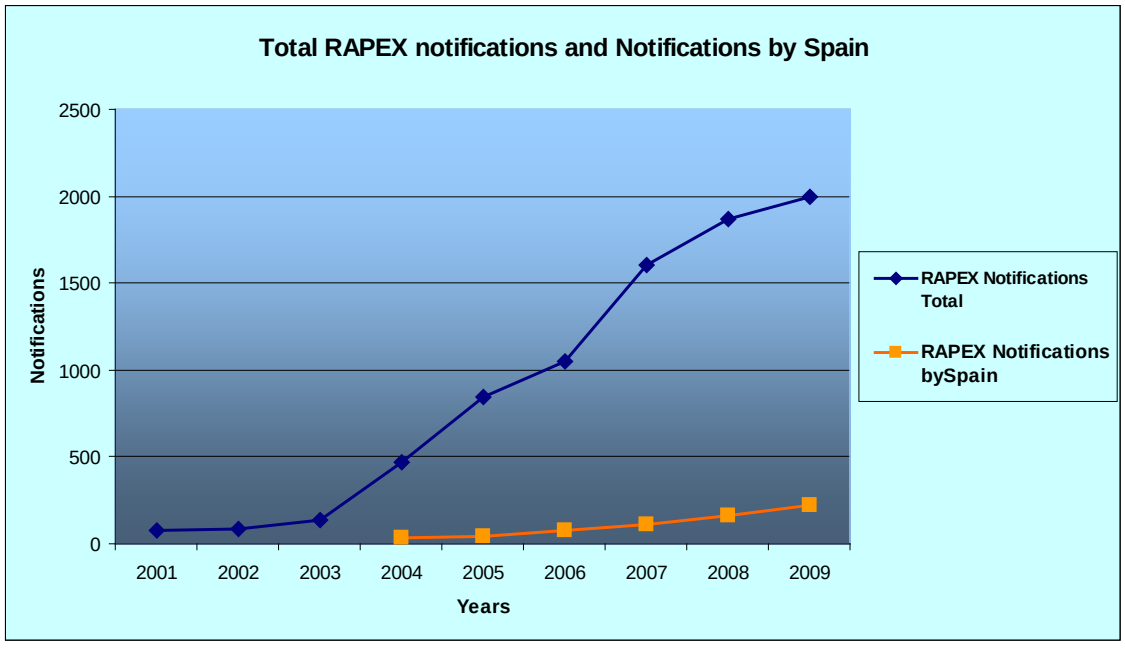
[1025] Keeping European consumers safe 2007 Annual Report on the Operation of the Rapid Alert System for non-food consumer products. (OJ L 11, 15.1.2002) at 16. This document is available at http://ec.europa.eu/consumers/safety/rapex/docs/rapex_annualreport2008_en.pdf

[1026] See European Commission, Keeping European Consumers Safe, 2009 Annual report on the operation of the Rapid Alert System for non-food consumer products, 21-23, RAPEX. This document is available at http://ec.europa.eu/consumers/safety/rapex/docs/2009_rapex_report_en.pdf

participators in 2007 was actually a decrease from the percentage they represented in 2006, when they accounted for 61% of the total.[1027]

Spain is one of the most active countries in product notifications under RAPEX. The Spanish case is an interesting example because there is a big difference between the amount of notifications generated by Spanish authorities overall and the amount of notifications generated by products with a Spanish origin. While Spain is very active in notifying European authorities of potentially unsafe products in the Spanish market, the amount of Spanish products exposed to RAPEX notifications is relatively small, considering the little impact of notifications of products with Spanish origin relative to the total amount of notifications.[1028]

Figure 5.3 – RAPEX notifications and notifications by Spain



[1027] Keeping European consumers safe 2007 Annual Report on the Operation of the Rapid Alert System for non-food consumer products. (OJ L 11, 15.1.2002) at 16. This document is available at http://ec.europa.eu/consumers/safety/rapex/docs/rapex_annualreport2008_en.pdf

[1028] See European Commission, Keeping European Consumers Safe, 2004-2009 Reports. RAPEX reports are available at http://ec.europa.eu/consumers/safety/rapex/stats_reports_en.htm. See Table 5.5 - Total RAPEX Notifications and Notifications By Spain 2001-2009 summarizing the results.

Not all notifications entail a measure adopted. Once the Commission receives a notification, it first checks that such notification conforms to the requirements of article 8 of the GPSD, which are very restrictive,[1029] and it determines whether the risk involved is such that it can only be effectively eliminated through the adoption of measures at the Community level.[1030]

The types of measures most commonly adopted by member states and the European Commission, as well as by producers and distributors themselves in response to the different safety notifications are: stopping a product's sales, withdrawing the product from the market, providing information to consumers about the risks related to the use of the product, and recalling a dangerous product from consumers.[1031] Some measures are compulsory, others are voluntary and others are compulsory but complemented by voluntary corrective action.

As can be seen from Figure 5.3, the number of notifications has increased. In parallel the number of measures, shown in Figure 5.4, has also increased.

The blue area shows notifications that have resulted in no measure either because they did not qualify for treatment under article 12 of the GPSD,[1032] or because they were treated as notifications under Article 11 of the GPSD.[1033] Those notifications not fitting under article 11 or article 12 GPSD were disseminated to the National Contact Points for information only so that other countries are aware of the safety problems, often linked to specific product categories. Consumers are warned in generic terms of typical risks with

[1029] Specifically Article 8(1)(b) to (f) of the GPSD. See also Article 13 of the GPSD.
[1030] In this sense, the European intervention only takes place at the inter-state conflict level. Article 13(1)(c) of the GPSD.
[1031] 50% of the total RAPEX measures taken during 2007 were adopted voluntarily by manufacturers and distributors. See the press release Memo/08/252 issued by the Directorate General on health and consumers on April 17, 2008. The Memo is available at http://europa.eu/rapid/pressReleasesAction.do?reference=MEMO/08/252&format=HTML&aged=0&language=EN
[1032] Article 12 of the GPSD provides for the adoption of measures taken by the competent authorities or voluntarily by producers and distributors for products presenting a serious risk.
[1033] Article 11 of the GPSD provides for the adoption of measures taken by the competent authorities on products posing a lesser risk.

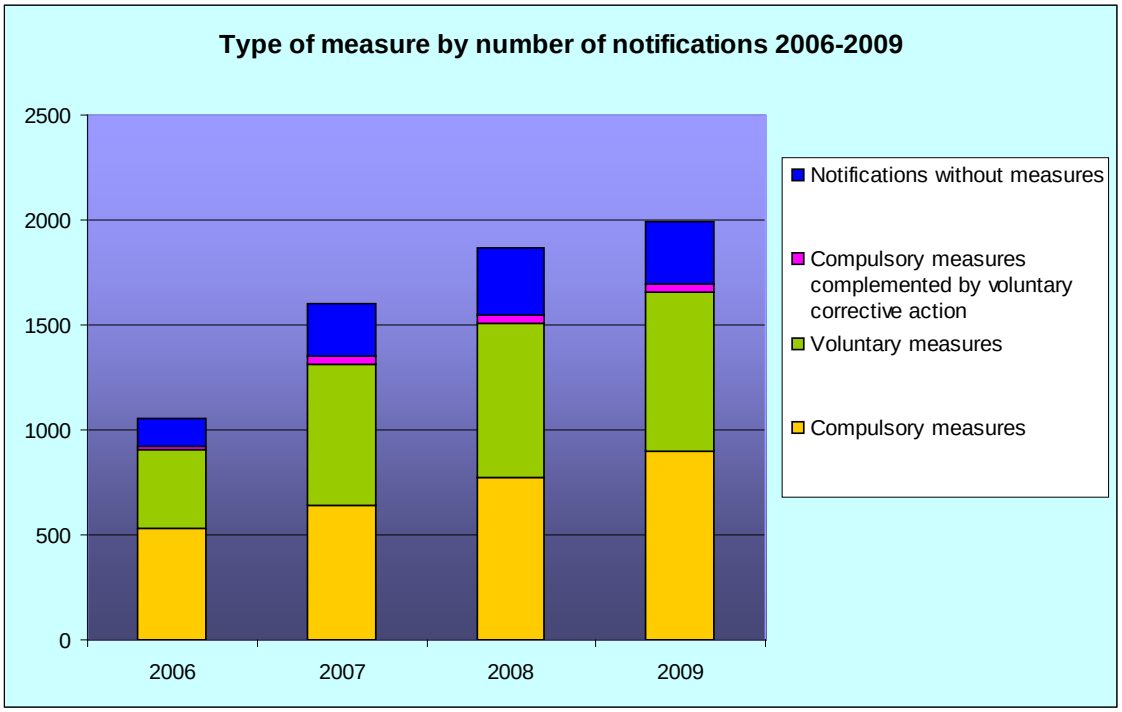
these product categories. These mainly concern notifications with insufficient information about the product or missing information on the producer or importer.[1034] As can be seen, the amount of notifications without measures has slightly increased and remains a significant percentage of RAPEX notifications.

The amount of voluntary measures adopted is represented by the green area. Voluntary measures represent an important percentage of notifications, as can be seen in Figure 5.4. The same may be said of compulsory measures, which are represented by the yellow and also represent an important percentage of the total amount of notifications. Finally, the amount of compulsory measures complemented by voluntary action does not seem relevant for the analysis.

It is interesting to observe that the proportion of voluntary and compulsory measures adopted is quite similar. Given that compulsory measures are taken at the initiative of the European Commission and voluntary measures are adopted at the initiative of the producer, it seems possible to suggest that the role of reputation of RAPEX notifications and their publicity might be important enough so that manufacturers have incentives to adopt measures at their own initiative.

[1034] During 2009, 124 notifications (7 % of all notifications sent through RAPEX) did not include information about the country of origin of the notified product. Even though still an important percentage, the number of cases with an unidentified country of origin decreased from 23% in 2004 to 7% in 2009. The remarkable evolution in terms of determining the products' country of origin has been interpreted by the European Commission as an indicator that market surveillance authorities have been increasingly aware of the importance of a products' traceability. See European Commission, Keeping European Consumers Safe, 2009 Annual report on the operation of the Rapid Alert System for non-food consumer products, 21-23 RAPEX. This document is available at
http://ec.europa.eu/consumers/safety/rapex/docs/2009_rapex_report_en.pdf

Figure 5.4 – Measures adopted by number of notifications 2006-2009[1035]



4.8 Post-marketing obligations

The objective of the GPSD, keeping unsafe products out of the market, is supported by a broad system of pre-marketing controls and post-marketing obligations.[1036] The GPSD's design takes into account the fact that consumer products are not subject to any pre-marketing verification by public authorities and therefore places

[1035] See Table 5.6 - Type of Measure by Number of Notifications 2006-2009 summarizing the results shown in figure 5.4.

[1036] Recital 17 of the GPSD. It is not clear whether the GPSD considers that pre-market obligations are the same level as post-marketing obligations. This is an important consideration given that the product risk may be the same before the product is marketed but its knowledge may not be the same because of hindsight problems. See Jeffrey J. Rachlinski, A positive Psychological Theory of Judging in Hindsight in BEHAVIORAL LAW & ECONOMICS, Cass Sunstein (Ed.), 100-112, Cambridge University Press (2000).

strong emphasis on market surveillance and enforcement. Hence, under the GPSD it is not enough for a producer to ensure the safety of a product at the time it is placed in the market; the producer must also be informed and up to date about product risks, must monitor these risks, and, in cases where the product has already been marketed, must warn, recall or withdraw products from the market once it becomes apparent that these products do not comply with the general safety obligation.[1037]

The main goal of such post-marketing obligations is to identify (1) products that should have been identified before and therefore not marketed at all because of their lack of safety, as well as (2) products that were not unsafe before they were marketed but became unsafe afterwards.[1038]

Compared to the 1992 GPSD, the 2001 GPSD includes extensive obligations regarding market surveillance.[1039] It establishes the powers authorities should have in order to be able to adopt certain measures and it provides principles that must be followed when exercising such powers, including the necessary proportionality between the seriousness of the risk involved and the measures adopted.[1040] In 2008, additional

[1037] Articles 3(4) and 5(1) of the GPSD.
[1038] Article 9 of the GPSD.
[1039] GPSD recital 24. It should be noted that the GPSD specifically includes post-marketing obligations but these obligations overlap with the post-marketing incentives created by the product liability directive for manufacturers for warning consumers and users of new product risks. These incentives are a result of the warning duties included in the product liability directive by which whenever a product manufacturer warns consumers and users of product risks that appeared after the product was marketed, liability for harm will not be imposed. Hence, manufacturers have clear incentives to warn of new risks that may present the product once it has been marketed. For a discussion of the interaction between the warning defense and product liability see Kathryn E. Spier, Product Safety, Buybacks and the Post-Sale Duty to Warn, Harvard Law and Economics Discussion Paper No. 597 (2009). Available at http://ssrn.com/abstract=1023125 arguing that strict liability with a warning duty or defense results in too many product recalls and excessive incentives for manufacturers to warn consumers and noting that social welfare is maximized when manufacturers are only required to issue cost -- justified warnings -- hence introducing a negligent-based duty to warn, despite of its difficulties to be implemented. For additional literature discussing the incentives to recall products and warn of new product risks arising after the product has been introduced in the market see L. Welling, A Theory of Voluntary Recalls and Product Liability, Southern Economic Journal, 57: 1092-1111 (1991); A. M. Marino, A Model of Product Recalls with Asymmetric Information, Journal of Regulatory Economics, 12:245-265 (1997) and more recently Omri Ben-Shahar, How Liability Distorts Incentives of Manufacturers to Recall Products, available at SSRN: http://ssrn.com/abstract=655804. (2005).
[1040] Article 8.2 of the GPSD.

European regulation reinforcing the market surveillance mechanisms for products covered by Community harmonization legislation and traceability of products was adopted.[1041]

The GPSD does not specify the mechanisms and infrastructure that member states should have,[1042] who should bear the costs of adopting measures against unsafe products, and what the consequences should be if the producer decides not to take action or takes inadequate action.[1043] All these decisions are left to be determined and adopted by member states.

Spain has more than 50 public bodies dealing with product safety and, more generally, with consumer protection. These bodies are dependent on either the central government or on the governments of the different autonomous communities into which Spain is divided.[1044]

The most important authority is the National Consumer Institute (INC),[1045] which is the authority responsible for protecting and promoting consumers' and users' rights. There is also: an Evaluation Committee,[1046] which monitors the RAPEX system's implementation in Spain; a Technical Commission for product safety,[1047] which provides information, at the request of the Spanish and European public authorities about the risks

[1041] See Regulation (EC) No. 765/2008, OJ L 218, 13.8.2008, p. 30 and Decision 768/2008/EC, OJ L 218, 13.8.2008, p. 82 setting out the requirements for accreditation and market surveillance relating to the marketing of products. Regulation 765/2008 laid down the obligation for competent authorities of the member status to carry out appropriate checks on the characteristics of products on an adequate scale on the European market and before those products are released for free circulation.
[1042] Christopher Hodges, EUROPEAN REGULATION OF CONSUMER PROTECTION SAFETY, 164, Oxford University Press (2005).
[1043] The lack of specification of the consequences for not complying with the obligations established by the GPSD is also present in New Approach Directives. Christopher Hodges, EUROPEAN REGULATION OF CONSUMER PROTECTION SAFETY, 149-164, Oxford University Press (2005).
[1044] This diversity can be explained by the decentralized political structure of Spain, that is structured in 17 Autonomous Communities, each of which counts with its consumer bodies. See http://www.consumo-inc.es/en/Seguridad/direcciones2.htm for a list of the different notification bodies of the Autonomous Communities.
[1045] The National Consumer institute is an authority created by the Spanish Government, in development of article 51 of the Constitution and consumer protection regulation. See http://www.consumo-inc.es/
[1046] See http://www.consumo-inc.es/Seguridad/organos.htm
[1047] See http://www.consumo-inc.es/Seguridad/organos.htm

presented by certain products; and a Contact Committee on product safety,[1048] which interacts with producers and distributors on product safety issues.

Whenever a producer or distributor wants to report information about a certain product risk it must file an on-line form on the web-site of the INC,[1049] and the INC will initiate an assessment of whether safety measures should be adopted and will circulate the notification to other product safety authorities of Spain's autonomous communities as well as the authorities of other European Union member states.

During 2007, Spain's product safety authorities dealt with 2225 product-safety procedures for non-food products,[1050] 609 of which were initiated by the Spanish autonomous communities and 1616 by the authorities of other European Union member states. There were also 316 notifications provided voluntarily by producers and distributors.[1051] The 2007 notifications and the notifications of prior years resulted in the withdrawal of 488,294 product units from the Spanish market. No information is available about safety measures or penalties, other than product withdrawals.

4.9 Looking for effectiveness: deciding between surveillance and enforcement mechanisms under the GPSD

One of the most interesting features of the GPSD is that it places responsibility for pre-market and post-market obligations on different agents. During the pre-marketing phase producers and distributors lead the process and are the ones responsible for

[1048] See http://www.consumo-inc.es/Seguridad/organos.htm
[1049] See http://www.consumo-inc.es/Seguridad/formularioNotificacion.jsp
[1050] Last information available is for the year 2007. These notifications represented an increase of 39% with respect to the notifications received during 2006. See Red de Alerta, Notificaciones de productos de consumo no alimenticios que pueden suponer un riesgo para la seguridad de los consumidores, at 12. The document is available at http://www.consumo-inc.es/Seguridad/informacion/pdf/resumen2007.pdf
[1051] See Red de Alerta, Notificaciones de productos de consumo no alimenticios que pueden suponer un riesgo para la seguridad de los consumidores, at 12. The document is available at http://www.consumo-inc.es/Seguridad/informacion/pdf/resumen2007.pdf

ensuring that the products they market are safe and comply with applicable rules. However, in the post-marketing phase, it is the member states that are primarily responsible for monitoring products that reach the market and for ensuring that product safety rules are enforced.[1052] While producers and distributors still have obligations in this phase, their roles are secondary to those of the states.[1053]

Some parameters might affect the efficacy of the post-marketing controls. The structure of domestic product safety authorities is not homogeneous among the different member states, which themselves range from centralized to decentralized or federal systems. At the same time, coordination problems may arise when several governmental departments are potentially responsible for monitoring consumer products.[1054] The failure of some member states to have a system of sanctions for non-compliance with the general safety obligation[1055] is remarkable and there is a surprising lack of information and transparency about the producers who have been sanctioned.[1056] Further, the

[1052] See Christopher Hodges, EUROPEAN REGULATION OF CONSUMER PROTECTION SAFETY, 206, Oxford University Press (2005) for a complete overview of the actors involved in product safety in all kind of products.
[1053] Article 5(1) of the GPSD.
[1054] Christopher Hodges, EUROPEAN REGULATION OF CONSUMER PROTECTION SAFETY, 182, Oxford University Press (2005).
[1055] For example, the French Consumer Code in articles 221-225 does not include a sanction for breach of the general safety obligation.
[1056] In fact a few years ago there was a case in Spain regarding sunflower oil. In that case, the Spanish government authorities issued a warning recommending consumers not to use sunflower oil because of the possibility of it being toxic and asking supermarkets and distributors to remove the bottles from the shelves so that consumers would not have access to this product. However, when asked about what specific brands and kind of sunflower oil that were supposedly toxic authorities did not disclose such information and did not inform about the measures adopted or penalties imposed on the manufacturers or importers of this kinds of oil. A few days later such warning was lifted and sunflower oil is now available in stores. For more information see International Herald Tribune, april 26, 2008, Spain issues health warning about tainted sunflower oil, The Associated Press, http://iht.nytimes.com/articles/ap/2008/04/26/europe/EU-GEN-Spain-Tainted-Sunflower-Oil.php?scp=1&sq=sunflower%20oil%20spain&st=cse; El Pais 01/05/2008, Arcadio Silvosa, Sanidade paraliza 3.000 kilos de aceite de Ucrania, http://www.elpais.com/articulo/Galicia/Sanidade/paraliza/3000/kilos/aceite/Ucrania/elpepiautgal/20080501elpgal_6/Tes; El Pais, 22/05/2008, Ricardo M de Rituerto, Bruselas prohíbe las importaciones de aceite de girasol de Ucrania. Kiev es incapaz de garantizar una exportación libre de contaminantes, Brussels http://www.elpais.com/articulo/sociedad/Bruselas/prohibe/importaciones/aceite/girasol/Ucrania/elpepisoc/20080522elpepisoc_6/Tes.

identification of the producer on the product or its packaging[1057] is an important element for ensuring traceability but is not a mandatory obligation in all member states.[1058] In light of an increasingly global market, there is a need for further coordination of market surveillance regulation between member states including the cooperation with custom authorities.[1059]

The problem may ultimately stem from a lack of political will to contribute to the success of this system. This was recognized by the European Council as early as 1994,[1060] when it stated that there was a lack of mutual confidence and transparency between the different administrations, and that this created problems and endangered the efficient and uniform enforcement of Community legislation affecting the functioning of the internal market across the member states. The Commission also has pointed out significant weaknesses in market surveillance under the 1992 GPSD.[1061] For that reason, in light of the failure of the member states to create appropriate domestic surveillance mechanisms, the amended GPSD included enhanced enforcement mechanisms. However, so far this does not seem to have completely solved the enforcement problem of the GPSD.

[1057] Article 5(1)(a) of the GPSD. A New Legislative framework decisions makes it obligatory for the name, registered trade name or registered trademark of the producer or imported as well as their address to be indicated in the product. See Decision 768/2008/EC, Annex I, Articles R2(6) and R4(3).

[1058] Report from the Commission to the European Parliament and to the Council on the implementation of the Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety, 13, COM (2008) 905 final. This document is available at http://ec.europa.eu/consumers/safety/prod_legis/docs/report_impl_gpsd_en.pdf

[1059] Report from the Commission to the European Parliament and to the Council on the implementation of the Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety, 13, COM (2008) 905 final. This document is available at http://ec.europa.eu/consumers/safety/prod_legis/docs/report_impl_gpsd_en.pdf

[1060] Communication from the Commission to the Council and the European Parliament on the Development of Administrative Co-operation in the implementation and Enforcement of Community Legislation in the Internal Market, COM (94) 29 final, 16.2.1994; adopted by the Council Resolution of 16 of June 1994 on the Development of Administrative Co-operation in the Implementation and Enforcement of Community Legislation in the Internal Market, OJ C179/1,1.7.1994.

[1061] Commission Report to the European Parliament and the Council on the Experience Acquired in the Application of the Directive 92/59/EEC on General Product Safety, COM (2000) 140 final.

5 Challenges Presented by the GPSD

Assessing the impact and effectiveness of the safety regime the GPSD establishes is a difficult task.[1062] The European Commission provides information regarding notification procedures and dangerous products, including these products' countries of origin and the kinds of danger they present. What is not available, however, is any data regarding product risks, effectiveness of monitoring and market surveillance, costs that the safety system imposes on European and domestic authorities, or the quantity and size of the penalties imposed. Without such data, it is difficult to make an evaluation and to suggest potential reforms that could be implemented so that the effectiveness of the system could be enhanced.[1063] Additionally, product safety is one of the main bases of European consumer protection, the other being product liability. In light of the interaction between these two regulatory bodies, being able to assess the functioning and analyze the performance of the product safety regime is crucial to improving the effectiveness of the overall European consumer protection system.

In 2005 Europe celebrated the twentieth anniversary of the New Approach and held a conference[1064] at which the European Commission's vice president for enterprise and industry, Günter Verheugen, stated that the New Approach had been successful and defended the extension of this regulatory model to industrial products.[1065] This was in

[1062] Some suggest that the GPSD has shown a positive impact on product safety. See Alberto Cavaliere, Product Liability in the European Union: Compensation and Deterrence Issues, European Journal of Law and Economics, 18: 299–318, 313 (2004).

[1063] Other authors have also argued that more information and more data is necessary for evaluating the performance of the regime and that a European Product Safety Agency should be created. However, such agency has not been created. See Christopher Hodges, EUROPEAN REGULATION OF CONSUMER PROTECTION SAFETY, 258-259, 261 Oxford University Press (2005).

[1064] The program of the conference is available at http://ec.europa.eu/enterprise/newapproach/new_approach_conference_en.htm.

[1065] Günter Verheugen is the Vice-President of the European Commission Responsible for Enterprise and Industry. The closing Speech at the European Conference on the 20th Anniversary of the New Approach 6 (Nov. 30, 2005) is available at

line with the opinion of the European Commission, in a recent evaluation of the implementation of the GPSD, which concluded that the Directive has proven to be a powerful tool for ensuring a high level of consumer protection.[1066]

Mr. Verheugen also pointed out flaws in the system, including a lack of confidence by consumers in the CE marking in certain product sectors and the unequal implementation of the system by member states.[1067] The lack of uniform implementation by the member states centers on two major issues: the definition of a safe product, which mostly impacts the pre-marketing phase, and the informational obligation imposed on producers and distributors, which mostly impacts the post-marketing product phase. These obligations, based on concepts that are essential to both the product safety regime and the product liability regime, should be further clarified and specified under this regulation so that producers know what they are exposed to and consumers are able to better assess the level of product risks and hence are able to have accurate expectations regarding product risks and product safety.

5.1 How does the producer know a product is safe?

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http://europa.eu.int/comm/enterprise/newapproach/pdf/verheugen_%20speech_%20anniversary_%20naga.pdf See also Günter Verheugen, Exchange of views of Vice-President Verheugen with the Internal Market and Consumer protection Committee (IMCO) European Parliament Internal Market and Consumer Protection Committee European Parliament, Brussels, 14. September 2006. This speech can be found at http://europa.eu/rapid/pressReleasesAction.do?reference=SPEECH/06/500&format=HTML&aged=1&language=EN&guiLanguage=en

[1066] Report from the Commission to the European Parliament and to the Council on the implementation of the Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety, 12, COM (2008) 905 final. This document is available at http://ec.europa.eu/consumers/safety/prod_legis/docs/report_impl_gpsd_en.pdf

[1067] Despite its challenges, voices defend that the consumer safety regulation in the United States should look at the European product safety regulation in light of its successful balance between consumer protection and free market protection. See in general Anthony Scascia, Safe or sorry: how the precautionary principle is changing Europe's consumer safety regulation regime and how the United States' Consumer Product Safety Commission must take notice, 58 Admin. L. Rev. 689 (2006).

The concept of safe product is a key element of the product safety regime. If a product is safe, the product may be marketed with no problem and the producer and distributor will have only the obligation to gather information and report product risks that become known after the product has been marketed. It should be noted that a safe product may still result in the manufacturer's liability in cases where the product is deemed defective and such defect causes harm to a product user.[1068]

It is sometimes said that the concept of a safe product in the GPSD is more objective than the concept of a defective product under the product liability directive[1069] because while the latter concept hinges on consumer expectations, the former is not based on them.[1070]

However, the definition of safe product is quite vague and it is difficult to establish the risks that should be taken into account when qualifying a product as unsafe. In the pre-marketing phase, it is only for product manufacturers to decide that a product is has passed the risk-utility test[1071] and is therefore safe under the GPSD.[1072] Public authorities only intervene once the product is already in the market.

The GPSD does not include any guideline for conducting the product's risk assessment and how the different knowledge about risks during the product's life will be considered. In other words, products are evaluated under the risk-utility test before they are marketed but once the product is in use and it has come to the attention of

[1068] See Chapter 6 of this dissertation. For an analysis of the interaction between the concepts of safe and defective product.
[1069] Council Directive 85/374 of 25 July 1985 Concerning Liability for Defective Products, 1985 O.J. (L210) 29.
[1070] Geraint Howells, Consumer safety in Europe: in search of the proper standards, in LEGAL VISIONS OF THE NEW EUROPE, B. Jackson and D. McGoldrick (eds), Graham & Trotman (1993). Other scholars have suggested the introduction of the concept of consumer expectations in the content of the general product safety obligation. See H-W. Micklitz, Principles of Justice in Private Law Within the European Union" in Principles of Justice and the Law at the European Union, 284-286, E. Paasivirta and K. Rissanen (eds.), Institute of International Economic Law, University of Helsinki, (1995).
[1071] Christopher Hodges, EUROPEAN REGULATION OF CONSUMER PROTECTION SAFETY, 98, Oxford University Press (2005).
[1072] The GPSD does not include any mechanisms or guidelines to ensure that producers place only safe products in the market. See Christopher Hodges, EUROPEAN REGULATION OF CONSUMER PROTECTION SAFETY, 98, Oxford University Press (2005).

authorities,[1073] risks are assessed again. But the GPSD does not refer to how the potential hindsight problems will be handled.[1074] The lack of definition of risk assessment procedures by the European Commission may sometimes lead to subjective results as well as in discrepancies among the risk assessors -- the producers and member states -- as to a product's safety.

The European Commission has recognized this problem and has qualified it as the risk assessment problem, and in 2006[1075] it initiated a revision of the risk assessment guidelines that are part of the RAPEX system. In doing so, it created a Working Group named IRAG (Improvement of Risk Assessment Guidelines)[1076] that identified the risk assessment problems and made some proposals that included guidance on risk assessment. However, the revision of the risk assessment processes has not yet been finalized.[1077]

5.2 The information obligations under the GPSD and the Product Liability Directive: What information is needed to comply with both directives?

Another important aspect of the GPSD is the obligation of producers to provide information to consumers about product risks throughout the product's foreseeable period

[1073] Christopher Hodges, EUROPEAN REGULATION OF CONSUMER PROTECTION SAFETY, 98, Oxford University Press (2005).
[1074] See Jeffrey J. Rachlinski, A positive Psychological Theory of Judging in Hindsight, in BEHAVIORAL LAW & ECONOMICS, 100-112, Cass Sunstein (Ed.), Cambrigde University Press (2000).
[1075] European Commission (SANCO) issued the report Establishing a Comparative Inventory of Approaches and Methods Used by Enforcement Authorities for the Assessment of the Safety of Consumer Products Covered by Directive 2001/95/EC on General Product Safety and Identification of Best Practices, Final Report (2006). This document can be found at http://ec.europa.eu/consumers/cons_safe/serv_safe/reports/risk_assessement_methods_en.pdf
[1076] Information about this working group and the European Commission workshop on risk assessment celebrated on December 2007 where the results of the working group where presented see, http://ec.europa.eu/consumers/safety/committees/index_en.htm
[1077] After incorporating the first comments, the Guidelines were put to a public internet consultation in 2008.

of use.[1078] This is an especially important area because if the producer complies with this obligation and warns of a product risk, this action may relieve it from potential liability for the harm the product might cause. If information about product risks is provided, then the product will not be deemed defective for inadequate warnings and instructions[1079] and the manufacturer will therefore not be liable for the potential harm caused by not providing the information -- the instructions and warnings -- regarding these product risks.

However, the obligation regarding information and warnings of product risks presents a classic problem that law and economics literature has tried to answer: How to determine when a risk is significant enough that information should be given about it, and in what level of detail should such information be given. That is, what is the amount of information that should be provided so that the informational obligation is fulfilled.[1080] Providing too little information would not induce consumers to adopt an optimal level of care but giving too detailed and excessive information regarding risks would not lead to an optimal outcome either.[1081]

The silence of the GPSD seems to leave this question open and subject to the cost-benefit analysis that product manufacturers will conduct when they gather the information about their products and distribute it among consumers.[1082] The GPSD seems to rely on the optimal result that will theoretically be reached when product manufacturers weigh the marginal costs of obtaining information about product risks with

[1078] Article 5(1) of the GPSD.
[1079] Article 7(f) of the product liability directive.
[1080] Douglas G. Baird, Robert H. Gertner and Randal C. Picker, GAME THEORY AND THE LAW, 79-121, Harvard University Press (1994).
[1081] W. Kip Viscusi, REGULATING CONSUMER PRODUCT SAFETY, 6, Washington, DC: American Enterprise Institute (1984). Viscusi understands that most product risks are easily perceived so providing information should pose little problem except for health risks.
[1082] Christopher Hodges, EUROPEAN REGULATION OF CONSUMER PROTECTION SAFETY, 121, Oxford University Press (2005).

the expected utility they will gain when complying with this obligation.[1083] Consequently, manufacturers will invest in finding information about their product risks up to the point where the marginal cost to acquire the information equals what they save in terms of expected liability.[1084]

However, even assuming that the amount of information provided was optimal, there is still some inconsistency regarding the information that must be provided in both the pre-marketing and the post-marketing phases that may influence the effectiveness and overall performance of the European product regulation regime.[1085]

All of the informational mechanisms included in the GPSD seem to imply that producers, when they apply the risk-utility test to their products, have information of all the risks presented by their products, even of those that do not arise from foreseeable product uses.[1086] However, this is an unrealistic assumption; even if feasible, it would not be economically affordable because it would represent incredibly high costs that would not be invested if they were higher than the expected liability the producer would save.[1087] Therefore, in light of the importance of such duty both from the product safety and the product liability perspective, it would be necessary for European authorities to lay down the content and scope of this obligation so that its application is uniform across states and manufacturers know the informational standard to which they are subject and can conduct a proper cost-benefit analysis and internalize the economic consequences of compliance with their duties under the European product regulation regime.[1088]

[1083] Richard A. Posner, ECONOMIC ANALYSIS OF LAW, 184, Aspen eds., 6th ed. (2003). Marginal costs are unitary costs. See also Hal R. Varian, INTERMEDIATE MICROECONOMICS, A MODERN APPROACH, 218-221, 360, W.W. Norton (1999).

[1084] Expected liability is determined by the probability of the damage and its magnitude. (Expected liability = P*L). See Richard A. Posner, ECONOMIC ANALYSIS OF LAW, 167, Aspen eds., 6th ed. (2003). See also Hal R. Varian, INTERMEDIATE MICROECONOMICS, A MODERN APPROACH, 218-221, 360, W.W. Norton (1999).

[1085] Christopher Hodges, EUROPEAN REGULATION OF CONSUMER PROTECTION SAFETY, 140, Oxford University Press (2005).

[1086] Article 2(b) and article 5.1 of the GPSD.

[1087] Richard A. Posner, ECONOMIC ANALYSIS OF LAW 169-170, Aspen eds. (6th ed. 2003).

[1088] Christopher Hodges, EUROPEAN REGULATION OF CONSUMER PROTECTION SAFETY, 141, Oxford University Press (2005).

The product safety regime is closely related to the product liability regime currently in force and it is not possible to analyze and evaluate the structure and performance of European product liability law without presenting and discussing the two regimes together. Only after this analysis it will be possible to evaluate European product regulation law as a whole, to assess whether its goals are being achieved, and to suggest how it might be improved.

I will turn now to present the interaction between the ex ante product safety regulation described and discussed in this chapter and the ex post liability law discussed earlier in this thesis.

CHAPTER 5 APPENDIX

Table 5.4
Total Number of RAPEX Notifications Circulated 2001-2009

	2001	2002	2003	2004[1089]	2005	2006	2007	2008	2009
TOTAL	76	84	139	468	847	1051	1605	1866	1993
Article 12	0	0	67	388	701	924	1355	1545	1699

Table 5.5
Total RAPEX Notifications and Notifications by Spain 2001-2009

	2001	2002	2003	2004	2005	2006	2007	2008	2009
RAPEX NOTIFICATIONS TOTAL	76	84	139	468	847	1051	1605	1866	1993
Notifications Spain				38	42	79	108	163	220

[1089] It should be noted that according to the report 2004, total number of notifications in 2004 is 388 even though in the subsequent RAPEX reports elaborated by the Directorate General of Health and Consumers such number -- 388 -- refers to the notifications under article 12 and the total number of notifications in 2004 being 468. See European Commission, Keeping European Consumers Safe, 2004 Annual report on the operation of the Rapid Alert System for non-food consumer products, RAPEX, http://ec.europa.eu/consumers/reports/report_rapex_04_en.pdf

Table 5.6
Type of Measure by Number of Notifications 2006-2009

	2006	2007	2008	2009
Compulsory measures	531	643	775	901
Voluntary measures	378	669	736	752
Compulsory measures complemented by voluntary corrective action	15	43	34	46
TOTAL NUMBER OF MEASURES	**924**	**1355**	**1545**	**1699**

CHAPTER 6

INTERACTION BETWEEN SAFETY AND LIABILITY RULES: THE JOINT USE OF EX ANTE AND EX POST PRODUCT REGULATION

European product regulation operates at three major phases of a product's lifecycle: before the product has been marketed, while it is being marketed, and after it has caused harm to a consumer or other user. Regulation of the first two phases is dominated by product safety law -- safety standards themselves in the pre-marketing phase, and notification obligations and enforcement mechanisms in the marketing phase. Regulation of the third phase is dominated by product liability law. Of course, there is also overlap in the phases to which each body of law applies, and there are also interactions between the two bodies, with their ex ante and ex post orientations.[1090] This chapter examines these interactions.

European consumer protection legislation, as a whole, and each body of law individually, aims at minimizing product risks by ensuring that only safe products reach the market and that injured victims receive compensation if a product causes harm. The literature generally distinguishes between four different mechanisms for minimizing product risks: the market, self regulation, government regulation, and tort law.[1091]

The literature on market-based mechanisms predicts that when markets function relatively well and information is available, consumers and users presented with otherwise substitutable products of the same price will choose the ones with the lowest

[1090] See W. Kip Viscusi, Toward a diminished role of tort liability: social insurance, government regulation, and contemporary risks to health and safety, 6 Yale J. on Reg. 65 (1989) arguing for a smaller role of the tort system when reducing risks.

[1091] See Steven Shavell, ECONOMIC ANALYSIS OF ACCIDENT LAW, Cambridge: Harvard University Press, 277-90 (1987) distinguishing between ex post and ex ante mechanisms as well as between privately or state initiated mechanisms. See also Michael Baram, Liability and its influence on designing for product and process safety, Safety Science 45, 11–30 (2007).

risks and the aggregate demand created by these choices will provide feedback to producers regarding consumer preferences for design and safety.[1092] The critique of this approach is that, as an empirical matter, markets have not produced optimal levels of product risks. While one may dispute what how optimality should be measured, there is strong evidence that consumers often lack perfect information and many markets do not function according to the classical model.[1093]

As an alternative to market regulation, the literature on self-regulation looks to safety standards voluntarily adopted by producers.[1094] Self-regulation has often been used in industries where corporate and professional associations prefer to establish their own safety standards to avoid government-imposed regulation.[1095] Self-regulation is similar to government safety regulation in that it operates largely in the pre-marketing phase, before the harm occurs, and self-regulation is arguably more effective than government regulation because the industry often possess better information about products than does

[1092] See generally Mitchell Polinsky and Steven Shavell, The uneasy case for product liability, 123 Harv. L. Rev. 1437 (2010) defending the market as the best mechanism to create incentives to manufacture safe products. See also John C. P. Goldberg and Benjamin C. Zipursky, The easy case for products liability law: a response to professors Polinsky and Shavell, 123 Harv. L. Rev. 1919 (2010) challenging the effectiveness of market mechanisms in creating incentives for safety.

[1093] The performance of market forces in creating incentives for safety have been broadly discussed in the literature and today there still seems to be remarkably different perspectives on this issue. For one of the most recent discussions see Mitchell Polinsky and Steven Shavell, The uneasy case for product liability, 123 Harv. L. Rev. 1437 (2010) defending the market as a mechanism -- even if not perfect -- to create incentives to manufacture safe products; John C. P. Goldberg and Benjamin C. Zipursky, The easy case for products liability law: a response to professors Polinsky and Shavell, 123 Harv. L. Rev. 1919 (2010) challenging Shavell and Polinsky's approach and Mitchell Polinsky and Steven Shavell, A Skeptical attitude about product liability is justified: a reply to professor Goldberg and Zipursky, 123 Harv. L. Rev. 1949 (2010).

[1094] This would be an ex ante privately initiated mechanism. See Steven Shavell, ECONOMIC ANALYSIS OF ACCIDENT LAW, Cambridge: Harvard University Press, 277-90 (1987).

[1095] For the use of self-regulation in Europe see Paul van der Zeijden and Rob van der Horst, Self-Regulation Practices in SANCO Policy Areas (2008) available at http://ec.europa.eu/dgs/health_consumer/self_regulation/docs/self-reg-SANCO-final.pdf and The Current State of Co-Regulation and Self-Regulation in the Single Market, EESC pamphlet series (2005). See also Andrzej Baniak and Peter Grajzl, Industry Self Regulation, Subversion of Justice, and Social Control of Torts, 23-24 (2007). This article is available at http://ssrn.com/abstract=1031324 arguing that when public legal institutions are vulnerable to subversion, delegating regulatory authority to the industry appears superior to governmental standard setting and courts imposed liability and arguing in favor of self-regulation as a desirable institutional arrangement in developing and transition economies. See Edward Glaeser and Andrei Shleifer, The Rise of the Regulatory State, Journal of Economic Literature, 41:2, 401-425, 420 (2003) arguing that in such cases, no government intervention and hence the functioning of the market alone would be the best way to minimize risks.

the government. On the other hand, there are obvious reasons to be skeptical that industries will voluntarily achieve socially optimal levels of risk, given the bottom line pressures and incentives for profit.

A third mechanism for minimizing product risks, of course, is government safety regulation, including ex ante standards and sanctions for non-compliance.[1096] The theory here is that governments are in the best position to set and enforce socially optimal risk levels.[1097] Whether this, in fact, occurs, depends on the functioning of the democratic process.[1098] One clear weakness is the vulnerability of government decision-makers to pressure from industry.[1099] Attempts to guard against this problem include the creation of independent standardization bodies or agencies.[1100]

The final mechanism for risk minimization is ex post tort law,[1101] based on the incentives for care created by exposure to liability for the harm caused by defective products.[1102] However, the effectiveness of the deterrent effect of tort liability strongly depends on the victim's pursuing their liability claims, the information available to courts

[1096] See Steven Shavell, ECONOMIC ANALYSIS OF ACCIDENT LAW, Cambridge: Harvard University Press, 277-90 (1987). See also Mitchell Polinsky and Steven Shavell, The uneasy case for product liability, 123 Harv. L. Rev. 1437 (2010) arguing that safety regulation is an effective mechanism to minimize product risks. For a skeptical view of this argument see John C. P. Goldberg and Benjamin C. Zipursky, The easy case for products liability law: a response to professors Polinsky and Shavell, 123 Harv. L. Rev. 1919 (2010).

[1097] This outcome will be achieved in cases where both the level of care and the accident occurrence are observable. But whenever one of these two parameters is not observable, the first best will not be achieved. Yolande Hiriart, David Martimort and Jerome Pouyet, On the optimal use of ex ante regulation and ex post liability, Economics Letters 84, 232 (2004).

[1098] For example, whenever courts are easy to influence and manipulate, the creation of safety incentives by the market is considered to be a socially optimal policy over other available alternatives. See Edward Glaeser and Andrei Shleifer, The Rise of the Regulatory State, Journal of Economic Literature, 41:2, 401-425 (2003).

[1099] When governments are weak, industry self-regulation may be superior than government standard settings or courts imposed liability. See Andrzej Baniak and Peter Grajzl, Industry Self-Regulation, Subversion of Justice, and Social Control of Torts (2007). This article is available at http://ssrn.com/abstract=1031324

[1100] An example of these independent bodies could be the three European standardization bodies such as the European Committee of Standardization (CEN), the European Committee for Electrotechnical Standardization (CENELEC) and the European Telecommunications Standards Institute (ETSI).

[1101] This would be an ex post, privately initiated mechanism. See Steven Shavell, ECONOMIC ANALYSIS OF ACCIDENT LAW, Cambridge: Harvard University Press, 277-90 (1987).

[1102] See Steven Shavell, Liability for Harm versus Regulation of Safety, 13 J Legal Stud. 2, 357 (1984).

so that court errors are minimized and the probability of tortfeasors being judgment proof and hence unable to compensate the victim for the harm suffered.[1103]

As explained in chapters 2 and 5, the mechanisms used in Europe to minimize product risks are ex ante government regulation (based on safety standards framed within a general obligation of introducing safe products to the market)[1104] and ex post product tort liability.[1105] These mechanisms, driven by the aspiration for a single market, share the goal of creating incentives to minimize product risks and hence product-related accidents.[1106] At the same time, the two mechanisms are fundamentally different:[1107] While product safety is a regulatory body based on ex ante safety standards and fines applicable once a product is deemed dangerous, product liability is an ex post liability-based regime that aims at creating incentives for investing in care[1108] as well as compensating victims for the harm caused by defective products.[1109]

In Europe, these two bodies, being applicable to different phases of a product's life, interact and share common goals: bringing safe product to the market while

[1103] See W. Kip Viscusi, Product Liability and Regulation: Establishing the Appropriate Institutional Division of Labor, The American Economic Review, Vol. 78, No. 2, pp. 300-304 (1988) suggesting that the limitations of liability under tort are not present in other mechanisms such as ex ante regulation. See also Richard A. Posner, ECONOMIC ANALYSIS OF LAW, 402, Aspen eds., 5th ed. (1998).
[1104] It should be noted that the GPSD also imposes post-marketing obligations given that there is a monitoring and an obligation to provide information regarding product risks known after the product has been marketed. See Recital 17 and Article 5(1) of the GPSD.
[1105] The European consumer protection model uses tort law to compensate injured victims of product accidents. W. Kip Viscusi, Toward a diminished role of tort liability: social insurance, government regulation, and contemporary risks to health and safety, 6 Yale J. on Reg. 65, 68 (1989) discussing the compensation role of tort law and arguing in favor of using alternative compensation mechanisms.
[1106] Steven Shavell, Liability for Harm Versus Regulation of Safety, 13 J. Legal Stud. 2, 357 (1984).
[1107] See Susan Rose-Ackerman, Regulation and the law of torts, The American Economic Review, vol. 81, num. 2, 54 (1991) arguing that the fundamental difference between tort law and regulation stems on procedures -- regarding who decides, when and based on what information --, not on their essence.
[1108] See Walter Oi, The Economic of Product Safety, Bell Journal of Economics and Management, vol.4, num 1, 3-28 (1973) for one of the first contributions on the relationship between liability and prices. Oi argued that given the tortfeasor's internalization, in the product context this will imply that product prices will reflect the expected liability manufacturers are exposed to.
[1109] See generally William Landes and Richard Posner, The positive economics theory of tort law, 15 Georgia Law Review 851 (1981), Steven Shavell, Strict liability versus negligence, 9 Journal of Legal Studies 1, 1-25 (1980).

minimizing the amount of defective products that cause product related accidents.[1110] Product liability, consistent with the deterrence and corrective justice goals of tort law, further aims to provide compensation to injured victims of defective products.[1111]

Law and economics literature have long viewed the two accident-minimizing mechanisms -- regulation and litigation -- as substitutes in deterring potentially harmful conduct. Today, as is the case with European product regulation, legal mechanisms often present a mix of regulation and litigation approaches, the performance of which will depend on the contexts in which they are applied. When the two mechanisms interact, it is possible that they will interfere with one another and jeopardize their shared goals. However, it is also possible for the complementary use of these two mechansims to be socially advantageous.[1112]

From a theoretical perspective, the effectiveness of their joint use depends on the specific context in which the interaction takes place and on many parameters such as the availability of information concerning the product risk, the potential amount of damages the product may cause and the likelihood of product victims pursuing their claims. But the effectiveness of the interaction between product safety and product liability also depends on whether the specific strengths of each legal mechanism are coordinated.

This chapter analyzes the regulatory context in which the product liability directive operates and the impact and effects of the interaction of ex ante product safety regulation with ex post product liability law in Europe. This chapter will further discuss how the two legal mechanisms could be better coordinated in order to enhance their joint performance.

[1110] See Steven Shavell, Liability for Harm versus Regulation of Safety, 13 J Legal Stud. 2, 357 (1984) for one of the first contributions analyzing the performance of each instrument.
[1111] See generally Gary Schwartz, Mixed Theories of tort law: affirming both deterrence and corrective justice, 75 Texas Law Review 1801 (1997).
[1112] Patrick W. Schmitz, On the joint use of liability and safety regulation, International Review of Law and Economics 20, 371-382 (2000).

1. The functioning of ex ante regulation and ex post liability as risk-minimizing mechanisms

When producers introduce a product in the market, the product may increase the risk of harm to consumers and users. This increase in risk can be characterized as a negative externality derived from the market transaction.[1113] Determining the most efficient way of dealing with this externality has been the focus of a broad literature in economics and, particularly, in the economic analysis of law.[1114]

Product safety regulation and product liability aim to minimize accident risks and, hence, create optimal incentives for product manufacturers to invest in product safety: safety regulation requires the potential injurer to take measures to prevent the accident from occurring while liability deters product accidents by making the potential injurer liable for the costs of such accident.[1115] Further, product liability aims to provide compensation for victims of accidents caused by defective products. Thus, product safety essentially impacts accident deterrence and product liability impacts both accident deterrence and victim compensation by making product manufacturers internalize the harm caused by defective products whenever product victims pursue their claims. Regulation has effects before the accident takes place while liability operates once the product accident has occurred as a consequence of a product defect.[1116] In this sense, regulatory standards focus on establishing safety standards and not on compensating the

[1113] John P. Brown, Toward an Economic Theory of Liability, Journal of Legal Studies, 2, 323-50 (1973); Peter Diamond, Single Activity Accidents, 3 Journal of Legal Studies 107-64 (1974) and Guido Calabresi, THE COSTS OF ACCIDENTS: A LEGAL AND ECONOMIC ANALYSIS, New Haven, CN: Yale University Press (1970) were the first authors who presented an analytical model of the use of liability as an instrument for controlling externalities.

[1114] See, for example, W. Kip Viscusi, The Regulation–Litigation Interaction, AEI Brookings Joint Center for Regulatory Studies Working Paper 01-13 (2001). Available at http://papers.ssrn.com/abstract_id=292645.

[1115] W. Landes and R. Posner, Tort Law as a Regulatory Regime for Catastrophic Personal Injuries, Journal of Legal Studies 13, 417-434 (1984).

[1116] In a way, regulation and ex post liability becomes an example of the distinction between private and legal enforcement. Steven Shavell, Liability for Harm versus Regulation of Safety, 13 Journal of Legal Studies 2, 357 (1984).

injured victim, assuming that such compensation will be provided by other means such as insurance, either private or public. In contrast, litigation aims at, in addition to making tortfeasors internalize the harm they cause, awarding compensation to the injured victim for the harm suffered.[1117]

The performance and effectiveness of product safety regulation in making product manufacturers invest in prescribed levels of care depend on whether a regulatory standard forces product manufacturers to invest a certain amount of care that may or may not be set at the optimal level. Likewise, product liability's effectiveness in creating incentives for accident deterrence depends on whether product manufacturers are subsequently exposed to liability.

1.1 Ex ante regulation

Regulatory standards aim to modify the behavior of potential tortfeasors before harm occurs regardless of whether harm ever takes place.[1118] The introduction of an ex ante regulation determining the required level of product safety is then justified not solely because a product presents risks, fails and causes accidents.[1119]

Government regulation of ex ante product safety is characterized by centralized government decisions about the level of investment in care that should be required for a

[1117] W. Kip Viscusi, The Regulation–Litigation Interaction, AEI Brookings Joint Center for Regulatory Studies Working Paper 01-13 (2001). Available at http://papers.ssrn.com/abstract_id=292645.
[1118] See Steven Shavell, Liability for Harm versus Regulation of Safety, 13 J Legal Stud. 2, 357 (1984).
[1119] Michael Spence, Consumer misperceptions, product failure, and producer liability. Review of Economic Studies, 44(3):561-72 (1977); Mark Geistfeld. Manufacturer moral hazard and the tort-contracts issue in products liability, International Review of Law and Economics, 15:241—252 (1995); Steven Shavell, FOUNDATIONS OF ECONOMIC ANALYSIS OF LAW, Harvard University Press (2003). Some authors have suggested the possibility of limiting or even eliminating product liability under tort in favor if a contractually-based liability. See George L. Priest. Can absolute manufacturer liability be defended? Yale Journal on Regulation, 9:237-263 (1992) and Paul H. Rubin, Courts and the tort-contract boundary in product liability, in Frank Buckley, ed., THE RISE AND FALL OF FREEDOM OF CONTRACT, Duke University Press (1999) and see generally Abraham L. Wickelgren, The inefficiency of contractually-based liability with rational consumers, 22 J.L. Econ & Org. 168 (2006).

given product.[1120] Thus, when ex ante regulation is used, the government defines and uniformly implements a safety standard that it has previously determined.[1121] The government's role does not end here, though. Once the safety standard is defined, it will aim to provide product manufacturers and potential tortfeasors with incentives to comply with the standard.[1122] In order to ensure compliance, the government will establish sanctions for non compliance, and enforcing these sanctions requires monitoring behavior.[1123] Hence, ex ante regulation requires an active government role in designing safety standards, encouraging and monitoring compliance and imposing sanctions for non-compliance.

When designing a safety standard, the ultimate goal is for the standard to create incentives for firms to invest in care so that accidents are minimized and to realign social and private incentives. When the safety standard accomplishes this goal, it is considered to be optimal. In order for a safety standard to be optimal, the marginal cost of additional care induced by the regulation should be equal to the expected reduction of harm resulting from the additional care.[1124]

In order to reach optimality, agency officials need information.[1125] The availability, amount and kind of information are the biggest problems regulatory

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[1120] Marcel Boyer and Donatella Porrini, Law versus Regulation: A Political Economy Model of Instrument Choice in Environmental Policy in A. Heyes, ed., LAW AND ECONOMICS OF THE ENVIRONMENT, Edward Elgar Publishing Ltd, 416pp. (2001).

[1121] In contrast, under tort, judges assign cases individually. See Susan Rose-Ackerman, Regulation and the law of torts, The American Economic Review, vol. 81, no 2, 54 (1991).

[1122] See Jacob Nussim and Avraham D. Tabbach, Controlling Avoidance: Ex-Ante Regulation versus Ex-Post Punishment, 46 Review of Law and Economics 4:1, 56 (2008) arguing that, in the criminal context, ex post punishment creates two opposing effects on incentives to comply awith the rule: increasing the price of avoidance of the rule while at the same time, increasing the benefit from investing in avoidance of the ex ante regulation of the criminal conduct.

[1123] Robert Innes, Enforcement costs, optimal sanctions, and the choice between ex-post liability and ex-ante regulation, International Review of Law and Economics 24(1), 29-48, 30 (2004).

[1124] See Steven Shavell, A Model of the Optimal Use of Liability and Safety Regulation, Rand J. Econ. 15(2), 271-280, 275-278 (1984) and Steven Shavell, Liability for Harm Versus Regulation of Safety, 13 J. Legal Stud. 2, 357 (1984).

[1125] Steven Shavell, A model of the optimal use of liability and safety regulation. Rand Journal of Economics 15(2), 271-280 (1984) noting that whenever regulators do not have perfect information about risks, the safety standard will not be optimal.

standards present.[1126] When performing risky activities, it is not uncommon that tortfeasors will have private information about the level of harm as well as about the probability of an accident. Regulators need this same information in order to establish optimal standards; if the regulator lacks information about either the probability or the level of harm it will not be in a good position to establish optimal standards.[1127] However, it should be noted that despite the often incomplete information government agencies have when they establish standards of care, government regulation might still be an effective institution for centralizing and generating information regarding the risks presented by certain kind of products as well as for disseminating such information and hence assisting private parties' as they take decisions.[1128]

But even when the government has perfect information about accident risks, government agencies often are too rigid in their structure to adjust standards to new technological developments. In addition, government agencies often must rely on expert advice and may be subject to pressure and potentiall "capture" by the regulated parties.[1129] Moreover, government standards are uniformly set across different parties; to the extent that these parties present varying levels of risk, the standards cannot hope to be

[1126] Victor P. Goldberg, The Economics of product safety and imperfect information, the Bell Journal of Economics and Management Science, 5:2, 683-688, 685 (1974).

[1127] The agency reference model has been proposed as a way to solve the informational problem of government agencies. This model suggests the creation of a repository of agency information focusing on the nature of the agency's cost-benefit determinations as well as the economic consequences of the different safety government regulations. In light of this information available, courts would look at the agencies in order to obtain the empirical information necessary when taking decisions. See Catherine M. Sharkey, Products liability preemption: an institutional approach, 76 The George Washington Law Review 101, 104-105, 134 (2008).

[1128] This is especially true in cases where information regarding risks is especially complex. In these kinds of cases, government regulation presents a comparative advantage with respect to litigation given the poor performance of the judicial system in producing risk-related information. See W. Kip Viscusi, Toward a diminished role of tort liability: social insurance, government regulation, and contemporary risks to health and safety, 6 Yale J. on Reg. 65, 75 (1989).

[1129] See Richard A. Posner, Theories of Economic Regulation, 5 Bell. J. Econ. Man. Sci. 335 (1974). presenting different versions of capture theory and Michael E. Levine, Regulatory Capture, in 3 THE NEW PALGRAVE DICTIONARY OF ECONOMICS AND THE LAW 267 (Peter Newman ed., 1998). For a discussion of regulatory capture in the context of environmental policy see Marcel Boyer and Donatella Porrini, Law versus Regulation: A Political Economy Model of Instrument Choice in Environmental Policy in A. Heyes, ed., Law and Economics of the Environment, Edward Elgar Publishing Ltd, 416 (2001).

optimal for all of them.[1130] Hence, global optimal standards are practically an unachievable goal.

An additional aspect to be considered in the design of safety standards is the level of specificity of the law establishing the required level of care.[1131] In this sense, the literature has often differentiated between standards and rules. A standard is open ended so that the adjudicator might make determinations based on the circumstances of the specific case.[1132] A rule is more specific and its application is more uniform and leaves no discretion to the adjudicator of the case.[1133] The difference between these two kinds of ex ante government safety regulations is important given that they entail different kinds of costs relevant depending on the case. Hence, rules are more costly to design but cheaper to adjudicate while the situation for standards is the opposite.[1134] From an ex ante perspective, rules provide better guidance to the subjects of the law, and from an ex post perspective, standards may be better able to adapt to the varying circumstances of the case.[1135] The aggregate cost between design and determination of compliance should control the legislature's determination.[1136]

As mentioned earlier, regulation entails not only designing the safety regulation but also enforcing compliance -- or controlling avoidance -- as well as imposing sanctions

[1130] Steven Shavell, A model of the optimal use of liability and safety regulation, Rand Journal of Economics 15(2), 271-280, 273 (1984).
[1131] Francesco Parisi, Harmonization of European Private Law: An Economic Analysis, Minnesota Legal Studies Research Paper No. 07-41 (2007). Available at SSRN: http://ssrn.com/abstract=1014385
[1132] An example of a standard would be the general obligation of safety established by the GSPD in article 3.2 of the GPSD and where compliance is established considering the specific circumstances of the case.
[1133] En example of rules would be the essential safety requirements included in some New Approach Directives. See Francesco Parisi, Vincy Fon and Nita Ghei The Value of Waiting in Lawmaking, European Journal of Law and Economics, 18: 131–148 (2004) showing that the optimal level of specificity of laws increase when they are applied and interpreted by specialized courts.
[1134] Francesco Parisi, Harmonization of European Private Law: An Economic Analysis, Minnesota Legal Studies Research Paper No. 07-41 (2007). Available at SSRN: http://ssrn.com/abstract=1014385
[1135] Vincy Fon and Francesco Parisi, On the Optimal Specificity of Legal Rules, George Mason University School of law, Law Studies Research Paper no. 04-32. This paper is available at http://ssrn.com/abstract=569401
[1136] See Issac Ehrlich and R. Posner, An Economic Analysis of Legal Rulemaking, Journal of Legal Studies 3, 257-286 (1974). See also Vincy Fon and Francesco Parisi, On the Optimal Specificity of Legal Rules, George Mason University School of law, Law Studies Research Paper no. 04-32. This paper is available at http://ssrn.com/abstract=569401

whenever pertinent. Both activities entail administrative costs.[1137] When monitoring whether agents are complying with the level of safety required by government regulation, the government must decide how often to monitor, when to monitor and whether to observe care, the occurrence of an accidence, or both events. It must, further, choose the sanctions to impose in light of the information available.[1138] Hence, safety regulation entails public costs in terms of maintaining regulatory agencies and the private costs of compliance. In contrast, the public cost of a liability system includes administrative expenses incurred by private and by public parties.[1139]

The administrative costs of regulation are incurred regardless of whether harm occurs. In this sense, ex ante regulation of care might be more efficient than imposing ex post liability for harm given that the government's enforcement of regulation sanctions all negligent conduct while liability only plays a role when an accident occurs, harm takes places and the victim pursues a claim. As a result, the required level of care can be obtained with a smaller investment in monitoring.[1140]

When monitoring or ensuring compliance, governments rely on observable variables in order to decide whether or not to impose sanctions. In this sense, whether care is observable or whether the occurrence of the accident is observable will condition

[1137] Establishing product safety standards induces product manufacturers to invest so that they are not punished for non-compliance -- or avoidance. It should be noted that the costs of controlling avoidance or compliance are different from increasing the costs of avoidance. See generally Chris Sanchirico, Detection Avoidance, 81 New York University Law Review 1331 (2006).

[1138] Robert Innes, Enforcement costs, optimal sanctions, and the choice between ex-post liability and ex-ante regulation, International Review of Law and Economics 24(1), 29-48, 30 (2004). See also Jacob Nussim and Avraham D. Tabbach, Controlling Avoidance: Ex-Ante Regulation versus Ex-Post Punishment, 46 Review of Law and Economics 4:1 (2008) arguing that, in the context of criminal detection and punishing, the probability of detecting and punishing a crime is positively correlated with the probability of detecting and ex post punishing avoidance.

[1139] Liability, in this sense, presents an important advantage given that most of administrative costs under liability are only incurred whenever harm occurs. Marcel Boyer and Donatella Porrini, Law versus Regulation: A Political Economy Model of Instrument Choice in Environmental Policy in A. Heyes, ed., Law and Economics of the Environment, Edward Elgar Publishing Ltd, 416 (2001).

[1140] Robert Innes, Enforcement costs, optimal sanctions, and the choice between ex-post liability and ex-ante regulation, International Review of Law and Economics 24(1), 29-48, 31 (2004). See also Steven Shavell, Liability for Harm versus Regulation of Safety, 13 J. Legal Stud. 2, 365 (1984).

the government strategy as well as the administrative costs of implementation of the government regulation.[1141]

In sum, although ex ante government regulation may be far from optimal as a result of imperfect information, the potential for agency capture, and the inefficiency of uniform application across varying parties, it has the potential, nonetheless, to significantly contribute to reducing product risks and hence to minimizing product-related accidents.[1142]

1.2 Ex post tort liability

Eliminating product risks entirely is neither possible nor economically efficient.[1143] An efficient level of risk reduction is one where the marginal costs of care equal the marginal benefits -- or marginal savings in expected harm and hence, expected liability. A liability system aims to create incentives for producers to control risks by internalizing expected damage costs (expected liability) in the form of production costs.[1144]

There are two major liability rules: strict liability and negligence. A pure strict liability system imposes liability for harm upon proof of the existence of the harm and of

[1141] In cases where both the level of care and the accident occurrence are observable, the first best outcome will be reached but whenever one of these two parameters is not observable, the first best will not be achieved. Yolande Hiriart, David Martimort and Jerome Pouyet, On the optimal use of ex ante regulation and ex post liability, Economics Letters 84, 232 (2004).

[1142] See generally A. Mitchell Polinsky and Steven Shavell, The Uneasy Case for Product Liability, 123 Harv. L. Rev. 1437 (2010) arguing that product safety regulation contributes to reducing product risks and hence product-related accidents.

[1143] Jean C. Buzby and Paul D. Frenzen, Food safety and product liability, 24 Food policy, 637-651, 638 (1999).

[1144] Liability is often questioned because of the availability of liability insurance and its potential impact on diluting the incentives created by the liability tortfeasors are exposed to. But even when tortfeasors insure against those risks, they still have incentives to invest in care and hence reduce risks because the insurance premiums often reflect the long-term risks they generate. See W. Kip Viscusi, Toward a diminished role of tort liability: social insurance, government regulation, and contemporary risks to health and safety, 6 Yale J. on Reg. 65 (1989).

a causal relationship between this harm and the torfeasor's conduct.[1145] Strict liability creates incentives for internalizing risks through the expected liability tortfeasors are exposed to, that is equivalent to the compensation awarded to the injured victim for the harm suffered. Under strict product liability, for example, product manufacturers will optimally invest in care and risk reduction depending on the expected liability to which they are exposed and on the cost of care. They will not invest in care when the cost of care is higher than the reduction in expected liability, as they would prefer to compensate victims for damages suffered than to invest in care, and hence risk reduction, that would be costlier than these damages.[1146] In contrast, liability under negligence depends on the tortfeasor not acting in accordance with a set standard of care.[1147]

The effectiveness and performance of liability under tort is based on the deterrent effect of the damages and liability to which tortfeasors are exposed when damage occurs.[1148] Under liability, the care taken by parties is a function of the harm they may cause. So the level of care is expected to increase with the increase of the potential harm caused by the tortfeasor as long as the level of liability the firm is exposed to is lower than the firm's assets.[1149]

The deterrent effect of tort law further depends on whether firms are able to anticipate the damage awards to which they will be subject whenever they cause harm. If information is perfect, potential tortfeasors can anticipate the probability of harm and its magnitude and hence the liability that courts will impose. Under these assumptions,

[1145] It also presents some disadvantage in cases where victims may be spread and the amount of damages too small so that they would not have incentives to pursue their claims or harm could be latent and appear after the statute of limitations of the claim expired. In these cases, tortfeasors would no internalize the harm they caused and hence would not adopt the optimal level of care they ought to and the deterrent effect of strict product liability would not be efficient. See Marcel Boyer and Donatella Porrini, Law versus Regulation: A Political Economy Model of Instrument Choice in Environmental Policy in A. Heyes, ed., Law and Economics of the Environment, Edward Elgar Publishing Ltd, 416 pp. (2001).
[1146] See Richard W. Wright, The principles of product liability, 26 Rev. Litig. 1067, 1099 (2007).
[1147] Robert Innes, Enforcement costs, optimal sanctions, and the choice between ex-post liability and ex-ante regulation, International Review of Law and Economics 24(1), 29-48, 30 (2004).
[1148] See Steven Shavell, Liability for Harm versus Regulation of Safety, 13 J Legal Stud. 2, 357-374 (1984).
[1149] Steven Shavell, A model of the optimal use of liability and safety regulation, Rand Journal of Economics 15(2), 273 (1984).

investment in care will be optimal so that they can minimize their exposure to liability.[1150]

But perfect information is a very strong assumption. For example, when talking about products, the probability of harm does not only depend on product manufacturers but also depends on consumers.[1151] Hence, the probability of harm is not totally controlled by product manufacturers. So when some assumptions are relaxed and the analysis is more realistic, tortfeasors are not assumed to be able to assess all these parameters and hence internalize the harm they cause through the tort system, and consumers are not assumed aware of all the information about product risks and the potential harm they are exposed to when using such product.[1152]

Together with imperfect information, additional parameters also undermine the deterrent effect of tort liability. These include the fact that not all victims pursue their liability claims, the probability of court errors and the probability of tortfeasors being judgment proof and hence unable to pay out damages that are awarded.[1153]

[1150] This is true when only compensatory damages are considered. Some have argued in favor of using punitive damages as an additional instrument to create incentives to invest in product safety given the public's interest in safe products. Further, the lack of insurance policies insuring for punitive damages could become a factor to reduce future hazards if manufacturers were forced to internalize potential liability for punitive damages they could not be shifted to insurance companies. See Alan I. Widiss, Liability Insurance Coverage For Punitive Damages? Discerning Answers To The Conundrum Created By Disputes Involving Conflicting Public Policies, Pragmatic Considerations And Political Actions, 39 Vill. L. Rev. 455, 503 (1994).

[1151] See A. Mitchell Polinsky and William P. Rogerson, Products Liability, Consumer Misperceptions, and Market Power, Bell Journal of Economics, The Rand Corporation, vol. 14(2), pages 581-589 (1983) comparing the effect of different liability regimes – strict liability, negligence and no liability – on the investment in safety and concluding that whenever consumers perceive the probability of harm to be lower than it is, it is socially optimal to shift liability to consumers in order to achieve a socially optimal equilibrium. See also Daniel Schwarcz, A Products Liability Theory for the Judicial Regulation of Insurance Policies, 48 William and Mary Law Review 1389, 1400 (2007). This article is available at http://ssrn.com/abstract=923423

[1152] W. Kip Viscusi, Toward a diminished role of tort liability: social insurance, government regulation, and contemporary risks to health and safety, 6 Yale J. on Reg. 65, 83 (1989).

[1153] W. Kip Viscusi, Product Liability and Regulation: Establishing the Appropriate Institutional Division of Labor, The American Economic Review, Vol. 78, No. 2, pp. 300-304 (1988) arguing that the limitations of tort liability are such that policy makers should rely on regulation to achieve accident minimization. See also Richard A. Posner, ECONOMIC ANALYSIS OF LAW, 402, Aspen eds., 5th ed. (1998) noting that the fixed costs of lawsuits of tort liability is a strong argument in favor of regulation.

First, liability does not create optimal incentives for the adoption of care because not all victims file tort claims in court. This results in tortfeasors not fully internalizing the costs of the harm they cause.[1154] Regulation and liability are structured around the need for third party action for their implementation. Regulation is required ex ante and compliance is required regardless whether harm has been caused; the third party action in the case of regulation is government action. In contrast, in order for liability to be imposed, harm needs to have occurred and the victim needs to pursue a claim.

When some victims do not pursue their claims under tort and hence the probability of being sued is lower than one, the tortfeasor´s exposure to liability is lower than the harm caused and liability is not efficient because the tortfeasor´s investment in care is lower than the socially optimal level.[1155] The lower the probability of being sued by an injured victim, the larger is the difference between the individual and the socially optimal investment in care.[1156] Further, even if victims pursue their tort claims, harm may not always be traced to its cause and tortfeasors may escape from being held liable.[1157]

Second, courts may commit errors in determining whether the victim's harm was caused by the tortfeasor's conduct and in assessing the level of damages. Sometimes the damage awards determined by courts do not always reflect the actual damages suffered by injured victims. The difference between these two levels of damages distorts the incentives of the tortfeasors for care and hence on the deterrent effect of liability under

[1154] Steven Shavell, A model of the optimal use of liability and safety regulation, Rand Journal of Economics 15(2), 271-280 (1984).
[1155] Steven Shavell, Liability for Harm Versus Regulation of Safety, 13 Journal of Legal Studies 2, 357-374 (1984). See also Eric Helland and Jonathan Klicky, The Tradeoffs between Regulation and Litigation: Evidence from Insurance Class Actions, Journal of Tort Law, vol. 1 issue 3 (2007).
[1156] Further, the private and social incentives for brining a legal claim are often different. When a party is deciding whether to pursue her legal claim, it does not take into account the legal costs that he induces others to incur and that would be a negative externality -- like for example, the social costs of using the courts or the defendant's legal costs -- and the positive externalities such as the deterrent effects on other potential tortfeasors that would result if the claim was brought. See Steven Shavell, The fundamental divergence between the private and the social motive to use the legal system, 26 J. Legal Stud. 575, 589-579 (1997). See also Eric Helland and Jonathan Klicky, The Tradeoffs between Regulation and Litigation: Evidence from Insurance Class Actions, Journal of Tort Law, vol. 1 issue 3 (2007).
[1157] Robert Innes, Enforcement costs, optimal sanctions, and the choice between ex-post liability and ex-ante regulation, International Review of Law and Economics 24(1), 29-48, 31 (2004).

tort. If the tort system created efficient deterrence, it should compensate all injured victims for the actual amount of harm suffered.[1158] Tort law is sometimes considered ineffective in areas where courts may have difficulties regarding certain technical issues, as for example, products liability.[1159] In cases like this, ex ante regulation is considered to have some advantages compared to liability under tort.[1160]

Third, the likelihood of a tortfeasor being judgment proof undermines the deterrent effect of tort liability as well. If there was no risk of the tortfeasor´s bankruptcy and a suit was always brought against the tortfeasor, tort liability would be optimal.[1161] But whenever tortfeasors do not have enough assets to pay for the damages awarded against them, tort liability cannot create optimal incentives for care given that these tortfeasors do not fully internalize the total amount of damage they cause and adopt care only up to the level of damages they will be able to pay. In these cases, limited assets may mean limited care.[1162]

The tortfeasor's judgment proof problem does not imply that tortfeasors do not internalize any liability. Tortfeasors internalize the liability level they can afford considering their assets and will determine their investment of care considering the level

[1158] W. Kip Viscusi, Toward a diminished role of tort liability: social insurance, government regulation, and contemporary risks to health and safety, 6 Yale J. on Reg. 65, 83 (1989).
[1159] Peter Huber, LIABILITY: THE LEGAL REVOLUTION AND ITS CONSEQUENCES, New York: Basic Books, (1988) and W. Kip Viscusi, Structuring an Effective Occupational Disease Policy: Victim Compensation and Risk Regulation, Yale Journal on Regulation, 2, 53-81 (1984).
[1160] See Charles D. Kolstad; Thomas S. Ulen; Gary V. Johnson, Ex Post Liability for Harm vs. Ex Ante Safety Regulation: Substitutes or Complements?, The American Economic Review, Vol. 80, No. 4. (1990), 888-901 developing a model of evidentiary uncertainty of the judicial standard of care. It should be noted that this argument for regulation is generally not robust enough to the optimal design of liability alternatives. See Aaron S. Edlin, Efficient standards of due care: Should courts find more parties negligent under comparative negligence?, International Review of Law and Economics, 14, 21–34 (1994) showing that despite the presence of evidentiary uncertainty, efficiency may be achieved with the implementation of negligence under tort as long as the negligence standard is set optimally. See also Susan Rose-Ackerman, Regulation and the Law of Torts, The American Economic Review, vol. 81, no. 2, Papers and Proceedings of the Hundred and Third Annual Meeting of the American Economic Association pp. 54 -58, 55 (1991).
[1161] Steven Shavell, Liability for Harm Versus Regulation of Safety, 13 Journal of Legal Studies 2, 357-374 (1984).
[1162] W. Kip Viscusi, Toward a diminished role of tort liability: social insurance, government regulation, and contemporary risks to health and safety, 6 Yale J. on Reg. 65, 83 (1989).

of liability they effectively will be able to afford.[1163] Hence, beyond that expected level of harm, tortfeasors become judgment proof and will not increase their investment in care even when it is socially optimal for them to do so.[1164]

In cases where the tortfeasor's judgment proof problem might be likely, regulation will become a better alternative because compliance with the regulatory standard is determined ex ante, that is, before the tortfeasor engages in the risky activity.[1165] Consequently, while the effectiveness of liability under tort is influenced by the potential bankruptcy of the tortfeasor, regulation is not affected by it because of the moment compliance is required.[1166] Hence, regulation would be preferred in these cases.[1167]

The limitations of tort liability as a mechanism for deterrence of product-related accidents have been widely discussed in the literature.[1168] Some authors have argued that product liability might not create incentives to invest in product safety in addition to the

[1163] The level of care adopted in these cases will be lower than the socially optimal level of care that should be adopted. See Patrick W. Schmitz, On the Joint Use of Liability and Safety Regulation, International Review of Law and Economics, 20:3, pp. 371-382 (2000) showing that whenever firms have heterogeneous assets, it may be optimal to supplement liability with regulation in order to increase the level of care poor firms would decide to adopt.

[1164] Steven Shavell, A Model of the Optimal Use of Liability and Safety Regulation, Rand J. Econ. 15(2), 271-280, 275-278 (1984) and Steven Shavell, Liability for Harm Versus Regulation of Safety, 13 J. Legal Stud. 2, 357-374 (1984).

[1165] Steven Shavell, Liability for Harm versus Regulation of Safety, 13 J. Legal Stud. 357, 360 (1984).

[1166] Steven Shavell, Minimum Asset Requirements and Compulsory Liability Insurance as Solutions to the Judgment-proof Problem, Rand Journal of Economics, vol. 36, num 1, 67-77, 74-75 (2005) noting that direct safety regulation and criminal liability could be instruments to combat the judgment-proof problem and encouraging research on the determination of which instrument would perform better and considering whether a combination between them would be advantageous.

[1167] Steven Shavell, Liability for Harm versus Regulation of Safety, 13 J. Legal Stud. 2, 365 (1984).

[1168] See George L. Priest, Products Liability Law and the Accident Rate, in LIABILITY: PERSPECTIVES AND POLICY, 184, 187-94 (Robert E. Litan & Clifford L. Winston eds. 1988) studying the effect of the significant increase in product liability litigation during the 1970 and 1980 on accident rates. See also Donald N. Dewees, David Duff & Michael Trebilcock, EXPLORING THE DOMAIN OFACCIDENT LAW: TAKING THE FACTS SERIOUSLY, 202-05 (1996) and Mark Geistfeld, Products Liability, in ENCYCLOPEDIA OF LAW AND ECONOMICS, vol. 1, § 11.11, Michael Faure ed., 2d ed. (2009) intending to asses the impact of product liability on product-related accidents and concluding is not able to draw conclusions. See also Mitchell Polinsky and Steven Shavell, The uneasy case for product liability, 123 Harv. L. Rev. 1437 (2010) arguing, based on limited evidence and limited literature, that product liability has had a marginal influence on product safety.

ones created by ex ante regulation and market forces in the form of loss of reputation.[1169] Ex ante regulation already requires product manufacturers to make certain investments in product safety, and these may not be enhanced by the incentives created by product liability.[1170] Additionally, market forces will create incentives for product manufacturers to invest in safety given that consumers, through the information reflected by product prices, will choose products that entail a high level of safety.[1171] The reputation that product manufacturers will lose as a consequence of manufacturing risky products already creates incentives for them to invest in product safety.[1172] This is especially true in widely sold products, where consumers have a higher level of information regarding product risks and hence on their level of safety.[1173]

Despite an understanding of the limitations presented by the tort system as a deterrent mechanism, European regulators chose a tort liability regime for product-related accidents and adopted a strict liability system (at least facially) in the product liability

[1169] See Mitchell Polinsky and Steven Shavell, The uneasy case for product liability, 123 Harv. L. Rev. 1437 (2010) presenting some examples and arguing that market forces and ex ante product safety regulation might be sufficient to create optimal incentives for product safety for widely sold products such as drugs, automobiles and consumer appliances and that, in these cases, product liability might be undesirable. But in products not widely sold, market forces and regulation might not be sufficient to encourage an optimal level of safety and product liability could be socially beneficial.

[1170] Mitchell Polinsky and Steven Shavell, The uneasy case for product liability, 123 Harv. L. Rev. 1437, 1472 (2010) arguing that the more widely sold product are, the bigger the regulator's interest in adopting ex ante product safety regulation; the more information the regulation will have regarding risks presented by the product and the more accurate safety requirements will be.

[1171] It should be noted that cognitive biases may decrease the consumers' ability to assess product risks and hence the impact of market forces on the incentives to invest in product safety. The more information consumers will have regarding product risks, the lower the impact of cognitive biases and the better the assessment of product risks. See generally Christine Jolls, Cass R. Sunstein & Richard Thaler, A Behavioral Approach to Law and Economics, 50 Stan. L. Rev. 1471 (1998) and Matthew Rabin, Psychology and Economics, 36 J. Econ. Literature 11, 24-31 (1998) analyzing the individual's cognitive biases.

[1172] See Alberto Cavaliere, Product Liability in the European Union: Compensation and Deterrence Issues, European Journal of Law and Economics, 18: 299–318, 300 (2004) arguing that corporate reputation also plays a role in creating incentives for accident deterrence.

[1173] The importance of market forces in creating incentives for investing in product safety strongly depends on the information available to consumers regarding product risks or on whether they have contracted first party accident insurance. See Guido Calabresi, THE COSTS OF ACCIDENTS: A LEGAL AND ECONOMIC ANALYSIS, 24-33 (1970) and later developed by Jon D. Hanson and Kyle D. Logue, The First-Party Insurance Externality: An Economic Justification for Enterprise Liability, 76 Cornell L. Rev. 129, 159-68 (1990). One of the most recent contributions is Mitchell Polinsky and Steven Shavell, The uneasy case for product liability, 123 Harv. L. Rev. 1437, 1451-1453 (2010).

directive. Product manufacturers are held liable for the harm caused by the products they market regardless of the adopted level of care as long as there is a determination that the product is defective. The underlying economic premise of strict product liability is that firms have incentives to produce safer products if they must fully compensate people harmed by them.[1174] This potential liability is part of the firms' anticipated costs of operation and firms will take the optimal amount of precautions when they intend to minimize them.[1175]

The asymmetric distribution of information between consumers and product manufacturers has also been an argument in favor of the adoption of the strict product liability regime. Product manufacturers are considered to have more and better information on product risks than consumers and hence are deemed to be in the position to most efficiently avoid accidents involving the products they manufacture and to provide instructions and warnings.[1176]

2. The joint use of ex ante regulation and ex post liability: from substitutes to complements

Ex ante regulation and ex post liability are very rarely applied individually.[1177] An example of the joint application of these mechanisms is European product regulation. In

[1174] See Susan Rose-Ackerman, Regulation and the law of torts, The American Economic Review, vol. 81, no 2, 56 (1991) differentiating between strict liability and strict product liability, that requires a determination of product defect.
[1175] For an application of these arguments to food products see Jean C. Buzby and Paul D. Frenzen, Food safety and product liability, 24 Food policy, 637-651 (1999).
[1176] Richard W. Wright, The principles of product liability, 26 Rev. Litig. 1067, 1099 (2007).
[1177] In light of the limitations presented above regarding the application of regulation and liability, their joint use aims at better minimizing risks through the creation of efficient incentives. See Steven Shavell, Liability for Harm Versus Regulation of Safety, 13 J. Legal Stud. 2, 365 (1984) and Steven Shavell, A Model of the Optimal Use of Liability and Safety Regulation, Rand J. Econ. 15(2), 271-280, 271 (1984).

light of the interaction of ex ante regulation and ex post liability in practice,[1178] the law and economics literature on this issue has evolved in analyzing performance when both mechanisms are used together.[1179] This theoretical analysis will be very useful when analyzing the joint performance of European ex ante product safety and ex post liability and the potential improvements that could be made to the regulatory model.

As shown in the previous section, the nature of these two mechanisms is significantly different and it is difficult to determine which instrument performs better in general terms because the advantages of each of the mechanisms depend on the context in which they operate, on the specific circumstances of the risk being regulated, and on the level of harm to which potential victims are exposed.[1180] Indeed, the differences in nature and performance between regulation and tort law as risk minimization mechanisms are essentially based on the amount and scope of the information needed, whether such information is available, which procedures -- whether judicial or administrative -- are relevant and what costs they entail, and finally, whether the remedies of each mechanism -- penalties and damage awards -- should cumulate or should be set off.[1181]

[1178] Ex ante and ex post instruments are frequently used jointly when minimizing the negative externalities caused by product related accidents. See in general Charles D. Kolstad; Thomas S. Ulen; Gary V. Johnson, Ex Post Liability for Harm vs. Ex Ante Safety Regulation: Substitutes or Complements?, The American Economic Review, Vol. 80, No. 4. (1990), pp. 888-901, section III.

[1179] See Steven Shavell, A Model of the Optimal Use of Liability and Safety Regulation, Rand J. Econ. 15(2), 271-80 (1984) and Steven Shavell, Liability for Harm Versus Regulation of Safety, 13 J. Legal Studies 2, 357-74 (1984).

[1180] Paul Burrows, Combining Regulation and Legal Liability for the Control of External Costs, International Review of Law and Economics 19:227-244 (1999). See also Andrew F., Daughety and Jennifer F. Reinganum, Products liability, signaling and disclosure, Vanderbilt University working paper no. 06-W25, 2 (2006) focusing on the incentives of both instruments in discloseing information about product risks and concluding that the performance of ex ante information regulation or the reliance on ex post liability depends on whether the firm faces substantial liability for the consumer's harm.

[1181] See John P. Brown, Toward an Economic Theory of Liability, The Journal of Legal Studies, Vol. 2, No. 2, 323-349 (1973), Peter A. Diamond, Single Activity Accidents, The Journal of Legal Studies, Vol. 3, No. 1, 107-164 (1974), Donald Wittman Prior Regulation versus Post Liability: The Choice between Input and Output Monitoring, 6 Journal of Legal Studies 1, 193-211 (1977), Robert Cooter, Lewis Kornhauser, and David Lane, Liability Rules, Limited Information and the Role of Precedent, Bell Journal of Economics, 10, 366-73 (1979), Steven Shavell, Liability for Harm versus Regulation of Safety, 13 The Journal of Legal Studies 2, 357-374. (1984) and Steven Shavell, A Model of the Optimal Use of Liability and Safety Regulation, The Rand Journal of Economics 15(2), 271-280 (1984) for a discussion of the efficiency aspects of regulation and liability for minimizing the externalities.

Under perfect information of product risks, ex ante safety regulation can be optimal in the sense that the standard of care can be set at the optimal level and create optimal incentives for care.[1182] In this case, safety regulation would be equivalent to tort liability since under both systems the tortfeasor would internalize the expected harm and hence would optimally invest in care.[1183]

When information is imperfect, the decision between ex ante regulation and ex post liability becomes complex. On one side, ex ante regulation may be inefficient because of the impossibility of setting the safety standard at the optimal level or the impossibility of verifying whether a product manufacturer or a tortfeasor has complied with such safety standard. Under these circumstances, liability is often considered to perform better than ex ante regulation given the information asymmetry between the regulator and the members of the industry where the industry is better informed than regulators regarding product risks, their probability of occurring, the cost of reducing such risks and the amount of product-related damages.[1184]

Further, whenever the tortfeasor's private information regarding product risks reflects a heterogeneous level of risk across tortfeasors, the optimal level of care should also be heterogeneous depending on the level of risk presented and hence liability would perform better than a uniform safety standard in these cases.[1185] When the level of risk

[1182] W. Kip Viscusi, Toward a diminished role of tort liability: social insurance, government regulation, and contemporary risks to health and safety, 6 Yale J. on Reg. 65, 71 (1989).
[1183] In both cases, regulation and strict liability, a contributory negligence defense may be necessary. A. Mitchell Polinsky, Strict Liability vs. Negligence in a Market Setting, The American Economic Review, Vol. 70, No. 2, 363-367 (1980).
[1184] See Charles D. Kolstad; Thomas S. Ulen; Gary V. Johnson, Ex Post Liability for Harm vs. Ex Ante Safety Regulation: Substitutes or Complements?, The American Economic Review, Vol. 80, No. 4, 888-901 (1990) noting that if ex ante regulation was used combined with ex posed liability under negligence, the level of care set by the regulation should be lower than if the ex post negligence rule was used alone. For additional literature on the issue see Steven Shavell, Liability for Harm versus Regulation of Safety, 13 J. Legal Stud. 2, 359 (1984); Steven Shavell, A Model of the Optimal Use of Liability and Safety Regulation, Rand Journal of Economics, 15(2), 271-80 (1984); Martin L. Weitzman, Prices Versus Quantities, Review of Economic Studies, 41, 477-91 (1974) and Susan Rose-Ackerman, Effluent Charges: A Critique, Canadian Journal of Economics, 6, 512-28 (1973).
[1185] However, if the tortfeasor's heterogeneity would entail significantly high enforcement costs, liability would not necessarily be preferred to regulation. Robert Innes, Enforcement costs, optimal sanctions, and

presented by tortfeasors is diverse and the regulatory standard is uniform for all of them, the application of the standard would result in over-regulation of tortfeasors that cause small accidents and under-regulation of tortfeasors that cause large accidents.[1186] As a result, the investment in safety would also be inefficient given that tortfeasors causing small accidents would over-invest in care while tortfeasors causing a high level of accidents would under-invest in care.[1187] From this perspective, when uncertainty is considered, liability under tort seems to perform better than ex ante regulation because it can better adjust to the specific circumstances of the case.[1188]

Additionally, the performance of ex ante regulation and export liability is also conditioned on the emergence of new risks. When new risks appear, liability seems to perform better given that information regarding the new risks could not be included in previously drafted safety standards.[1189]

In order to create incentives to adopt action when new risks arise, product manufacturers are often subject to recall obligations so that they have incentives for recalling dangerous products or for withdrawing them from the market[1190] even though such obligations might result in too little recalls relative to the social optimum.[1191] The argument is that product manufacturers have information -- that may or may not be public -- about product risks when the product has been marketed. Further, product manufacturers are aware that courts may or may not be able to determine whether there is

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the choice between ex-post liability and ex-ante regulation, International Review of Law and Economics 24(1), 29-48, 46 (2004).

[1186] Charles D. Kolstad; Thomas S. Ulen and Gary V. Johnson, Ex Post Liability for Harm vs. Ex Ante Safety Regulation: Substitutes or Complements?, The American Economic Review, Vol. 80, No. 4. 888-901, 894 (1990).

[1187] Charles D. Kolstad; Thomas S. Ulen; Gary V. Johnson, Ex Post Liability for Harm vs. Ex Ante Safety Regulation: Substitutes or Complements?, The American Economic Review, Vol. 80, No. 4. 888-901, 895 (1990).

[1188] Steven Shavell, Liability for Harm versus Regulation of Safety, 13 J. Legal Stud. 2, 365 (1984).

[1189] Michael Baram, Liability and its influence on designing for product and process safety, Safety Science 45, 11–30, 12 (2007).

[1190] The GPSD includes recall obligations for product manufacturers when new product risks appear. See recitals 16 and 23 and article 3(4) and 5(1) of the GPSD.

[1191] Omri Ben-Shahar, How Liability Distorts Incentives of Manufacturers to Recall Products (2005), available at SSRN: http://ssrn.com/abstract=655804 or doi:10.2139/ssrn.655804

a causal relationship between the product and the harm the victim suffered or even whether the victim increased the probability of harm. The uncertainty over these variables implies that the liability to which the manufacturer is exposed in practice is lower than what a given liability rule provides. Hence, the manufacturer has low incentives to recall products even when aware of new product risks. Further, even when otherwise determined to recall products, the manufacturer knows that such recall may spark some lawsuits that might not have been otherwise filed.[1192] Consequently, manufacturers will be reluctant to recall products and decide to leave the product in the market and be exposed to the liability for harm. As a result, the purpose of tort liability regarding recalling risky products might have the opposite effect than the one it intended.

With respect to complex risks, sometimes private parties may have better knowledge of benefits and costs of reducing the risk of the activity in question. When that is the case, a liability system has the advantage of creating incentives to optimally invest in care given that parties have optimal information to avoid over-investing or under-investing in care.[1193] If, in contrast, regulators have better knowledge of the risks involved in an activity because of the possibility of centralizing the information and decisions, regulation would be superior to liability given that public authorities may have higher expertise in establishing regulatory standards than individual judges when determining whether to impose liability in a certain case.[1194] However, if the asymmetry of private information regarding risks is large, potential tortfeasors may be better informed than regulatory authorities regarding such complex risks and hence ex post

[1192] Because such recall may be interpreted as a confession of the manufacturer that the product is harmful and consider that the injury they suffered might have been caused by the product and not for other causes. See Omri Ben-Shahar, How Liability Distorts Incentives of Manufacturers to Recall Products (2005), available at SSRN: http://ssrn.com/abstract=655804 or doi:10.2139/ssrn.655804

[1193] Marcel Boyer and Donatella Porrini, Law versus Regulation: A Political Economy Model of Instrument Choice in Environmental Policy in A. Heyes, ed., Law and Economics of the Environment, Edward Elgar Publishing Ltd, 416 (2001).

[1194] W. Kip Viscusi, The Regulation–Litigation Interaction, AEI Brookings Joint Center for Regulatory Studies Working Paper 01-13 (2001). Available at http://papers.ssrn.com/abstract_id=292645.

liability would perform better than ex ante regulation.[1195]

Ex ante regulatory standards and ex post liability are implemented independently from each other but the consequences and performance of each mechanism is linked to that of the other. There is an absence, however, of formal or informal mechanisms for coordinating their different roles.[1196] This can be seen clearly in the case of European product regulation.

Neither ex ante regulation nor ex post liability alone leads all parties to exercise the socially desirable levels of care.[1197] Their joint use may enhance the performance of each instrument[1198] but the determination of the most efficient combination between ex ante regulation and ex post liability strongly depends on the specific circumstances of the risk being regulated and the level of harm to which potential victims are exposed.[1199]

The literature on this question has evolved from simple models based on the assumption of perfect information to more sophisticated models trying to introduce parameters that could better reflect the reality of government agencies when designing safety standards as well as the limitations faced by courts when establishing liability. The first contributions to the literature assumed perfect information under both regulation and

[1195] Robert Innes, Enforcement costs, optimal sanctions, and the choice between ex-post liability and ex-ante regulation, International Review of Law and Economics 24(1), 29-48, 46 (2004).
[1196] W. Kip Viscusi, The Regulation–Litigation Interaction, AEI Brookings Joint Center for Regulatory Studies Working Paper 01-13 (2001). Available at http://papers.ssrn.com/abstract_id=292645.
[1197] Steven Shavell, A model of the optimal use of liability and safety regulation. Rand Journal of Economics 15(2), 271-280 (1984) arguing that liability is inefficient due to the injurers' limited wealth and court's enforcement errors and regulation is inefficient because of the uniform care standard is applied to all injurers. See also Steven Shavell, Liability for Harm Versus Regulation of Safety, 13 J. Legal Stud. 2, 365 (1984) and Donald Wittman, Prior Regulation Versus Post Liability: The Choice Between Input and Output Monitoring, 6 J. Legal Stud. 1, 193, 193 (1977).
[1198] See Steven Shavell, A model of the optimal use of liability and safety regulation, Rand Journal of Economics 15(2), 271-280 (1984) for being the first to claim that a hybrid model of liability and regulation can do better than either of them alone. It should be noted that Shavell, in this first paper of 1984, strongly relies on the assumption that liability does not create optimal incentives because of enforcement errors. See Charles D. Kolstad; Thomas S. Ulen and Gary V. Johnson, Ex Post Liability for Harm vs. Ex Ante Safety Regulation: Substitutes or Complements?, The American Economic Review, Vol. 80, No. 4, 888-901 (1990) also assuming that liability is inefficient due to the uncertainty about the court's behavior.
[1199] See Susan Rose-Ackerman, Regulation and the law of torts, The American Economic Review, vol. 81, no 2, 58 (1991) arguing for a comprehensive view of the relationship between tort law and statutory regulation in order to achieve deterrence and compensation.

liability.[1200]

The law and economics literature originally analyzed these two mechanisms as if they were substitutes[1201] for one another.[1202] If both legal mechanisms were substitutes, a broad ex ante regulatory body would imply low litigation and at the same time, where there was no ex ante regulation, a significant amount of litigation should be expected.[1203] Hence, their joint use would not be necessary.

For example, ex ante safety regulation aims to create incentives of care for potential tortfeasors so that the risk of an accident is minimized. When the standard of care is set at an optimal level, ex post liability is not necessary and the investment in safety will be optimal without it.[1204] Consequently, exposing tortfeasors to liability is not optimal because such liability would require the same level of care set by the standard and hence would not provide any additional incentive to the tortfeasor regarding risk

[1200] Guido Calabresi, The Costs of Accidents, New Haven: Yale University Press (1970); M.L. Weitzman, Prices versus Quantities, Review of Economic Studies 41, 447-491 (1974) and Donald Wittman, Prior Regulation vs Post Liability: The Choice between Input and Output Monitoring, 6 Journal of Legal Studies 1, 193-212 (1977).

[1201] The theoretical analysis on the optimal combination between regulation and litigation sometimes includes considerations of regulation and litigation as substitutes. Despite the lack of empirical evidence on whether regulation and litigation behave as substitutes in practice, in the context of class actions, there does not seem to be a tradeoff between regulation and litigation. Instead, evidence seems to suggest that regulation and litigation somehow induce levels of care that exceed the socially optimal. See Eric Helland and Jonathan Klicky, The Tradeoffs between Regulation and Litigation: Evidence from Insurance Class Actions, Journal of Tort Law, vol. 1 issue 3 (2007).

[1202] The economics literature has characterized the harm caused by risky activities to third parties as an externality and suggested two instruments to reduce the impact of these externalities: regulation before the accident occurs, that is, regulation ex ante in the form of safety standards or Pigouvian taxes and ex post policies, in the form of tort liability. These instruments were often characterized as substitutes by the literature. See Donald Wittman, Prior Regulation Versus Post Liability: The Choice Between Input and Output Monitoring, 6 J. Legal Stud. 1, 193 (1977). Later developments in the literature discussed their joint implementation, not as substitute regulations but as complements. See Steven Shavell, A Model of the Optimal Use of Liability and Safety Regulation, Rand J. Econ. 15(2), 271-280, 275-278 (1984) and Steven Shavell, Liability for Harm Versus Regulation of Safety, 13 J. Legal Stud. 2, 357 (1984).

[1203] So if ex ante regulation and ex post litigation were substitutes, one would expect that the higher the standard of care set by the regulation, the lower the role for litigation. See Eric Helland and Jonathan Klicky, The Tradeoffs between Regulation and Litigation: Evidence from Insurance Class Actions, Journal of Tort Law, vol. 1 issue 3 (2007). See also Alan Schwartz, Statutory Interpretation, Capture and Tort Law: The Regulatory Compliance Defense, Am. L. & Econ. Rev. 2(1) (2000).

[1204] The optimal level of care will be achieved when either there is no ex post liability or the probability of bringing a tort claim is zero. Consequently, the regulatory standard alone will be optimal. See Mitchell Polinsky and Steven Shavell, The uneasy case for product liability, 123 Harv. L. Rev. 1437 (2010) arguing that product liability would be superfluous if the ex ante level of product safety is optimal.

reduction.[1205]

At the same time, ex post liability aims to create incentives for investment in care through the exposure to liability. Knowing that they will face liability, tortfeasors consider the probability of an accident and the liability amount and will have incentives to invest in care in order to avoid being held liable and having to compensate the injured victim.[1206] If liability would create optimal incentives for the adoption of care,[1207] using in addition ex ante regulation would not be socially optimal.[1208]

Consequently, the choice between either mechanism in the early literature was conditioned only by the comparison between the imperfections of each mechanism and in light of their substitution; the optimal instrument was the one that would result in lower administrative costs.[1209]

A second phase of this analysis in the literature was based on considering ex ante regulation and ex post liability as complements instead of substitutes. The complementary interaction between these two mechanisms may take place in cases where, for example, the law provides additional incentives for care whenever safety standards are not strict enough; where standards set minimum levels of safety and rely on litigation under tort to create incentives to adopt additional care or where regulatory standards are set at the optimal social level and litigation under tort imposes either strict liability or a standard of care lower than the one required by the regulation.[1210]

[1205] Robert Innes, Enforcement costs, optimal sanctions, and the choice between ex-post liability and ex-ante regulation, International Review of Law and Economics 24(1), 29-48 (2004).

[1206] This would be the case under, for example, a negligence tort rule. See Richard A. Posner, ECONOMIC ANALYSIS OF LAW, Aspen eds. (2004).

[1207] Steven Shavell, Liability for Harm versus Regulation of Safety, 13 J. Legal Stud. 2, 365 (1984).

[1208] This result is obtained under the assumption that all injurers face the same wealth constraint and hence are equally solvent. Patrick W. Schmitz, On the joint use of liability and safety regulation, International Review of Law and Economics 20, 371-382, 372 (2000).

[1209] For a parallel analysis in the criminal law context see Jacob Nussim and Avraham D. Tabbach, Controlling Avoidance: Ex-Ante Regulation versus Ex-Post Punishment, 46 Review of Law and Economics 4:1 (2008).

[1210] In those cases, ex ante regulatory standards should be set at a level that, if regulation was used alone it would provide a suboptimal level of safety. If the regulatory standards were set at the socially optimal level, (meaning that the marginal costs of precaution were equal to the expected marginal benefits) the interaction with tort law would result in inefficient results. See Charles D. Kolstad; Thomas S. Ulen; Gary

A leading contributor in the analysis of the two mechanisms as complements was Shavell,[1211] who showed that the joint use of ex ante regulation and ex post liability was socially advantageous considering that the use of either instrument alone did not result in the socially desirable level of care because of the information problems faced by regulatory agencies and the limitations of courts in determining liability.[1212]

Shavell noted that the efficient combination between ex ante regulation and ex post liability was strongly based on four different inefficiencies: the fact that the suit may not be brought against the injurer;[1213] the limited resources of the injurer and hence the possibility of the tortfeasor being judgment-proof;[1214] the imperfect knowledge of the regulator regarding the damage, and the setting of one single standard of care for all tortfeasors presenting different levels of risk.[1215] For Shavell, the optimal complementary use of ex ante regulation and ex post liability followed from the limited efficiency of liability due to enforcement errors and from the tortfeasor's potentially limited assets -- the judgment proof problem -- with the resulting possibility of escaping from liability as well as from the inefficient application of a single safety standard to all potential tortfeasors regardless their risk levels. These four scenarios represent the different combinations of ex ante regulation and ex post liability.

V. Johnson, Ex Post Liability for Harm vs. Ex Ante Safety Regulation: Substitutes or Complements?, The American Economic Review, Vol. 80, No. 4. (1990), pp. 888-901. at 891-92

[1211] Steven Shavell, Liability for Harm versus Regulation of Safety, 13 J. Legal Stud. 2, 365 (1984).

[1212] Models discussing the efficiency of each instrument separately such as the Shavell (Steven Shavell, Liability for Harm versus Regulation of Safety, 13 J. Legal Stud.2, 365 (1984)) concluded that liability is inefficient because of the risk of the tortfeasor's judgment proof and regulation is also inefficient because the regulatory standard applies to all injurers uniformly while their behavior is different. Some authors claimed that instead of substitutes, regulation and liability are complementary in a way that they may distort the effectiveness of each other. See Christian Ewerhart and Patrick W. Schmitz, Ex Post Liability for Harm vs. Ex Ante Safety Regulation: Substitutes or Complements? Comment, The American Economic Review, Vol. 88, No. 4, 1027 (1998) presenting five propositions illustrating the distortion to the incentives to adopt care of ex post liability when ex ante regulation is available.

[1213] In these cases ex ante regulation would be preferred over liability. These would be cases where the harm was so diffused that individuals would have little incentive to sue and could not or would face great difficulties to organize class action lawsuits in order to seek compensation for the harm suffered.

[1214] In these cases ex post liability would not effectively create incentives to adopt care and hence deter accidents. Hence, ex ante regulation would be preferred to ex post liability.

[1215] Steven Shavell, Liability for Harm versus Regulation of Safety, 13 J. Legal Stud. 2, 365 (1984).

The enforcement errors derived from not being able to verify compliance with the safety standard has been further analyzed in the literature. As mentioned above, whenever compliance with the safety standard cannot be observed, regulation might be inefficient because of moral hazard problems[1216] and the joint use of ex ante regulation and ex post liability might be justified.[1217] Regulation may result in over or under protection depending on the firm causing few or many accidents, while at the same time it may entail over or under investment in care.[1218] In these cases ex post liability could be used to improve these inefficiencies[1219] through a dual function: First, it would adjust the firm's incentives to adopt the required level of care and at the same time, it would be a form of consumer insurance.[1220]

Firms would signal the safety of their products by providing information regarding the level of product risks[1221] and the potential damage they may cause.[1222] This information would benefit consumers that could have access to information regarding

[1216] If courts or adjudicators could not determine whether a firm has complied with the standard firms would not have incentives for compliance and for investing in care. Yolande Hiriart, David Martimort and Jerome Pouyet, On the optimal use of ex ante regulation and ex post liability, Economics Letters 84, 231–235 (2004).

[1217] Yolande Hiriart, David Martimort and Jerome Pouyet, On the optimal use of ex ante regulation and ex post liability, Economics Letters 84, 234 (2004).

[1218] Charles D. Kolstad; Thomas S. Ulen; Gary V. Johnson, Ex Post Liability for Harm vs. Ex Ante Safety Regulation: Substitutes or Complements?, The American Economic Review, Vol. 80, No. 4, 888-901, 894-895 (1990). This result has led many authors to highlight the importance of setting the legal standard at the socially optimal level in order for negligence to create efficient incentives of precaution. Robert D. Cooter and Thomas S. Ulen, An Economic Case for Comparative Negligence, (1986). Available at: http://works.bepress.com/robert_cooter/25

[1219] Richard Craswell and John E. Calfee, Deterrence and Uncertain, Legal Standards, Journal of Law, Economics and Organization, 2, 279-303 (1986).

[1220] The problem of this approach is that the amount of optimal investment in care may not be equivalent to the optimal insurance for the consumer. See Michael Spence, Misperceptions, product failure and producer liability, the Review of Economic Studies, vol. 44, no 3, 561-572, 561 (1977) arguing that in order to be optimal, liability to the consumer should be supplemented with producer's liability to the state.

[1221] Andrew F., Daughety and Jennifer F. Reinganum, Products liability, signaling and disclosure, Vanderbilt University working paper no. 06-W25 (2006) deriving a relationship between the firm's marginal cost in safety and the firm's incentives to signal through prices or disclose through information and concluding that whenever the firm's marginal cost is increasing in safety, a firm with a high-safety product should choose to disclose over signal through prices and choose the opposite when the firm's marginal cost is decreasing.

[1222] Yolande Hiriart, David Martimort and Jerome Pouyet, On the optimal use of ex ante regulation and ex post liability, Economics Letters 84, 234 (2004).

product risks that product manufacturers would not disclose if they did not have incentives provided by these two regulatory instruments to do so.

Firms have private information about the level of product safety. Whenever firms do not voluntarily disclose the level of product safety, consumers might be able to infer the level of safety from the product's price.[1223] Product prices include, among other things, production costs as well as the manufacturer's expected liability. Hence, the safer a product is, the lower the expected liability and the higher the product price will be.[1224]

When prices perfectly signal the firm's investment in safety, consumers should be offered a lower price in exchange of higher risk and hence higher expected losses and should be asked for a higher price in exchange of a lower level of risk and hence lower expected losses.[1225] However, prices do not always reflect the firm's safety investment.[1226] There are cases where the firm has private information about the product's safety and such information is not available to consumers. In these cases, prices

[1223] There is a significant amount of literature analyzing the issue of firm's disclosure of information regarding product risks. See Boyan Jovanovic, Truthful Disclosure of Information, Bell Journal of Economics 13, 36-44 (1982) assuming that the firm knows the product quality but its disclosure is costly. Kathleen M. Hagerty, and Michael J. Fishman. Mandatory versus Voluntary Disclosure in Markets with Informed and Uninformed Customers, Journal of Law, Economics, and Organization 19, 45-63 (2003) present a model in which disclosure and signaling are not substitutes (as they are in our model), but complements, due to an externality between different types of consumers; Mitchell A. Polinsky and Steven Shavell, Mandatory versus Voluntary Disclosure of Product Risks, NBER Working Paper No. 12776 (2006) where they analyze the impact of mandatory disclosure rule on the incentives to acquire it in a context where firms face liability for harm and can disclose information about product risks at no cost; Andrew F. Daughety and Jennifer F. Reinganum, Competition and Confidentiality: Signaling Quality in a Duopoly When There is Universal Private Information, in GAMES AND ECONOMIC BEHAVIOR, 58, 94 -120 (2007); Andrew F., Daughety and Jennifer F. Reinganum, Products liability, signaling and disclosure, Vanderbilt University working paper no. 06-W25 (2006) and Andrew F. Daughety and Jennifer F. Reinganum. "Secrecy and Safety," American Economic Review 95, 1074-91 (2005) assuming that the acquisition of information is costless but its disclosure is costly depending on the marginal cost of safety. The product safety level will be reflected by the product price. In their model, disclosure and signaling are substitutes.

[1224] But this is not true when products are unsafe. When the firm faces a high level of expected liability, the higher the price should be. In order to avoid not selling products, the firm will signal safety by a lower price from its full information value. See generally Andrew F., Daughety and Jennifer F. Reinganum, Products liability, signaling and disclosure, Vanderbilt University working paper no. 06-W25 (2006). See also Andrew F. Daughety, Jennifer F. Reinganum, Product Safety: liability, R&D and signaling, the American Economic Review, vol. 85 no. 5, 1187-1206, 1189 (1995).

[1225] Andrew F. Daughety, Jennifer F. Reinganum, Product Safety: liability, R&D and signaling, the American Economic Review, vol. 85 no. 5, 1187-1206, 1189 (1995).

[1226] Paul Burrows, Consumer Safety under Products Liability and Duty to Disclose, International Review of Law and Economics 12, 457-478 (1992).

are not a good mechanism to signal the firm's investment in safety.[1227]

Sometimes, though, product manufacturers will have incentives to voluntarily disclose information about product risks. As long as the costs of disclosure are not prohibitive, the safer products are, the higher the incentives firms will have to voluntarily disclose their level of safety.[1228] The firm's exposure to ex post liability, impacts the firms' incentives to disclose the product's level of safety. So when ex ante product safety regulation does not create optimal incentives to invest in safety, ex post liability may serve this function.[1229]

If the ordinary consumer faces low information costs and can judge product safety based on accurate information provided by the product manufacturer, the consumer's actual and reasonable expectations are equivalent.[1230] In a situation like this, products that allow for accurate expectations of safety should not be subject to subsequent liability under tort. But an ordinary consumer often cannot make an accurate assessment of safety because information costs are significant and products might be more dangerous than expected by the consumer.[1231] In such cases, the duties to warn about product risks as well as the consumer expectations test in force in European product liability play important roles in creating incentives for product manufacturers to provide a sufficient amount of product safety information so that they can avoid having their products

[1227] Michael Baram, Liability and its influence on designing for product and process safety, Safety Science 45, 11–30, 25, 29 (2007) arguing that the decision over design is one of the many decisions firms take and if such decision should be adopted with respect to product's safety, a safer design should reduce the firm's expected losses. Otherwise, the firm's decisions over the product might not be adopted considering the product's level of safety.

[1228] Andrew F., Daughety and Jennifer F. Reinganum, Products liability, signaling and disclosure, Vanderbilt University working paper no. 06-W25, 18-19 (2006).

[1229] The consumers' informational problem was one of the arguments used to justify the imposition of strict product liability on product sellers in the U.S. during the 1970s. See Mark A. Geistfeld, Products liability, New York University School Of Law, Law & Economics Research Paper Series Working Paper NO. 09-19, 320 (2009).

[1230] Mark A. Geistfeld, Products liability, New York University School of Law, Law & Economics Research Paper Series Working Paper NO. 09-19, 309 (2009).

[1231] Mark A. Geistfeld, Products liability, New York University School of Law, Law & Economics Research Paper Series Working Paper NO. 09-19, 309 (2009).

considered defective.[1232] If the product's level of safety is not the one the consumer is entitled to expect and causes harm, the consumer expectations test is not met and hence the product might be defective and liability will be imposed.[1233] If some consumers are naively optimistic, they will always purchase a product as if it was of high safety and high safety firms will have less incentives to disclose safety information. Low safety firms will still not have incentives for voluntary disclosure.[1234] Thus, the joint use of ex ante product safety regulation and ex post product liability might also be a way for creating efficient incentives for information disclosure.

In addition to the inefficiencies studied by Shavell, Kosltad, Ulen and Johnson[1235] argued for the joint use of liability and regulation in light of the difficulty in defining the required standard of care and the risk that this results in firms choosing suboptimal care levels. Rose-Ackerman proposed three situations in which ex ante regulation and ex post liability could be complementary:[1236] First, tort may be used as a stopgap applicable in the absence of stringent safety statutes. Second, ex ante regulatory standards may be intended as minimums, with tort functioning to supplement them. Third, ex ante regulatory standards may be set at the optimal level, with tort imposing either strict liability or a negligence standard of care lower than the one required by the safety regulations.

Schmitz[1237] was critical with these analyses and argued that ex ante regulation and ex post liability did not have to be jointly applied because ex ante regulation alone could

[1232] It should be noted that this analysis is not applicable to bystanders, who do not have expectations about the product's level of safety.
[1233] See Mark A. Geistfeld, Products liability, New York University School Of Law, Law & Economics Research Paper Series Working Paper NO. 09-19, 309-310 (2009).
[1234] Andrew F., Daughety and Jennifer F. Reinganum, Products liability, signaling and disclosure, Vanderbilt University working paper no. 06-W25 (2006).
[1235] Charles D. Kolstad; Thomas S. Ulen; Gary V. Johnson, Ex Post Liability for Harm vs. Ex Ante Safety Regulation: Substitutes or Complements?, The American Economic Review, Vol. 80, No. 4., 894-895, 888-901 (1990).
[1236] Susan Rose-Ackerman, Regulation and the law of torts, The American Economic Review, vol. 81, no 2, 55 (1991).
[1237] Patrick W. Schmitz, On the joint use of liability and safety regulation, International Review of Law and Economics 20, 371-382 (2000).

always achieve a socially optimal outcome.[1238] Liability could also result in efficient results as long as it was set to create optimal incentives. In cases where the optimal outcome could be achieved through the application of one instrument, it could never be advantageous to jointly apply ex ante regulation and ex post liability.

This is especially true in cases where wealth is uniform among tortfeasors.[1239] Where tortfeasors have different wealth, liability would be preferred when tortfeasors have significant financial resources while regulation would be preferred when tortfeasors have limited ones.[1240] Additionally, according to Schmitz, whenever parties are subject to ex ante regulation and ex post liability, tortfeasors will adopt the higher level of care derived from tort liability and hence it will be socially desirable to set the regulatory standard at a lower level than if ex ante regulation was used alone.[1241] This result would hold as long as the level of care under regulation was verifiable and the level of harm and the tortfeasor's wealth were also verifiable under tort.[1242]

Whenever ex ante regulation and ex post liability are jointly used, coordination might be needed in order to enhance the potential of each mechanism to create incentives

[1238] Patrick W. Schmitz, On the joint use of liability and safety regulation, International Review of Law and Economics 20, 371-382, 372 (2000) questioning the model presented by Charles D. Kolstad; Thomas S. Ulen and Gary V. Johnson, Ex Post Liability for Harm vs. Ex Ante Safety Regulation: Substitutes or Complements?, The American Economic Review, Vol. 80, No. 4, 80, 888-901 (1990) and arguing that they could not explain why liability should be used at all given that their model of pure regulation could always reach and implement the socially optimal outcome.

[1239] See Patrick W. Schmitz, On the joint use of liability and safety regulation, International Review of Law and Economics 20, 371-382, 376 (2000). This result opposes the one obtained by Steven Shavell, A model of the optimal use of liability and safety regulation, Rand Journal of Economics 15(2), 271-280, 272 (1984) for which the joint use of ex ante regulation and ex post liability was optimal assuming uniform wealth across potential tortfeasors.

[1240] See Patrick W. Schmitz, On the joint use of liability and safety regulation, International Review of Law and Economics 20, 371-382, 376 (2000).

[1241] See Patrick W. Schmitz, On the joint use of liability and safety regulation, International Review of Law and Economics 20, 371-382 (2000). This confirms central conclusions Steven Shavell, Liability for Harm versus Regulation of Safety, 13 J. Legal Stud. 2, 357 (1984) and Charles D. Kolstad; Thomas S. Ulen; Gary V. Johnson, Ex Post Liability for Harm vs. Ex Ante Safety Regulation: Substitutes or Complements?, The American Economic Review, Vol. 80, No. 4, 888-901, 894-895 (1990), even though the underlying logic is different.

[1242] Patrick W. Schmitz, On the joint use of liability and safety regulation, International Review of Law and Economics 20, 371-382, 377 (2000).

for safety.[1243] Without coordination, society will not invest optimally to achieve the goals of creating efficient incentives for risk minimization while at the same time providing appropriate compensation to injured parties.[1244] Such coordination depends on the tort law rule -- negligence or strict liability -- that interacts with ex ante safety regulations. The issues arising from ex ante regulation with negligence or with strict product liability are different and hence the optimal combination between them also differs.

2.1 Ex ante safety regulation and negligence-based liability

Under a negligence-based liability rule, tortfeasors are liable only for the harm caused when not complying with the standard of care required by the negligence rule. So in order to avoid being held liable, potential tortfeasors have incentives to comply with this rule. Ex ante regulation should be superior to negligence liability in cases where courts do not have access to sufficient information to determine the optimal level of care; but it should be inferior to negligence liability whenever the information obtained ex post is better than that available to the regulator ex ante when setting the level of due care.[1245]

The joint use of ex ante safety regulation and ex post negligence liability will result in firms modifying the investment in care in certain cases.[1246] Whenever the level of care required by ex ante safety regulation is equivalent to the one required by the

[1243] See generally Mitchell Polinsky and Steven Shavell, The uneasy case for product liability, 123 Harv. L. Rev. 1437 (2010). See also Christopher Hodges, Competition Enforcement, Regulation and civil justice: what is the case?, Common Market Law Review 43: 1381-1407 (2006) arguing that private liability litigation does not replace the function of ex ante regulation and in light of the overlapping scope of application of both instruments, the duplication of incentive mechanisms without coordination between them may result in inconsistencies.

[1244] See in general W. Kip Viscusi, Toward a diminished role of tort liability: social insurance, government regulation, and contemporary risks to health and safety, 6 Yale J. on Reg. 65 (1989).

[1245] Steven Shavell, Liability for Harm versus Regulation of Safety, 13 J. Legal Stud. 2, 359 (1984).

[1246] Charles D. Kolstad; Thomas S. Ulen; Gary V. Johnson, Ex Post Liability for Harm vs. Ex Ante Safety Regulation: Substitutes or Complements?, The American Economic Review, Vol. 80, No. 4, 888-901, 900 (1990).

standard of negligence under tort, compliance with the standard will be the most efficient decision for the tortfeasor. In such cases, liability under negligence will not be effective and ex ante regulation will suffice.[1247]

If, instead, the level of care induced under negligence is too low and hence the level of accidents too high and the ex ante regulatory standard is higher than the standard set by the negligence rule, compliance with the ex ante regulatory standard will ensure avoiding liability under tort. But if the negligence standard under tort is higher than the standard of care set by the ex ante regulation, tortfeasors will comply with the negligence standard but the outcome will be inefficient[1248] and the existence of ex ante safety regulation will only exacerbate the inefficiency.[1249]

Another aspect that is worth noting is the impact of uncertainty regarding one or both standards of care on the tortfeasor's level of care chosen.[1250] If, for example, the standard of care set by negligence liability is known by the potential tortfeasor and the ex ante government standard is not, the potential tortfeasor would decide to comply with the level of care under negligence to avoid liability. If, instead, the standard established by the regulation is known but the negligence standard under tort is uncertain, the injurer would reduce the investment in care because it would know that non-compliance with the

[1247] Susan Rose-Ackerman, Regulation and the law of torts, The American Economic Review, vol. 81, no 2, 57 (1991)

[1248] In such case, the marginal costs of safety set by negligence under tort will exceed its marginal benefits. See Susan Rose-Ackerman, Regulation and the law of torts, The American Economic Review, vol. 81, no 2, 57 (1991).

[1249] Charles D. Kolstad; Thomas S. Ulen; Gary V. Johnson, Ex Post Liability for Harm vs. Ex Ante Safety Regulation: Substitutes or Complements?, The American Economic Review, Vol. 80, No. 4., 888-901, 898 (1990). Obtaining the same result see also Paul Burrows, Combining Regulation and Legal Liability for the Control of External Costs, International Review of Law and Economics 19:227-244, 1999 at 238. See also Susan Rose-Ackerman, Regulation and the Law of Torts, The American Economic Review, vol. 81, no. 2, Papers and Proceedings of the Hundred and Third Annual Meeting of the American Economic Association pp. 54 -58, 56 (1991) discussing the role of punitive damages in creating efficient incentives for care.

[1250] See Paul Burrows, Combining Regulation and Legal Liability for the Control of External Costs, International Review of Law and Economics 19:227-244, 231 (1999) for the first discussion on the impact of uncertainty in the combination between ex ante regulation and negligence under tort.

negligence standard would not necessarily result in liability.[1251]

Consequently, it is not possible to draw general conclusions regarding the effects of the interaction between ex ante safety regulation and a negligence rule under tort given that their performance strongly hinges on the information available and on the context in which the interaction takes place.

2.2 Ex ante safety regulation and strict liability under tort

Whenever the liability rule under tort is strict liability instead of negligence, the tort system aims to minimize the accidents caused by products[1252] through the creation of incentives for optimally investing in product safety based on the internalization of the expected liability to which tortfeasors are exposed regardless of their investment in care as a consequence of the compensation injured victims seek.[1253]

The amount of information available to the parties involved, including their perception of product risks, are key elements that will determine the performance of the strict liability system. Under perfect information, a strict liability rule will be optimal whenever damages are set to an amount equal to the harm caused by the tortfeasor. If an ex ante regulatory standard is added, the two mechanisms will not enhance their combined effectiveness. Their joint impact, instead, will be equivalent to that of each optimal mechanism functioning alone.

In contrast, when the information about product risks is imperfect, the joint performance of ex ante regulation and ex post liability will depend on whether consumers

[1251] In this case, certainty about the standard would improve the performance of the joint use of instruments. Paul Burrows, Combining Regulation and Legal Liability for the Control of External Costs, International Review of Law and Economics 19:227-244, 235-236 (1999).
[1252] Alan Schwartz, Statutory Interpretation, Capture, and Tort Law: the regulatory compliance defense, American Law and Economics Review 2(1), 6 (2000).
[1253] Richard A. Posner, ECONOMIC ANALYSIS OF LAW, Aspen eds. (2004) and Thomas J. Miceli, ECONOMICS OF THE LAW, Oxford University Press (1997).

can or cannot perceive product risks.[1254] Some consumers will be able to correctly assess product risks (to the extent that such risks have not been eliminated by the ex ante safety standards) and they will decide whether they are willing to assume them. If consumers do not adequately perceive product risks, they may be eventually exposed to risks they did not knowingly choose to take. Whether more or less consumers are able to correctly perceive product risks will be crucial when determining whether the joint use of ex ante safety regulation combined with ex post strict liability is optimal. If consumers correctly perceive product risks and hence belong to the first group, strict product liability alone will allow them to decide whether they are willing to purchase cheaper but more dangerous products and hence the combination will be unnecessary.[1255] But if consumers misperceive product risks, allowing them to negotiate the tradeoffs between price and safety will not be optimal for them. In these cases, introducing ex ante safety regulation could increase their welfare.[1256]

Consequently, depending on whether or not consumers can adequately assess product risks, introducing ex ante regulation together with strict product liability may or may not result in an increase in consumer welfare.

2.3 Using ex ante regulation and ex post liability together: the decision over the compliance defense

When ex ante regulation and ex post litigation are jointly used, one of the major questions that arises is whether their interaction enhances their individual performance

[1254] Victor P. Goldberg, The Economics of product safety and imperfect information, the Bell Journal of Economics and Management Science, 5:2, 683-688, 685 (1974).
[1255] Walter Y. Oi, The economics of product safety, The Bell Journal of Economics and Management Science, vol. 4, no. 1, 3-28 (1973).
[1256] Victor P. Goldberg, The Economics of product safety and imperfect information, the Bell Journal of Economics and Management Science, 5:2, 683-688, 687 (1974).

and if so, how the two mechanisms may be best coordinated.[1257] As discussed above, the joint performance of the two mechanisms depends on context and circumstances in which these mechanisms are implemented.

One of the most important coordination mechanisms used is the compliance defense.[1258] This defense focuses on two major issues with evidentiary implications:[1259] whether a tortfeasor's compliance with the regulatory standard should be a defense to subsequent liability under tort,[1260] and whether non-compliance with the standard should amount to negligence per se under tort.[1261] In the latter case, liability under tort is imposed not based on a specific liability rule but instead based on a violation of the regulatory safety standard.[1262]

When non-compliance with the safety standard constitutes negligence per se, parties have incentives to comply with the safety standard even when it is not optimal for them to do so. In these cases, imposing liability for non-compliance would clearly be inefficient because parties would not be investing optimally in care regardless of the liability rule under tort.[1263]

[1257] Alan Schwartz, Statutory Interpretation, Capture, and Tort Law: the regulatory compliance defense, American Law and Economics Review, 2(1), 6 (2000).
[1258] W. Kip Viscusi, The Regulation–Litigation Interaction, Working Paper 01-13, available at http://papers.ssrn.com/abstract_id=292645 (2001).
[1259] Paul Burrows, Combining Regulation and Legal Liability for the Control of External Costs, International Review of Law and Economics 19:227-244 (1999).
[1260] In this case, the negligence standard could not be stricter than the regulated standard. Steven Shavell, Liability for Harm versus Regulation of Safety, 13 Journal of Legal Studies 2, 365 (1984).
[1261] In this case, the negligence standard could not be less strict than the regulated standard. See Steven Shavell, Liability for Harm versus Regulation of Safety, 13 Journal of Legal Studies 2, 365 (1984). See also Paul Burrows, Combining Regulation and Legal Liability for the Control of External Costs, International Review of Law and Economics 19:227-244, 228 (1999).
[1262] Two main factors will determine the outcome in preemption cases: the degree of consistency between the regulatory standard and the investment in care generated by liability and the perceived degree of independence of the agency defining the safety standard. See Keith N. Hylton, Preemption and Products Liability: a positive theory, Boston University School of Law, Working paper series, law and economics, no 03-17 (2007).
[1263] For a strong defense of the compliance defense that would shield firms from tort liability when complying with product safety standards see Alan Schwartz, Statutory Interpretation, Capture, and Tort Law: the regulatory compliance defense, American Law and Economics Review, 2(1), 6 (2000).

The compliance rule in European product liability law is that non-compliance with ex ante safety regulation triggers a rebuttable presumption of an unsafe product.[1264] In contrast, compliance with the standard is evidence of reasonable conduct but does not shield the tortfeasor from liability.[1265] In the product context, compliance with ex ante regulatory safety standards is evidence of investing in safety and hence of a safe product but may or may not result in subsequent liability.

As can be observed, there is an asymmetry between the treatment of compliance with the standard and non-compliance with it. A possible justification for the different treatment might be the consideration of ex ante safety standards as minimum safety levels but not maximums. In other words, an injured plaintiff should be able to argue that a higher level of safety than the one required by the ex ante safety regulation should be applied in a certain case and hence liability should be imposed.[1266]

Viewing the question more broadly, it is possible to distinguish three different forms of the compliance defense: First, compliance with product safety regulation could be a complete defense to ex post liability. Second, compliance could be incomplete, that is, could shield a product manufacturer from ex post liability or not depending on the circumstances. Finally, compliance could be a narrow defense that could operate only in a few specific cases.

In the first form, a complete compliance defense, compliance with an ex ante regulatory standard would shield the injurer from subsequent liability. In such case, the regulatory standard would function as a signal of the standard of safety and hence of the

[1264] Non-compliance with a safety standard would generally amount to negligence per se in a tort suit. European products regulation combines safety standards and strict liability in tort in that compliance with safety standards is presumption of safe product but does not shield the manufacturer from liability under tort. In contrast, non-compliance with safety regulations results in administrative fines and may or may not be combined with tort liability in case such product would be considered unsafe and defective.
[1265] W. Kip Viscusi, Toward a diminished role of tort liability: social insurance, government regulation, and contemporary risks to health and safety, 6 Yale J. on Reg. 65, 100-101 (1989).
[1266] See Susan Rose-Ackerman, Regulation and the law of torts, The American Economic Review, vol. 81, no 2, 55 (1991).

investment in safety required to product manufacturers.[1267] Beyond this level of safety required by the ex ante regulatory standard, potential tortfeasors would not have any incentive to invest in safety. Hence, liability under tort as a consequence of the violation of ex ante safety regulation would not have any effect on efficiency. As a result, given that compliance with ex ante safety regulation would be optimal for the product manufacturer regardless of the optimality of the standard set by the regulation, if the regulatory standard were set at the optimal level, the investment in safety would be optimal but if the standard were sub-optimal, the outcome of this regulatory structure would also be suboptimal and hence inefficient.[1268] It should be noted that ex ante safety regulations often are designed to create incentives to invest in a level of safety higher than the economically efficient level. In these cases, compliance would function as a signal of adequate investment in product safety even though the final outcome would be inefficient because potential tortfeasors would over-invest in safety.[1269]

A second possible interaction between ex ante safety regulation and ex post liability under tort is through an incomplete compliance defense. Under this scheme, compliance with ex ante regulation would be a defense only in certain circumstances. In these cases, the existence of the regulated standard would only reduce the probability of liability but would not eliminate it.[1270] So for example, depending on whether the ex post negligence standard was uncertain or unknown, the joint use of ex ante regulation and ex post liability might be welfare-enhancing compared to the use of either ex ante regulation and ex post liability alone. So whenever the tort negligence standard was uncertain, the

[1267] Paul Burrows, Combining Regulation and Legal Liability for the Control of External Costs, International Review of Law and Economics 19:227-244, 242 (1999).
[1268] See W. Kip Viscusi, Product Liability and Regulation: Establishing the Appropriate Institutional Division of Labor, The American Economic Review, Vol. 78, No. 2, pp. 300-304 (1988) arguing that whenever potential tortfeasors meet an efficient standard of care, there should be a coordinated strategy between the multiple instruments – ex ante safety regulation and ex post product liability - that overlap and allow some form of a compliance defense.
[1269] W. Kip Viscusi, Product Liability and Regulation: Establishing the Appropriate Institutional Division of Labor, The American Economic Review, Vol. 78, No. 2, pp. 300-304 (1988).
[1270] Paul Burrows, Combining Regulation and Legal Liability for the Control of External Costs, International Review of Law and Economics 19:227-244, 241-243 (1999).

joint application of ex ante regulation and ex post liability with an incomplete compliance defense would be preferred to either instrument alone. In such cases, the uncertainty over the negligence standard combined with an incomplete compliance defense will create incentives for investing in product safety.[1271] In contrast, in cases where the liability standard is known, an incomplete compliance defense would introduce uncertainty that could result in over investment – and hence suboptimal investment – in product safety. In light of the structure of product regulation in Europe, such a scheme does not seem the most adequate given that ex ante product regulation is combined with ex post strict liability whereby the information available about an ex post negligence safety standard becomes irrelevant.

A third potential interaction would be a very restricted or entirely absent compliance defense, as currently in place in the European product regulation. Under this structure, potential tortfeasors who comply with ex ante safety standards are nonetheless subject to ex post liability under tort with some exceptions determined by the ex ante regulation. The potential liability costs under tort create incentives for an investment in safety above the efficient level, resulting in an inefficient outcome.[1272]

The absence or narrowness of a compliance defense may have additional effects depending on the expected liability to which potential tortfeasors might be subject. If expected liability is low, firms will have incentives to invest in product safety in order to reduce or even eliminate liability costs while still having incentives to market their products. But if expected liability is high, firms may have incentives to avoid liability and decide not to innovate or to even withdraw products from the market in order to avoid being subject to high liability levels.[1273]

[1271] Paul Burrows, Combining Regulation and Legal Liability for the Control of External Costs, International Review of Law and Economics 19:227-244, 241-243 (1999).
[1272] W. Kip Viscusi, Product Liability and Regulation: Establishing the Appropriate Institutional Division of Labor, The American Economic Review, Vol. 78, No. 2, pp. 300-304 (1988).
[1273] These effects may depend on the specific industry potential tortfeasors are part of. See Michael Moore and W. Kip Viscusi, Promoting Safety through Workers' Compensation: The Efficacy and Net Wage Costs

Under the current product regulation scheme in force in Europe, structured around a restrictive compliance defense, the tortfeasor can be sanctioned twice: first, through the administrative sanctions provided by the government's ex ante safety regulation and second, through the liability eventually imposed as a result of the claim brought by the injured victim.[1274] Consequently, under this scheme, the tortfeasor could eventually face a double penalty.[1275]

The debate over the compliance defense has generated many arguments, both in favor of and against its use.[1276] While Shavell[1277] assumes that in certain cases, denying the compliance defense and imposing liability would result in an efficient outcome, Viscusi[1278] does not share this approach and asserts that denying the compliance defense will create inefficient incentives for safety because of the victim's overcompensation resulting in the tortfeasor's over-investment in safety.[1279] Again, depending on the risk

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of Injury Insurance, Working Paper, Northwestern University (1988) showing the negative effects of liability in innovation in many areas such as aviation, chemicals, pharmaceuticals or medical industry.

[1274] Paul Burrows, Combining Regulation and Legal Liability for the Control of External Costs, International Review of Law and Economics 19:227-244, 231 (1999).

[1275] If there were full penalties from the two instruments, the impacts of the compliance defense and the negligence per se rule depend on the level of the safety standards relative to the social level of efficient precaution. But if penalties were coordinated and the regulatory standard efficiently established the result would be efficient. See Paul Burrows, Combining Regulation and Legal Liability for the Control of External Costs, International Review of Law and Economics 19:227-244, 237 (1999).

[1276] See Catherine M. Sharkey, Products liability preemption: an institutional approach, 76 The George Washington Law Review 101 (2008) arguing in favor of the application of a regulatory compliance defense considering the institutional – state or federal – agency framework. See also Keith N. Hylton, Preemption and Products Liability: A Positive Theory 7–8 (Boston Univ. Sch. of Law Working Paper Series, Working Paper No. 03-17), available at http://ssrn.com/abstract=433661 identifying tour factors that can be used to determine whether there will be preemption of regulatory agencies over courts before product cases: first, the agency's expertise; second, the local knowledge of product risks; third, the likelihood of the agency capture and finally, the predictability of the standard. Depending on the importance of each of these factors, preemption will be desirable or not.

[1277] See Steven Shavell, Liability for Harm Versus Regulation of Safety, 13 J. Legal Stud. 2, 365 (1984) arguing that ex post liability might induce parties who present an above average risk of harm to adopt additional precautions beyond the ones required by the ex ante regulatory standard and such outcome might be beneficial.

[1278] W. Kip Viscusi, Product Liability and Regulation: Establishing the Appropriate Institucional Division of Labor, 78 American Economic Review, Papers and Proceedings, 300-304 (1988).

[1279] The denial of the compliance defenses is efficient as long as the damages are optimally set. See Paul Burrows, Combining Regulation and Legal Liability for the Control of External Costs, International Review of Law and Economics 19:227-244 (1999).

involved in the situations to be regulated and the evidentiary issues raised by them, the introduction of the compliance defense might be advisable or not.

3 Toward a comprehensive approach to European product regulation: The interaction between ex ante safety regulation and ex post liability

European product regulation, when viewed comprehensively, encompasses three major product phases: before a product is marketed while the product is in the market, and once the product, while in the market, causes harm to a consumer or to a product user. The first phase, the pre-market phase, is regulated by the broad body of product safety law discussed in chapter 5. During the second product phase, European product regulation requires product recalls and imposes obligations on product manufacturers and distributers to provide notifications of product risks. The third phase, once a defective product has caused harm to a user or consumer, is discussed in chapter 2.[1280]

From a practical perspective, the regulatory interaction between ex ante product safety and ex post product liability in Europe is a fact.[1281] These two mechanisms are jointly applicable to many products and in different product phases, and they interact and share common goals: bringing safe products to the market while minimizing the amount of defective products that cause product-related accidents, while compensating victims

[1280] See W. Kip Viscusi, Toward a diminished role of tort liability: social insurance, government regulation, and contemporary risks to health and safety, 6 Yale J. on Reg. 65 (1989) arguing for a diminished role of the tort system when reducing risks.

[1281] This interaction also takes places in the United States where the Consumer Product Safety Commissions issues voluntary ex ante standards while at the same time liability is imposed for the harm caused by defective products. The prospect of liability judgments directly impacts the manufacturer's decisions on investment in care. See Lucille M. Ponte, Guilt By Association In United States Products Liability Cases: Are The European Community And Japan Likely To Develop Similar Cause-In-Fact Approaches To Defendant Identification?, 15 Loy. L.A. Int'l & Comp. L.J. 629 (1993) and George L. Priest, Products Liability Law and the Accident Rate, in LIABILITY, PERSPECTIVES AND POLICY 184 (Robert E. Litan & Clifford Winston eds., 1988).

when products do cause harm.[1282]

Product safety law, presented earlier, represents the emphasis of the European model on regulation that adopts the form of a set of pre-market requirements for product manufacturers so that the amount of unsafe products that reach the market is minimized.[1283] European product safety regulation does not contain liability provisions but rather, as explained earlier, it is based on safety standards, enforcement mechanisms and the imposition of fines in case of non-compliance.[1284]

These standards and pre-requisites that manufacturers must comply with before a product is marketed should not be thought of as equivalent to a negligence standard. There are clear similarities between both concepts such as the fact that in both cases manufacturers have incentives to comply with them (which is their common goal). However, there are significant differences regarding the consequences of non-compliance. Under negligence, compliance with the required level of care allows manufacturers to avoid liability whereas compliance with product safety regulations allows manufacturers to avoid fines and penalties but not liability, given that a product that causes harm may still be deemed defective.

In order for product safety regulation to reach optimal deterrence, two conditions must be met. First, standards must be set at the optimal level so as to require optimal levels of investment in safety.[1285] If standards are not optimal, tortfeasors will be under-deterred (in case they are required too little care) or will not comply with the rule (in case they were required to invest in excessive, and non-cost-effective care). Consequently,

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[1282] The compensation goal is exclusive of the product liability system. See Susan Rose-Ackerman, Regulation and the Law of Torts, The American Economic Review, vol. 81, no. 2, 54, 57 (1991) noting that the difference between tort law and regulation might be explained from the perspective of the distribution of benefits and harms but mostly refers to procedures and further arguing that the relationship between tort law and regulation should be revisited from the perspective of the incentives they create.

[1283] See Council Directive 2001/95/EC of December 3, 2001 on General Product Safety O.J. (L 11) (January 15, 2002). For U.S. product safety regulation and case law see Richard C. Ausness, The case for a "strong" regulatory compliance defense, 55 Maryland Law Review 1210 (1996).

[1284] Susan Narita, Product Liability Claims in Europe, Swiss Reinsurance Company, Zurich, 8 (1996).

[1285] See A. Mitchell Polinsky, AN INTRODUCTION TO LAW AND ECONOMICS, 3rd ed. 113-125 (2003).

non-optimal standards do not result in the desired level of safety investment.

Second, once the safety standard is established, they must be enforced. If non-compliance is not penalized or the costs of not complying are low, manufacturers may decide to pay fines, when imposed, instead of altering their products' characteristics to comply.[1286] Consequently, compliance with such safety requirements must be monitored.

In sum, in order to maximize accident deterrence through product safety regulation, optimal standards must be defined and subsequently enforced.[1287] With respect to the optimality of safety standards, there is evidence suggesting that standards are very rarely set at the optimal level. Further, as explained earlier, the procedure for designing standards, which is often inflexible, long and complicated, makes it difficult to modify them once they become outdated.[1288] Additionally, safety standards often are the result of the influence of lobbies, which tends to ensure that the standards are designed with some bias towards the interests of the industry.

At the same time, enforcement is far from perfect. The enforcement of the European product safety regulation is deferred to domestic authorities that must have adequate powers to ensure action is taken when dangerous products are detected in the market.[1289] Up to today, some member states have not provided the adequate resources to carry out market surveillance, provide information to the business community and impose penalties,[1290] which weakens the effectiveness of the enforcement mechanisms. But there are reasons for optimism when considering the positive and increasing evolution of the

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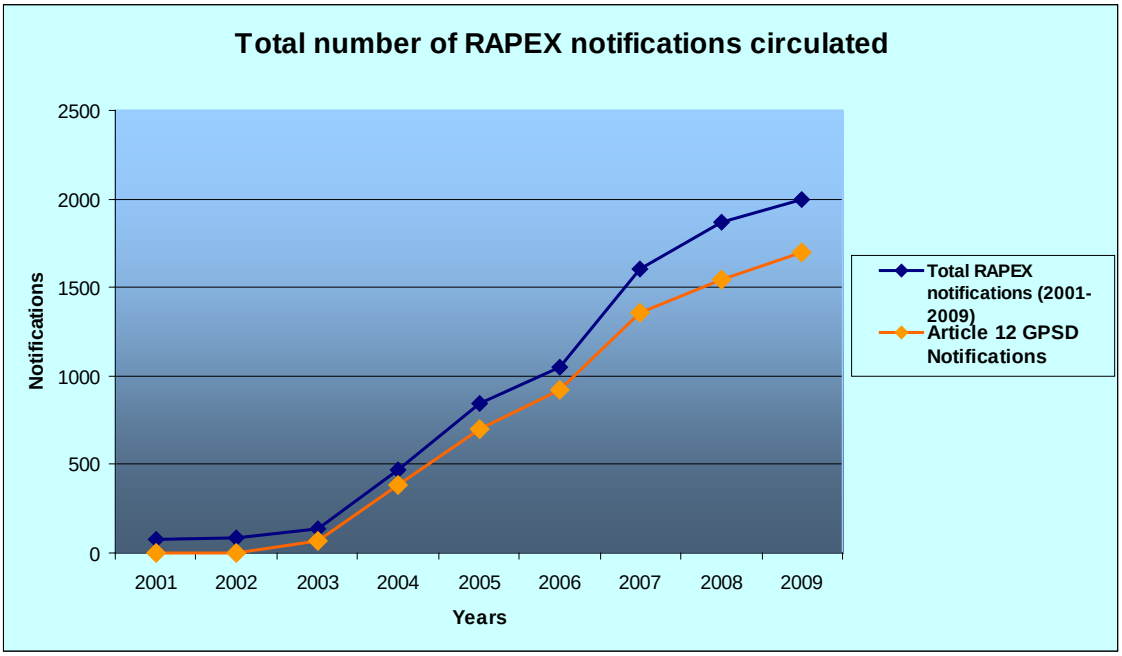
[1286] W. Kip Viscusi, REGULATING CONSUMER PRODUCT SAFETY, American Enterprise institute for Public Policy Research, 26 (1984).
[1287] Which is defined as the level of care where the marginal costs of adopting care are equal to the marginal benefits in accident reduction. See A. Mitchell Polinsky, AN INTRODUCTION TO LAW AND ECONOMICS, 3rd ed., 82 (2003).
[1288] Geraint G. Howells, The relationship between product liability and product safety – understanding a necessary element in the European Product Liability through a comparison with the U.S. position, 39 Washburn L. J. 305, 318 (2000).
[1289] Andrew C. Spacone, Strict Liability in the European Union - Not a United States Analog, 5 Roger Williams U. L. Rev. 341 (2000) arguing that enforcement of product safety is far from satisfactory.
[1290] See Christopher Hodges, EUROPEAN REGULATION OF CONSUMER PRODUCT SAFETY, 206, Oxford University Press, (2005).

RAPEX notifications. Despite the existing room to improve, there are reasons to believe the ex ante enforcement mechanisms are increasingly used and effective.[1291]

Figure 6.1 – Total number of RAPEX notifications circulated 2001-2009



The strict product liability regime established by the product liability directive also impacts the minimization of product accidents through the creation of optimal incentives for potential tortfeasors so that they are forced to internalize the cost of the harm caused by def ective products.[1292]

But such incentives are effective only as long as there is enforcement of the strict liability rule to which injurers are subject.[1293] The enforcement mechanisms under the

[1291] Alberto Cavaliere, Product Liability in the European Union: Compensation and Deterrence Issues, European Journal of Law and Economics, 18: 299–318, 313 (2004).
[1292] See A. Mitchell Polinsky, AN INTRODUCTION TO LAW AND ECONOMICS, 3rd ed. 113-125 (2003)
[1293] Alberto Cavaliere, Product Liability in the European Union: Compensation and Deterrence Issues, European Journal of Law and Economics, 18: 299–318, 311 (2004).

product liability directive, which are based on litigation, are quite different from those of the product safety regulation, which are based on enforcement by public authorities. Thus, product liability is effective only as long as injured victims pursue their product liability claims and those claims are properly adjudicated to ensure that the injurer provides compensation for harm caused.[1294]

In light of the diverse social, legal and cultural context in Europe, over twenty years after the adoption of the product liability directive it is impossible to assess the Directive's actual impact. The drafters and the industry[1295] had very strong expectations about how the Directive would change the European product liability reality but it seems clear that the Directive has caused neither a clear increase in the level of product liability litigation, nor an increase in the rate of insurance premiums nor an increase in the contracted private insurance coverage as was expected.[1296]

A possible explanation for the absence of greater litigation by product victims is that ex ante regulation may have simply increased the level of safety of products in the market (through pre-marketing requirements as well as recalls) and thereby kept the number of product victims low.[1297]

This does not mean that the introduction of the product liability directive was without any effect. While litigation has not increased to the extent expected, there has been some increase during the past decade in the number and success rate of product

[1294] The impact of the GPSD on claims is very indirect. See Susan Narita, Product Liability Claims in Europe, Swiss Reinsurance Company, Zurich, 10 (1996).
[1295] Andrew C. Spacone, Strict Liability in the European Union - Not a United States Analog, 5 Roger Williams U. L. Rev. 341, 346 (2000).
[1296] See Anita Bernstein, L'Harmonie Dissonante: Strict Products Liability Attempted in the European Community, 31 VA. J INT'L L. 673, 677-79 (1991), Sandra N. Hurd & Frances E. Zollers, Desperately Seeking Harmony: The European Community's Search for Uniformity in Product Liability Law, 30 AM. BUS. L.J. 35, 47-65 (1992), Mark Mildred, Litigation Rules and Culture: The European Perspective, 23 N.Y.U. Rev. L. & Soc. Change 433, 441 (1997) and Andrew C. Spacone, Strict Liability in the European Union - Not a United States Analog, 5 Roger Williams U. L. Rev. 341, 347- 348 (2000).
[1297] See Alberto Cavaliere, Product Liability in the European Union: Compensation and Deterrence Issues, European Journal of Law and Economics, 18: 299–318, 311 (2004) arguing that the tortfeasor's loss of reputation might be stronger than the incentives created by the exposure to liability, that in Europe is quite low.

liability claims in Europe, as well as in the amount of settlements.[1298] Strong conclusions on this issue are difficult to draw because there is an absence of data on product accidents and on product liability judgments at the European level. In Spain, however, there is a valuable source of information on this question: a comprehensive collection of Spanish product liability judgments performed by the professors and researchers of the Civil Law Department of Universitat Pompeu Fabra, in Barcelona.[1299]

Before presenting this information, some caveats should be made. First, the information provided by product liability judgments does not include cases where product victims decide not to pursue their claims. So the amount of judgments is not equivalent to the amount of injured victims. Further, product liability judgments do not include cases where the parties settle, either after the claim has been filed but before the judgment or before any claim has been filed. This information would be important for fully assessing product accidents and product liability in Spain or of the rest of Europe.

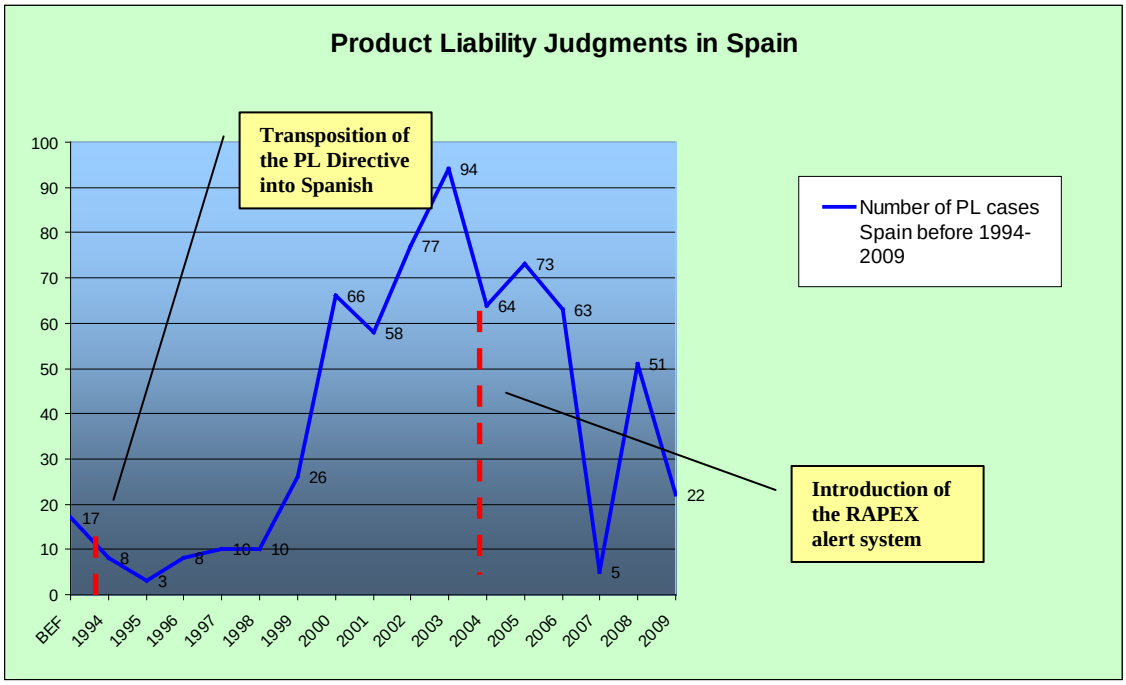
The product liability judgments collected by this research group,[1300] while not reflecting all product accidents caused by defective products in Spain, provide the best available picture of product liability cases in Spain. As can be seen from Figure 6.2, despite the number of product liability judgments being relatively low -- just over 600 cases in 20 years -- these cases have increased since the product liability directive has been in force. Looking at the evolution of product liability judgments, we can see an upward trend with a peak in the year 2003, followed by a downward trend.

[1298] See LOVELLS, PRODUCT LIABILITY IN THE EUROPEAN UNION: A REPORT FOR THE EUROPEAN COMMISSION, 31, 37 (2003) noting a noticeable increase in the number of product liability claims in the different European member states after the introduction of the product liability directive. See also John Meltzer Reform Of Product Liability in the EU: New Report Finds General Satisfaction, 71 Def. Counsl. J. 42, 47 (2004).

[1299] For information of the research group see http://www.upf.edu/dretcivil/. It should be noted that these are cases filed and finished with a judgment, which does not necessarily mean that the product was deemed defective or that the injured victim obtained compensation. Hence, the judgments collected include all cases where a lawsuit was filed based on a product liability claim regardless of its outcome. See Pablo Salvador and Fernando Gómez (eds.), TRATADO DE RESPONSABILIDAD CIVIL DEL FABRICANTE, Civitas, 979-1111 (2008).

[1300] See table 6.1 of product liability judgments in Spain at the end of this chapter.

Figure 6.2 – Product liability judgments in Spain



Even though the diagram above shows that product liability judgments have increased in amount, it is not possible to conclude that these judgments are representative of product liability accidents or product liability claims filed in Spain.

European product safety and product liability regulation are independent legal mechanisms that responded to different legislative motivations -- product liability was conceived to eliminate barriers to trade and product safety as an instrument of consumer protection. However, despite such formal autonomy,[1301] from a normative perspective, European product safety regulation and the product liability directive are simultaneously applicable to certain products and hence interact.[1302] Two major areas of interaction will

[1301] European product safety and European product liability instruments are independent in the sense that any right afforded by one of them does not interfere with the ones provided under the other. See Frances E. Zollers, Sandra N. Hurd, Peter Shears, Product Safety in the United States and the European Community: a comparative approach, 17 Md. J. Int'l L. & Trade 177, 188 (1993).
[1302] Susan Narita, Product Liability Claims in Europe, Swiss Reinsurance Company, Zurich, 8 (1996).

be discussed here: their common scope of application and further, the interaction between their central parameters: the concepts of safe and of defective products.

3.1 Movables v. Non-food consumer products

The scope of application of the European product safety regulation and the product liability regime is quite similar.

The GPSD applies only to products intended for consumers or likely to be used by consumers whether they are new, used or reconditioned and to products not covered by any specific community regulation applicable to them.[1303] Therefore, manufacturers must comply with any specific provisions applicable to their products and with the general safety duty imposed by the GPSD[1304] and enforced by member states.[1305]

Additionally, RAPEX is an alert system for dangerous consumer non-food products intended for consumers or likely under reasonably foreseeable conditions to be used by consumers.[1306] Hence, the RAPEX system provided by the GPSD is applied to consumer products -- not including food products -- covered by the GPSD,[1307] as well as to products covered by New Approach Directives.[1308]

[1303] Article 2(a) of the GPSD.
[1304] Article 3(2) of the GPSD.
[1305] Frances E. Zollers, Sandra N. Hurd, Peter Shears, Product Safety in the United States and the European Community: a comparative approach, 17 Md. J. Int'l L. & Trade 177, 189 (1993).
[1306] The RAPEX system does not cover all consumer products. For food and feed, a specific alert system (RASFF), similar to RAPEX, is in place. Specific systems are in place also for medical devices and pharmaceuticals. See European Commission, Keeping European Consumers Safe, 2009 Annual report on the operation of the Rapid Alert System for non-food consumer products, RAPEX. This document is available at
http://ec.europa.eu/consumers/safety/rapex/docs/2009_rapex_report_en.pdf
[1307] The GPSD, in its article 2(a) defines consumer products as
"*any product intended for consumers or likely, …, to be used by consumers*"
[1308] Some New Approach Directives include notification procedures known as "Safeguard Clause," that aims to check the grounds for domestic measures which seek to restrict the free movement of products. However, this mechanism is different from the goals aimed by the RAPEX system, which intends to create the framework for a rapid exchange of information on dangerous products in order to protect the consumers' health and safety. See the European Commission Guidelines for the management of the

In contrast, the product liability directive is applicable to movable products, which includes finished goods as well as raw materials and components incorporated in a finished product -- that could be movable or immovable.[1309]

Movables are not necessarily equivalent to consumer products.[1310] It seems reasonable to consider non-food consumer products as a subgroup to movables. In other words, it seems reasonable to consider that non-food consumer products are movables but not all movables are non-food consumer products. Consequently, the scope of application of the GPSD and other safety regulation seems to fall within the scope of application of the product liability directive. Thus, it is possible to say that products subject to the European product safety regulation are also subject to product liability but not all products subject to the product liability directive are also subject to product safety regulation.[1311]

For the purpose of this research it is of special importance that both regulatory bodies apply to consumer products.[1312]

Community Rapid Information System (RAPEX) and for notifications presented in accordance with Article 11 of Directive 2001/95/EC, 24. This document is available at http://ec.europa.eu/consumers/cons_safe/prod_safe/gpsd/rapex_guid_en.pdf

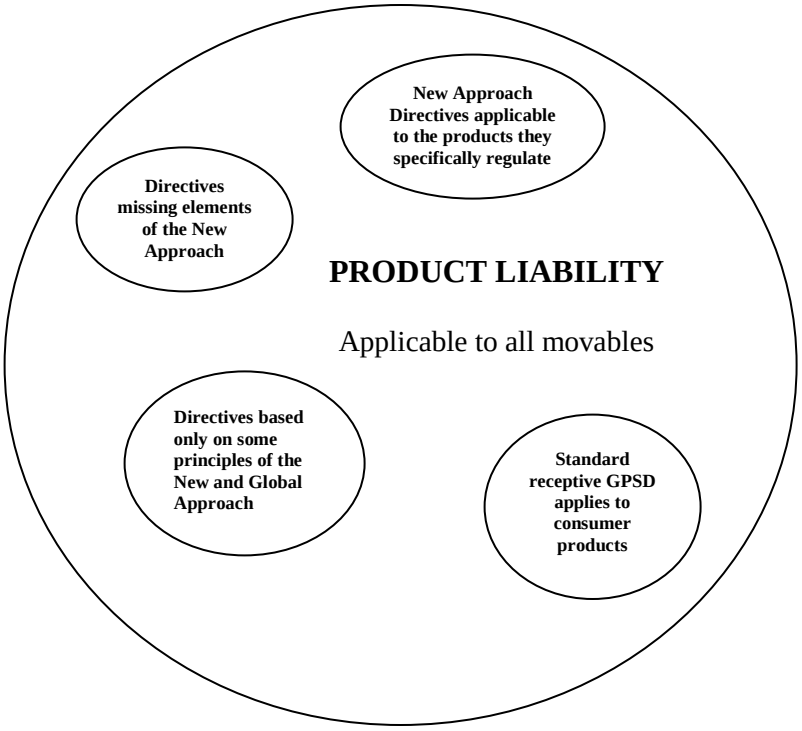
[1309] Article 2 of the product liability directive.

[1310] The exact definition of movables I provided by the domestic laws of the member states. Patrick Thieffry, Philip Van Doorn and Simon Lowe, Strict Product Liability in the EEC: Implementation, Practice and Impact on U.S. Manufacturers of Directive 85/374, 25 Tort & Insurance Law Journal 65, 70 (1989-1990).

[1311] An example of this last group would be food products that are excluded from the scope of application of the GPSD but subject to the product liability directive.

[1312] Christopher J. S. Hodges, Product Liability In Europe: Politics, Reform And Reality, 27 Wm. Mitchell L. Rev. 121, 129 (2000).

Figure 6.3 – Scope of Application of Pre-Market and Post-Market Controls



3.2 Safe v. dangerous

In addition to the common scope of application of European product safety and product liability regulations, the central concepts of both regulations are also related. Is an unsafe product under the GPSD[1313] defective under the product liability directive?[1314] Conversely, is a defective product under the product liability directive unsafe under European product safety regulation?

From a general perspective or even from a linguistic standpoint, unsafe and defective are not synonymous concepts. As defined in the European regulatory bodies regarding consumer products, the two concepts have a lot in common given that safe

[1313] See article 2 of the GPSD. Sometimes the directive refers to a "dangerous product," but this is simply a product which does not meet the definition of a "safe product." See article 2(c) of the GPSD

[1314] Council Directive 85/374 of 25 July 1985 Concerning Liability for Defective Products, 1985 O.J. (L 210) 29.

products are defined in article 2 of the GPSD and balance actual product risks[1315] so that products do "not present any risk or only the minimum risks compatible with [their] use."[1316] This is similar -- but not equivalent -- to the assessment of consumer expectations established by the product liability directive to determine whether a product is defective.[1317]

Safety under the GPSD requires other aspects to be taken into account as well, including (1) the categories of consumers at risk from the product (especially children and the elderly), (2) the characteristics of the product, including composition, packaging, instructions for assembly or installation and maintenance; the product's effect on other products, (3) the presentation of the product, including labeling, warnings, instructions for use and disposal, (4) and any other indications or information regarding the product.[1318]

The GPSD defines safe products based on product characteristics and based on a product's compliance with safety rules at both the European and the domestic levels.[1319] In this sense, a product is deemed safe if it conforms to the specific European safety legislation applicable to it,[1320] or, in the absence of such legislation, if it complies with the specific domestic safety rules in the member state in which the product is marketed.[1321]

As mentioned above, under the product liability directive a product is defective if it does not meet the consumer expectations test. The expectations of consumers are not

[1315] The Directive uses the risk-utility test to define a safe product. Article 2(b) clearly states a risk-utility analysis by stating that a product is safe when it does present "*only the minimum risks compatible with the product's use*." Note that the defectiveness test used by the Council Directive 85/374 of 25 July 1985 Concerning Liability for Defective Products, 1985 O.J. (L 210) 29 is the consumer's expectations test.
[1316] Article 2(b) of the GPSD.
[1317] Geraint G. Howells, The relationship between product liability and product safety – understanding a necessary element in the European Product Liability through a comparison with the U.S. position, 39 Washburn L. J. 305, 336 (2000).
[1318] Article 2(b) of the GPSD.
[1319] See Article 3(2) and article 3(3) of the GPSD.
[1320] Article 3(2) of the GPSD.
[1321] Article 3(2) of the GPSD.

met when a product fails to provide the safety that a consumer is entitled to expect.[1322] The essential element of the defectiveness standard is the expectations of consumers on the product's safety and hence there is no risk-utility balancing of the costs and benefits to product sellers and users.[1323]

Consequently, both concepts -- safety and defect -- are not equivalent but overlap, which results in an interaction between the legal norms and regulations laid out in Europe's product safety and product liability systems.[1324]

3.3 The compliance defense in European product regulation: a restricted approach

European product safety and product liability laws are independent and autonomous, but they are also related through a restricted version of a compliance defense. Compliance with, for example, the general safety duty or with any obligation stated in the GPSD, does not prevent a product from being subsequently considered defective under the product liability directive. And at the same time, non-compliance with the GPSD could raise a presumption of an unsafe or defective product and result in liability under the product liability directive.

The product liability directive does not include a compliance defense as such, except in cases where the safety regulation, issued by public authorities, is mandatory and the product's defect results from compliance with it.[1325] This defense relates to the

[1322] Article 6 of the product liability directive. See also Geraint G. Howells & Mark Mildred, Is European Products Liability More Protective Than The Restatement (Third) Of Torts: Products Liability?, 65 Tenn. L. Rev. 985, 994 (1998).
[1323] The expectation of consumers is not the only element to consider given that "all relevant circumstances" such as the presentation of the product should also be taken into account. Preamble of the product liability directive.
[1324] The defectiveness standard of the product liability directive heavily relies on the expectations on safety a consumer -- or the public at large -- are entitled to expect and the safety standard under the GPSD relies on the level of safety compatible with the product's use.
[1325] Article 7 (d) of the product liability directive.

relevance of safety standards in the context of product liability. The scope of this defense remains uncertain even today, but the idea behind it is that whenever regulatory standards exist, compliance should provide a defense to avoid liability.[1326] However, not just any safety standard provides a defense to product manufacturers: only mandatory standards issued by public authorities. In order to be able to claim this defense, it is necessary to prove that it was not possible to manufacture the product in a non-defective way while at the same time complying with mandatory regulations applicable to it.[1327] Hence, if the product could have been manufactured in a non-defective manner and still comply with mandatory regulations, the defense is not available.[1328]

The introduction of this defense has been justified based on the idea that producers "cannot be placed between disobedience and liability"[1329] but it has hardly been applied in the member states.[1330] Some courts have understood that the violation of voluntary standards might be admissible evidence, even though not conclusive, of product defectiveness[1331] but compliance with regulations or mandatory standards or the fact that the product has been licensed or tested is no defense to liability.[1332]

[1326] This is a way the European Commission understands encourages compliance with safety standards.
[1327] Article 7(d) of the product liability directive. However, it will be necessary to provide evidence to show that the product manufacturer has used all the information available at the time the product was manufactured and therefore that he complied with the state of the art or the state of scientific and technical knowledge of that time.
[1328] Hans C. Taschner, EEC Strict Liability in 1992: The New Product Liability Rules, 371 Practising Law Institute 81 (1989) indicating that this provision should be strictly interpreted and very narrowly applied.
[1329] Hans C. Taschner, EEC Strict Liability in 1992: The New Product Liability Rules, 371 Practising Law Institute 81 (1989).
[1330] In Spain there is only one case where it is possible to interpret that the court justified not imposing liability on a manufacturer of defective prosthesis that caused depression to the patient based on the argument that under binding European regulation in force, imposing liability was not justified. Opinion written by Hon. Nicolás Díaz Méndez, Magistrate of the Appellate Court of Madrid (Court of Appeals of Madrid) of June 3, 2005 (AC 997).
[1331] This is the interpretation of this defense used by German and Austrian courts. See Stephan Lenze, Product Safety Regulations and Defect' European Product Liability Review 24, 21 (2006).
[1332] But in cases where the scientific and technical knowledge did not allow discovering product risks, compliance with mandatory standards may be evidence that there is no product defect and therefore no liability is imposed. See Esther v. AEI Inc. (manufacturer) y Collagen Biomedical Aesthetic Iberica, S.A. (importer), Court of Appeals of Vizcaya 20.4.05 (JUR 2005\200889; Hon: María Carmen Keller Echevarría) and Blanca v. Collagen Biomedical Aesthetic Iberica, S.A. (importer), Court of Appeals of Barcelona 4.3.05 (JUR 2005\116914; Hon: Joaquín de Oro-Pulido López).

It should be noted that despite the autonomy of European product safety and product liability regulations, non-compliance with product safety regulations might have an indirect, but significant impact in a subsequent liability trial given that non-compliance with product safety regulations improves the chances of success of a plaintiff's claim while increasing the willingness of non-complying manufacturers to settle.[1333]

4 Ex ante and ex post liability: finding the adequate role for each mechanism

European product safety and product liability overlap in their scope of application and in their shared goal of minimizing product risks and product-related accidents. The European legislature, however, does not seem to have a specific concern about the coordination measures that could be adopted to enhance their joint performance. As figure 6.4 reflects, product manufacturers -- or producers, using the GPSD terminology -- are subject to product safety regulations while at the same time exposed to product liability.

Figure 6.4 - Interaction between
European Product Safety and Product Liabiliy Regulations

Product Safety / Product Liability	**Liability**	**No-liability**
Compliance	Safe / Defective	Safe / Non-Defective
Non-compliance	Unsafe / Defective	Unsafe / Non-Defective

[1333] See W. Kip Viscusi, Product Liability and Regulation: Establishing the Appropriate Institutional Division of Labor, The American Economic Review, Vol. 78, No. 2, pp. 300-304 (1988); W. Kip Viscusi, The Determinants of the Disposition of Product Liability Claims and Compensation for Bodily Injury, Journal of Legal Studies, vol. 15 No. 2, 321- 346 (1986) and W. Kip Viscusi, Product Liability Litigation with Risk Aversion, 17 Journal of Legal Studies 1 (1988).

4.1. Reaching the ideal outcome: Safe and non-defective products

The best imaginable situation in terms of effectiveness of product regulation would be where a product met the product safety requirements and consequently would be safe and at the same time, would not be subsequently defective. In this case, regardless of whether the product would cause harm to a consumer, the producer would be neither subject to administrative fines nor liable under the product liability directive.[1334]

As mentioned above, there is no information available regarding the exposure of products to safety and liability measures. This data would be crucial when determining whether the amount of safety notifications and product liability judgments is significant compared to the overall amount of products marketed -- regardless of their origin of manufacture.

Despite missing such important data, it seems reasonable to consider that in light of the number of safety notifications -- less than 2000 in any given year since 2004[1335] -- and the number of product judgments in Spain -- always below 90 annually[1336] -- the vast majority of products are both safe and non-defective and hence fit in this category. It is difficult to determine the percentage of all marketed products that would fit into this optimal category but in light of the information available, it seems reasonable to state that a majority of products are both safe and non-defective. Hence, it seems possible to suggest that product regulation in Europe might not be optimal but is, nonetheless, performing reasonably well.

[1334] In this case, if the product would cause harm the product manufacturer could have a regulatory compliance defense under which the product manufacturer would not be exposed to liability if he could prove that the product defect was a consequence of compliance with product safety regulation in force when the product was manufactured. See article 7 (d) of the product liability directive, stating that

> *The producer shall not be liable as a result of this Directive if he proves:*
>
> > *(d) that the defect is due to compliance of the product with mandatory regulations issued by the public authorities*

[1335] See Figure 6.1 above.

[1336] See Figure 6.2 above.

4.2. When ex ante safety requirements are not effective: Unsafe but non defective products

Another possible regulatory situation of a product marketed in Europe is one where the product is unsafe but non-defective. In this case, public authorities would impose a penalty for non-compliance with safety regulations and hence for being unreasonably risky -- unsafe -- but no liability would arise under the product liability directive. As explained earlier, an unsafe product is not conceptually equivalent to a defective product. In light of the different sanctions arising from product safety and defect regulations, injured victims, if any, would not be compensated for the harm suffered because product safety regulations do not include compensation mechanisms for victims.

This situation would correspond to products that are in the RAPEX notifications chart but are not included in the product categories of product liability judgments.[1337] Examples of these products would be furniture, with an average of 12 safety notifications per year and jewelry,[1338] with an average of 7 safety notifications per year since 2006.[1339] In Spain, for example, there is no recollection of judgments for harm caused by any of these two product categories.

A hypothesis that could explain this situation would be that ex ante safety measures are so effective that any unsafe product was recalled or withdrawn from the market and hence there is no further possibility for these products to cause harm and be deemed defective. If this were the case, ex ante measures would successfully prevent unsafe -- or dangerous -- products from causing harm once in the market.

[1337] It should be noted that as explained earlier, RAPEX notifications are not equivalent to measures adopted. Hence, it could be that some products were notified as unsafe but that once examined, were not considered unsafe and hence adopting measures was not justified.
[1338] See table 5.2 above.
[1339] See table 5.2 above.

4.3. Relying on ex post solutions: Safe but defective products

Another possible situation is one where a product is safe and hence complies with the safety requirements established by product safety regulation but once marketed causes harm to a product user or consumer and such harm is a consequence of a product defect within the product liability directive.

In such a case, product safety regulations would not preempt product liability and therefore compliance would not shield a product manufacturer from being exposed to subsequent liability. As mentioned above, the compliance defense under article 7(d) of the product liability directive is very restrictive, applicable only in the case of mandatory regulations issued by public authorities that result in the product being defective. Thus, liability may be imposed when the injured victim brings a product liability claim and the defect was not a consequence of compliance with mandatory regulations.

Using the product categories of the tables above, these would be products included in table 6.1, product liability judgments in Spain, but of which there is no product safety notification, as shown in table 5.2. Examples of these products would be elevators, fireworks or bottles, where there are product liability judgments but there is no recollection of RAPEX safety notifications.[1340]

4.4. Ex ante product safety and ex post product liability responding together: Unsafe and defective products

A last situation would be where both mechanisms -- product safety and product liability -- are applicable as a consequence of the unsafe and defective conditions of a

[1340] See table 6.1 below.

certain product. This would be cases where a product does not meet product safety standards applicable to it and is therefore deemed unsafe -- and administrative penalties are imposed -- while at the same time, its defective condition causes harm to a victim and triggers liability.

As mentioned above, both regulations would be simultaneously applicable so that product safety compliance would be evidence of safety but would not shield the product manufacturer from liability because compliance has no weight on the determination of a product being defective.[1341] At the same time, non-compliance with product safety standards is evidence of a product being unsafe but is not conclusive evidence of the product being defective. Hence, assuming that the product causes an injury and the victim brings a claim and meets the burden of proof under the product liability directive -- proof of defect, harm and a causal relationship between them -- the manufacturers of the unsafe product would have to pay both an administrative penalty to the responsible state or administrative agency and a liability award to the victim.

In the European context, these would be products that have had safety notifications -- and if the information was available, would have caused a safety measure to be adopted -- and there would further be a product liability judgment imposing a liability award. Examples of these products would be electrical appliances, motor vehicles or chemical products.[1342]

It would be interesting to observe whether product safety measures influence subsequent product liability judgments or, conversely, whether a significant amount of product liability judgments create incentives to adopt safety measures and hence result in lower safety notifications. Unfortunately, in light of the data available, it is not possible to draw conclusions regarding the incentives created by these two regulatory mechanisms and to determine whether there is any enhanced effect of their joint application.

[1341] See article 7 (d) of the product liability directive.
[1342] See tables 5.2, above and 6.1, below.

5 Working together: a proposal for enhancing the joint performance of European product safety and product liability

As explained above, the interaction between European product safety and product liability regulations is a fact despite their formal regulatory autonomy and independence.[1343] A comprehensive approach in analyzing the relationship and interaction between statutory law and tort law as ways of minimizing product risks and improving victims' compensation should be adopted in order to save administrative and litigation costs.[1344] There is room for welfare enhancing measures in European product regulation.

European product regulation holds product manufacturers to a voluntary standard-based product safety regulation -- with some exceptions[1345] -- while also exposing them to strict product liability under tort for the harm caused by defective products.[1346]

[1343] See generally Alan Schwartz, Statutory Interpretation, Capture, and Tort Law: the regulatory compliance defense, American Law and Economics Review, 2(1) (2000) defending the role of the U.S. Congress in enacting product safety regulation that would preempt state law safety regulation and where compliance with federal safety standards would prevent a product manufacturer from potential claims under tort. See also Joachim Zekoll, American Law in a Time of Global Interdependence: U.S. National Reports to the XVIth International Congress of Comparative Law: Section II Liability for Defective Products and Services, 50 Am. J. Comp. L. 121 (2002) for a discussion on the interaction between ex ante product regulation and ex post product liability in the U.S. system.

[1344] There is a broad body of literature arguing in favor of adopting a more comprehensive approach of the different legal instruments affecting the tortfeasors' decision in investment in safety. See Susan Rose-Ackerman, Regulation and the Law of Torts, The American Economic Review, vol. 81, no. 2, Papers and Proceedings of the Hundred and Third Annual Meeting of the American Economic Association pp. 54 -58, 57 (1991). See also W. Kip Viscusi, Product Liability and Regulation: Establishing the Appropriate Institutional Division of Labor, The American Economic Review, Vol. 78, No. 2, pp. 300-304 (1988).

[1345] As explained in Chapter 5 compliance with product safety standards is mostly voluntary except for products subject to New Approach Directives, that represent a relatively minor percentage of consumer products marketed in the European market, the manufacturers of which are mostly subject to the horizontal safety obligation included in article 3 (1) of the GPSD.

[1346] This relationship between product safety regulation and product liability – non compliance being negligence per se and compliance being evidence but not excluding liability under tort – is also included in the Restatement of the Law (1997), regarding federal statutes establishing product safety measures to be adopted and tort liability. For a discussion on the European product regulation model within consumer law see Jules Stuyck, European Consumer Law After The Treaty Of Amsterdam: Consumer Policy In Or Beyond The Internal Market?, Common Market Law Review 37: 367-400, 375 (2000).

Considering the theoretical background presented earlier and the European product regulation structured through ex ante product safety regulation and strict liability under tort, the key element that determines the joint performance of these two instruments when deterring product accidents is whether the information about product risks is available to all parties involved -- consumers, manufacturers or regulatory agencies -- and if not available to all parties, which one is better informed about product risks and hence is in a better position to adopt measures in order to reduce and if possible, avoid product-related accidents. The amount of information available regarding product risks will hence determine the relationship between the two regulatory bodies forming European product regulation -- ex ante safety regulation and ex post liability under tort.

Two different situations should be distinguished: a context with perfect information about product risks and a context where consumers do not have access to all information regarding product risks.

When information regarding product risks is perfect, either regulatory model of accident minimization, ex ante safety regulation and ex post liability, will perform optimally.[1347] Under perfect information, regulatory agencies will be able to set the standard of care at an optimal level and hence efficiently minimize product-related accidents and strict liability under tort will also perform optimally as long as damages are set at the level of harm caused by the tortfeasor.[1348] In light of the optimal performance of each instrument when implemented alone, the joint use of ex ante regulation and strict product liability does not enhance or improve the performance of the regulatory system as a whole and hence one of the instruments ends up being redundant.

[1347] The equivalent outcomes of different rules -- regulation, liability rules or contracts -- when information about product risks is perfect has long been settled in the literature. For early discussions on this issue see A. Michael Spence, Consumer Misperception, Product Failure, and Producer Liability, Review of Economic Studies, vol. 44, núm. 3, pp. 561-572 (1977); Dennis Epple / Artur Raviv, Product Safety: Liability Rules, Market Structure, and Imperfect Information, American Economic Review, vol. 68, núm. 1, 80-95 (1978).

[1348] Guido Calabresi, The Costs of Accidents, New Haven: Yale University Press (1970) and Donald Wittman, Prior Regulation vs Post Liability: The Choice between Input and Output Monitoring, 6 Journal of Legal Studies 1, 193-212 (1977).

Information regarding product risks may be derived from either general knowledge about product risks or the manufacturers' voluntary disclosure through instructions or warnings.[1349] Hence, the availability of the information does not necessarily depend on manufacturers' decisions to disclose. Rather, when dealing with widely sold products, risks are generally known and the information provided by product manufacturers becomes less essential.

Consequently, whenever information is perfect, using ex ante safety regulation or ex post liability results in the same outcome: product manufacturers optimally invest in safety and consumers purchase the efficient amount of product and the use of either instrument alone would be enough to achieve an efficient outcome because the joint scope application and the effectiveness of both instruments overlaps.[1350] Thus, in view of the horizontal obligation of introducing safe products into the market included in the GPSD,[1351] it should be possible for consumers to waive or even to shield product manufacturers from ex post product liability through a compliance defense.[1352] In this

[1349] Mitchell Polinsky and Steven Shavell, The uneasy case for product liability, 123 Harv. L. Rev. 1437, 1451-1453 (2010) differentiating the consumers' level of information depending on whether products are widely or not widely sold.

[1350] This result is consistent with the Coase theorem that predicts that when transaction costs are zero – and hence information is costless -- the initial assignment of property rights or liability rules is irrelevant because individuals will reach an optimal outcome regardless of the initial assignment. See Ronald Coase, The Problem of Social Cost, 3 Journal of Law and Economics 1 (1960).

[1351] Article 3(1) of the GPSD.

[1352] W. Kip Viscusi, Product Liability and Regulation: Establishing the Appropriate Institutional Division of Labor, The American Economic Review, Vol. 78, No. 2, pp. 300-304 (1988) arguing that regardless of the availability of a compliance defense, firms may introduce evidence of compliance in order to show that their investment in safety responded to a risk-utility analysis and that the product should not be deemed defective. See also Catherine M. Sharkey, Products liability preemption: an institutional approach, 76 The George Washington Law Review 101 (2008) introducing an institutional approach to the interaction between product safety and product liability through the analysis of the preemption between state and federal product safety regulation. See Steven Shavell, Liability for Harm Versus Regulation of Safety, 13 J. Legal Stud. 2, 365 (1984) arguing against the compliance defense based on the argument that liability may induce high risk individuals to take precautions at a level above the one required by the ex ante regulation. In these cases, Shavell suggests that the regulatory standard would not need to be as rigorous as if regulation was applied alone and should be interpreted as a minimum level of precaution.

context, ex post product liability would not be welfare enhancing and would entail an unnecessary waste of resources.[1353]

But there are other contexts in which consumers do not have access to perfect information of product risks. These are cases in which product manufacturers fail to disclose such information or in which general information about their risks is unavailable because the products are not widely sold or because the risks they present are not generally known.

Whenever the information about product risks is not perfect, the joint performance of ex ante safety regulation and ex post strict liability depends on whether consumers can perceive product risks so that they can decide, according to their preferences, whether they accept the tradeoff between a lower price and higher product risks than the ones set by the ex ante regulatory standard of care.[1354] If consumers could adequately -- even though imperfectly -- perceive product risks, they could accurately decide whether they are willing to trade a lower price for higher product risks and either regulatory model -- ex ante product safety or ex post product liability -- could result in optimal outcomes.[1355] If that was the case, the reasoning presented above would apply.

If consumers would have imperfect information about product risks or could not adequately perceive them, they could not accurately decide the tradeoff between product price and risks and hence would be subject to risks they would not be willing to accept. In these cases, the regulatory structure should be different and there could be room for jointly applying ex ante product safety regulation and ex post liability.[1356]

[1353] Product safety would perform a deterrent function that might be effective because of the threat product manufacturers would face in reputation losses. See Alberto Cavaliere, Product Liability in the European Union: Compensation and Deterrence Issues, European Journal of Law and Economics, 18: 299–318, 300 (2004).

[1354] Victor P. Goldberg, The Economics of product safety and imperfect information, the Bell Journal of Economics and Management Science, 5:2, 683-688, 685 (1974).

[1355] Walter Y. Oi, The economics of product safety, The Bell Journal of Economics and Management Science, vol. 4, no. 1, 3-28 (1973).

[1356] Victor P. Goldberg, The Economics of product safety and imperfect information, the Bell Journal of Economics and Management Science, 5:2, 683-688, 687 (1974).

When these two regulations are jointly implemented, the next question is how they should interact. Whenever ex ante regulation and ex post liability are jointly implemented, as explained above, four different situations potentially arise: (1) safe and defective products, (2) safe and non-defective products, (3) unsafe and defective products, and (4) unsafe and non-defective products. As mentioned above, given that safety and defectiveness are not synonymous concepts and one does not imply the other, the compliance defense is the most common mechanism used in order to allow coordination between them under certain circumstances.

The compliance defense shields a product manufacturer from product liability in different degrees when products cause harm to consumers or users but comply with safety regulations applicable to them.

As explained above, compliance with European safety regulation shields a product manufacturer from liability only in cases where the regulation was mandatory and because of compliance with such regulation, the product became defective.[1357] In all other cases, compliance with product safety regulation prevents a product from being considered unsafe and is admissible but non-conclusive evidence in a subsequent liability claim.[1358] Hence, compliance may prevent a product from being qualified as unsafe but not from being considered defective and therefore subject to liability under tort. At the same time, non-compliance is evidence of a product being unsafe and if subsequently caused harm, potentially defective.[1359] The restrictive approach adopted by the European

[1357] See article 7(d) of the product liability directive. See also Sandra N. Hurd and Frances E. Zollers, Product Liability in the European Community: Implications for United States Business, 31 American Business Law Journal 245, 261 (1993).
[1358] The Restatement (Third) of Torts: Products Liability §4(b) also establishes that compliance with safety regulation does not preclude a finding of defect. Additionally, if compliance is with a federal statute intended to preempt state tort law, liability is precluded given that compliance with a federal statute raises an absolute defense.
[1359] W. Kip Viscusi, Product Liability and Regulation: Establishing the Appropriate Institutional Division of Labor, The American Economic Review, Vol. 78, No. 2, pp. 300-304 (1988).

model of product regulation is not the approach adopted in many other jurisdictions that opted for a broader scope of the defense.[1360]

The current regulatory scheme in Europe, uniformly applied regardless of the level of information about product risks and the consumers' awareness of such risks, is not necessarily the most efficient scheme and may result in over-investment in safety, and in undermining the competitive position of European industry with respect to other legal systems with lower safety requirements.

The interaction between ex ante product safety and ex post product liability in European product regulation as well as the scope of the compliance defense should be revisited and a parameter such as the information about product risks available to consumers should be taken into account when determining whether ex ante product safety regulation and ex post product liability should be jointly used and if so, how they should interact.

If information about product risks was perfect, either because of the manufacturer's voluntary disclosure through instructions or warnings or because of the nature of the product -- because the product is widely sold and its risks generally known,-

[1360] For example, in the U.S., the provisions regarding the compliance defense provided by the Restatement (Third) establishing that the violation of applicable product safety regulation renders a product defective have been adopted be different U.S. jurisdictions. See Restatement (Third) of Torts: Products Liability 4 provides that

> §4. *Non compliance and compliance with product safety statutes or regulations*
>
> *In connection with liability for defective design or inadequate instructions or warning:*
>
> *(a) a product's noncompliance with an applicable product safety statute or administrative regulation renders the product defective with respect to the risks sought to be reduced by the statute or regulation; and*
>
> *(b) a product's compliance with an applicable product safety statute or administrative regulation is properly considered in determining whether the product is defective with respect to the risks sought to be reduced by the statute or regulation, but such compliance does not preclude as a matter of law a finding of product defect.*

So in order to deem a product defective as a consequence of non-compliance with product safety regulation, the regulation must have been pertinent to the specific claim of defect in the sense that compliance would have reduced the product risks and the product non-defective. This is the solution adopted in the majority of jurisdictions but not in all of them. In some jurisdictions such as California, the violation of ex ante safety regulation creates a rebuttable presumption of defect. Finally, another group of jurisdictions such as New Jersey, consider that non-compliance is just admissible evidence of a product defect. See Dan B. Dobbs, THE LAW OF TORTS, 1034 (2000).

- the joint use of ex ante safety regulation and ex post product liability does not bring any advantage but represents a waste of resources. Either ex ante product safety regulation or ex post product liability alone would allow for creating optimal incentives for investing in care. In light of the ex ante European product safety regulation and the horizontal safety obligation included in the GPSD, enforcing ex post liability under tort does not appear to be efficient given that consumers in this context can perform a trade-off between risks and price and hence product liability becomes redundant.[1361] In this context, the European legislature should consider adopting a complete compliance defense that would shield product manufacturers who complied with ex ante product safety requirements from liability under tort.[1362] In these cases, if a product was safe, and hence the level of risk presented by the product is shown to be efficient,[1363] either through compliance or through instructions or warnings, ex post liability under tort should not be imposed.[1364]

A concern regarding product safety could arise. However, it should be remembered that this structure would be defined for widely sold products for which risks are generally known and for which regulatory agencies set safety standards. Hence, the incentives for investing in safety would be created through the safety requirements of government safety regulations as well as through market forces and the role of reputation that would encourage manufacturers to produce and introduce in the market safe

[1361] W. Kip Viscusi, Steven R. Rowland, Howard L. Dorfman, Charles J. Walsh, The Effect of Products Liability Litigation on Innovation: Deterring Inefficient Pharmaceutical Litigation: An Economic Rationale for the FDA Regulatory Compliance Defense, 24 Seton Hall L. Rev. 1437 (1994).
[1362] See W. Kip Viscusi, Product Liability and Regulation: Establishing the Appropriate Institutional Division of Labor, The American Economic Review, Vol. 78, No. 2, pp. 300-304 (1988).
[1363] In cases where the ex ante regulatory standard or the incentives to invest in safety were inefficient, product liability would still not become necessary given that market forces might be the principal force for the creation of incentives for investing in safety. See W. Kip Viscusi, Product Liability and Regulation: Establishing the Appropriate Institutional Division of Labor, The American Economic Review, Vol. 78, No. 2, pp. 300-304 (1988) and Michael Moore and W. Kip Viscusi, Promoting Safety through Workers' Compensation: The Efficacy and Net Wage Costs of Injury Insurance, Working Paper, Northwestern University (1988).
[1364] W. Kip Viscusi, Product Liability and Regulation: Establishing the Appropriate Institutional Division of Labor, The American Economic Review, Vol.. 78, No. 2, pp. 300-304 (1988).

products.[1365] In light of the emphasis on safety of European product regulation, the reported level of compliance with it and its increasing enforcement shown by the increasing level of notifications of unsafe products reported through the RAPEX system,[1366] the diminished role of ex post products liability in this context should not be an issue.[1367]

In contrast, when information about product risks is not perfect, either because product manufacturers do not disclose it or because these products are not widely sold and hence their risks are less known, consumers cannot adequately assess product risks and hence cannot make optimal tradeoffs between higher or lower product risks for lower or higher product prices.[1368] In these cases there is a role for the joint use of ex ante product safety and ex post liability under tort. When information about product risks is not available to consumers, ex ante product safety and ex post product liability could be jointly used in order to achieve a more efficient outcome than if these two regulatory mechanisms were used alone. Hence, despite the broad European product safety regulation, when product risks are not widely known, there is a role for ex post liability under tort.[1369] The interaction between ex ante product safety and ex post liability in these

[1365] See Mitchell Polinsky and Steven Shavell, The uneasy case for product liability, 123 Harv. L. Rev. 1437, 1451-1453 (2010) defending this approach and advocating for reducind the role of product liability in these cases.
[1366] See section 4.3 of Chapter 5, above. See also Annex II of the GPSD and European Commission, Keeping European Consumers Safe, 2009 Annual report on the operation of the Rapid Alert System for non-food consumer products, RAPEX. This document is available at http://ec.europa.eu/consumers/safety/rapex/docs/2009_rapex_report_en.pdf
[1367] See Mitchell Polinsky and Steven Shavell, The uneasy case for product liability, 123 Harv. L. Rev. 1437, 1450-1453 (2010) arguing that because of the volume of sales as well as the presence in the market of widely sold products, consumers have more information about product risks available as well as regulatory agencies have more incentives to issue regulations regarding a certain investment in safety.
[1368] See Mitchell Polinsky and Steven Shavell, The uneasy case for product liability, 123 Harv. L. Rev. 1437 (2010) arguing that products liability is desirable for non-widely sold products and undesirable for widely-sold products, the risks of which are most commonly known.
[1369] Mitchell Polinsky and Steven Shavell, The uneasy case for product liability, 123 Harv. L. Rev. 1437 (2010) considering that the role of product liability as a mechanism to create incentives to invest in care should be limited to non-widely sold products.

cases could be articulated through a restricted compliance defense like the one in force today in the product liability directive.[1370]

A step towards maximizing the coordination between the two regulatory models that jointly configure product regulation in Europe should be adopted in order to maximize the performance of the overall system of European product regulation. Consequently, European product law should, on one hand, broadly look at the overall regulation products are subject to in their different stages in order to assess their global impact in creating incentives for accident minimization and hence in minimizing product-related accidents. The law should also distinguish between widely sold products and non-widely sold products when the information ab out the risks they present is different and provide a different regulatory treatment for each product category. Such structure would enhance the joint performance of both mechanisms and would take advantage of the full potential of the nature and substance of each regulatory mechanism that configures European product regulation.

[1370] Article 7(d) of the product liability directive.

Table 6.1 - Product Liability Judgments in Spain over Time

PRODUCT CATEGORY	BEF	1994[1371]	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	TOTAL
FIREWORKS	2	3	0	1	0	0	0	16	6	2	3	4	6	2	0	3	0	**48**
BOTTLES	2	0	2	2	1	1	3	9	5	9	4	1	4	6	0	2	0	**51**
ELECTRICITY	0	0	0	0	2	1	2	5	4	14	25	6	2	14	0	13	13	**101**
ELECTRICAL APPLIANCES	3	0	0	0	1	0	0	2	1	4	2	5	6	2	1	0	1	**28**
GAS	2	2	0	1	1	5	5	18	15	13	25	12	0	5	1	3	2	**110**
TOYS	0	0	0	0	0	0	0	0	0	1	0	0	1	0	0	1	0	**3**
MACHINERY	0	0	0	1	1	0	0	0	0	1	2	2	3	0	1	0	0	**11**
ELEVATORS	0	0	0	0	0	0	1	1	0	0	0	0	0	1	0	0	0	**3**
EXTINGUISHER	1	0	0	0	1	0	0	0	0	1	0	0	0	0	0	0	0	**3**
CONSTRUCTION MATERIALS	0	0	0	0	0	1	0	2	2	1	5	2	7	3	0	1	0	**24**
MEDICINES	0	0	0	0	1	0	1	2	1	2	3	1	0	2	0	4	0	**17**
HEALTH PRODUCTS	0	1	0	0	0	1	3	1	3	2	2	3	9	5	0	0	0	**30**
PROD. for DOMESTIC USE	1	0	0	1	0	0	2	1	2	6	2	4	5	2	0	5	1	**32**
CHEMICAL PRODUCTS	4	1	0	0	1	0	1	1	3	3	3	3	7	4	1	2	0	**34**
VEHICLES	0	1	0	2	0	0	1	3	8	15	12	10	18	12	0	15	3	**100**
OFFICE SUPPLIES	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	**1**
ELECTRONICS	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0	**2**
COSMETIC PRODUCTS	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	**1**
BICYCLES	0	0	1	0	1	0	0	0	1	0	0	1	0	0	0	0	0	**4**
TOTAL	**15**	**8**	**3**	**8**	**10**	**9**	**19**	**61**	**51**	**74**	**88**	**54**	**68**	**59**	**4**	**51**	**21**	**603**

1371 The Directive 85/374 was transposed into Spanish law by law 22/1994 (http://www.boe.es/boe/dias/1994/07/07/pdfs/A21737-21739.pdf). Today it remains in force through the RDL 1/2007 (http://www.boe.es/boe/dias/2007/11/30/pdfs/A49181-49215.pdf)

CHAPTER 7

COMPENSATION OF PRODUCT-RELATED ACCIDENT VICTIMS IN EUROPE: SOURCES, INTERACTION AND EFFECTS

The last chapter of this thesis focuses on the compensation of victims of product-related accidents. As with other types of accidents, the basic sources of compensation to which the victims of product-related accidents may turn are the tortfeasor, via the imposition or threat of liability and damages awards, and collateral sources such as the providers of private and public insurance.

Compensation is one of the most interesting aspects of the product regulation model in force in Europe. With the U.S. model of product liability as a reference, the structure and content of European product regulation have often been justified as a way to provide injured victims with an easy and effective mechanism for seeking compensation for product-related harm.[1372] The context of the U.S. and European product liability systems, however, are dramatically different. In particular, social insurance plays a crucial role in compensating victims in Europe, and this distorts the impact of product liability.

The nature of tort law as a compensation instrument has been widely discussed in the literature.[1373] Tort law aims to compensate victims and place them in the same position they would have been in had the accident not taken place.[1374] The extent to

[1372] See the preamble of the product liability directive emphasizing the importance of compensation of injured victims of product-related acccidents.

[1373] See Gary T. Schwartz, Mixed Theories of Tort Law: Affirming Both Deterrence and Corrective Justice, 75 Tex. L. Rev. 1801 (1997) and George L. Priest, Modern Tort Law and Its Reform, 22 Val. U. L. Rev. 1, 5 (1987) noting that modern tort law has two goals: minimizing accident rates as well as providing compensation for those who suffer accidents caused by products or services. See also Beatrice A. Beltran, Posner and tort law as insurance, 7 Conn. Ins. L. J. 153 (2000) arguing that today tort law serves more as a deterrence mechanism than as a compensatory instrument and hence should not be regarded primarily as a form of insurance.

[1374] Steven Shavell, FOUNDATIONS OF ECONOMIC ANALYSIS OF LAW, Belknap Press of Harvard University Press, 177- 220 (2004).

which tort law achieves this goal, of course, is conditioned on victims pursuing their claims. Product liability, as a subcategory of tort law, is no different in this respect.

One of the European Commission's goals in adopting the product liability directive was to make tort law an effective compensation system for the harm caused by products. In particular, the Commission included the directive's strict liability regime on the assumption that this would facilitate product victims' claims for compensation.[1375] In light of the scarce product liability litigation in Europe,[1376] however, it does not appear that product liability is being used by product victims as their main compensation mechanism. This may be attributed, in part, to the parameters presented already -- procedural factors, the sometimes non-strict nature of the liability imposed by the directive, and the interaction between product liability and product safety regulations that in certain situations might have affected the probabilities of injured victims of prevailing in court. It may also be the result of the existence and role of European social insurance.

To understand how insurance operates as a compensation mechanism, it is important to distinguish between private and public insurance. Both share the same compensation rationale -- compensating victims regardless of fault -- but differ in their operation. In particular, private insurance is funded through insurance premiums that are

[1375] See the preamble of the product liability directive.

[1376] See Jane Stapleton, Bugs in Anglo-American Products Liability in Product liability in comparative perspective, edited by Duncan Fairgrieve, Cambridge, 295 (2005) noting that the level of product liability litigation remains significantly low because injured victims do not generally pursue their product claims. See also Robert W. McGee, Who Really Benefits from Liability Litigation?, num. 24, Dumont Institute Policy Analysis (1996) noting that Liability costs in the United States are 15 times higher than in Japan and twenty times higher than in Europe. See Eleonora Rajneri, Interaction between the European Directive on Product Liability and the former liability regime in Italy, in Product Liability in Comparative Perspective, Duncan Fairgrave (ed.) 67 - 84, Cambridge University Press (2005) for an analysis of the impact of the adoption of the product liability directive in Italy. See also Sheila L. Birnbaum, Legislative reform or retreat? A response to the product liability crisis, 14 Forum 251, 253 (1978-1979) noting that the introduction of strict product liability in the U.S. resulted in a substantial increase in the frequency of product liability cases as well as on the size of settlement awards. See also Sheila L. Birnbaum, Legislative reform or retreat? A response to the product liability crisis, 14 Forum 251, 253 (1978-1979) noting that the introduction of strict product liability in the U.S. resulted in a substantial increase in the frequency of product liability cases as well as on the size of settlement awards.

set for different pools of insured parties according to their levels of risk,[1377] whereas public insurance -- social insurance -- is funded through taxpayer contributions that are not linked to risk. In addition, private insurance is often held by potential tortfeasors, and operates as part of the compensation system by ensuring that these parties are able to compensate victims if they cause harm; public insurance, on the other hand, is a direct source of compensastion for the victims themselves.

There is no comprehensive treatment of these basic systems for compensating the victims of product-related accidents.[1378] Tort, private insurance, and public insurance are all regulated individually and independently, without attention to the combined role and effect of each system on the tortfeasor's incentives for care and on the victim's incentives to seek compensation.

This Chapter lays out each of the compensation mechanisms as they exist in Europe, explains the mechanisms in place for coordination between them, and discusses the inefficiency and challenges presented by this overall system. The chapter suggests that social insurance systems may be bearing most of the costs of product-related accidents in Europe, and that this warrants a reconsideration of Europe's overall product liability model.[1379]

[1377] See in general Tom Baker, Risk, Insurance and (the social construction of) Responsibility, University of Connecticut School of Law Working Paper Series 8 (2002). This article is available at http://lsr.nellco.org/uconn/ucwps/papers/8 considering that insurance is not only a loss spreading instrument but is also a form of social responsibility based on five different arguments: accountability, trustworthiness, causation, freedom and solidarity.

[1378] See Kenneth S. Abraham, Private Insurance, Social Insurance, and Tort Reform: Toward A New Vision Of Compensation For Illness And Injury, 93 Colum. L. Rev. 75, 77 (1993) arguing for a comprehensive treatment of compensation schemes.

[1379] Eleonora Rajneri, Interaction Between the European Directive on Product Liability and the Former Liability Regime in Italy, Global Jurist Topics, Vol. 4, Issue 1 num. 3 (2004) suggesting that European consumers do not have an interest in pursuing their product liability claims because they already receive compensation through social insurance.

1 Tort law -- product liability -- as a victim's compensation system

Tort law has two major functions: deterring accidents by creating incentives for care and compensating victims of accidents once they have occurred.[1380] From an ex ante perspective -- before the accident has taken place -- tort law aims at creating incentives to potential tortfeasors for investing in care so that the amount of accidents is minimized.[1381] Preventing all accidents, however, would be infinitely costly and would require cessation of nearly all human activity, given that most activities can eventually cause harm. In other words, preventing all accident is impossible in practice. Therefore, rather than try to eliminate all risk,[1382] tort law seeks to minimize the expected losses caused by accidents up to a level where the cost of preventing them is lower than the amount of damage they cause.

The effectiveness of tort law as a deterrent mechanism is imperfect.[1383] It reduces accidents but not at the predicted level.[1384] However, the deterrent effect of tort law

[1380] See George L. Priest, Modern Tort Law and Its Reform, 22 Val. U. L. Rev. 1, 5 (1987) noting that there are two main goals of tort law: minimizing accidents and giving injured victims an insurance-like mechanism for seeking compensation. See also James A. Henderson, Jr., Coping With the Time Dimension in Products Liability, 69 Cal. L. Rev. 919, 935-38 (1981) noting three values of products liability: first, compensating victims of defective products; second, requiring those who cause harm to make their victims whole and third, shifting the social costs of risky activities from innovent victims to who directly benefited from them.

[1381] Accident minimization does not mean aiming at eliminating accidents at any cost. From a law and economics perspective, only accidents that are cost effective to eliminate, that is, those where the cost of precautions is lower than the reduction in expected liability costs, should be eliminated. See Steven Shavell, FOUNDATIONS OF ECONOMIC ANALYSIS OF LAW, Belknap Press of Harvard University Press, 177 - 220 (2004). See also Beatrice A. Beltran, Posner and tort law as insurance, 7 Conn. Ins. L. J. 153, 175 (2000) describing the incentives created by the tort system on potential tortfeasors to invest in safety.

[1382] See Stephen D. Sugarman, Doing Away with Tort Law, 73 Cal. L. Rev. 555, 573, fn.67 (1985) explaining that the goal of deterrence is not eliminating all accidents because that would imply ceasing all activities but seeking to achieve an optimal level of accidents.

[1383] See Gary T. Schwartz, Reality in the Economic Analysis of Tort Law: Does Tort Law Really Deter?, 42 U.C.L.A. L. Rev. 377, 378-79 (1994) considering that tort law provides a significant amount of deterrence but less than predictions indicate. See also Beatrice A. Beltran, Posner and tort law as insurance, 7 Conn. Ins. L. J. 153, 187 (2000) arguing that tort law should not be required to provide an absolute level of accident deterrence and arguing that its performance as a deterrent instruments should be evaluated in relative or marginal terms.

[1384] William M. Landes & Richard A. Posner, THE ECONOMIC STRUCTURE OF TORT LAW, 10, Harvard University Press (1987) noting that tort law performs moderate deterrence.

should not be evaluated by itself but instead jointly with other parameters that simultaneously contribute to minimize tort accidents. These include market forces, which create incentives for accident minimization through reputation, and ex ante product safety regulation, which aims to minimize accidents by encouraging compliance with product safety standards.[1385] In this sense the threat of liability under tort -- the threat of being exposed to liability -- alone or combined with other factors, serves as a deterrent mechanism.[1386]

In addition and related to its role in deterring accidents,[1387] tort liability is also an important instrument of compensation for injured victims.[1388] Through tort law, injured victims may seek compensation[1389] from those responsible for their harm.[1390] Through the compensation function, the incentives to adopt care -- i.e., accident deterrence -- are enhanced and reinforced.[1391]

From a compensation perspective, the goal of tort law is to leave the injured victim in the same position she would have been in had the accident not taken place.[1392]

[1385] See Mitchell Polinsky and Steven Shavell, The uneasy case for product liability, 123 Harv. L. Rev. 1437 (2010) arguing that in light of all these factors, product liability has a marginal effect on deterrence. See also Alberto Cavaliere, Product Liability in the European Union: Compensation and Deterrence Issues, European Journal of Law and Economics, 18: 299–318, 300 (2004).

[1386] Beatrice A. Beltran, Posner and tort law as insurance, 7 Conn. Ins. L. J. 153, 190 (2000).

[1387] See Gary T. Schwartz, The Ethics and the Economics of Tort Liability Insurance, 75 Cornell L. Rev. 313, 363 (1990) arguing that deterrence is a more important tort goal than retributive justice or loss spreading.

[1388] See Ralph A. Winter, The Liability Insurance Market, The Journal of Economic Perspectives, vol. 5, no 3, 115-136 (1991).

[1389] See Robert G. Berger, The impact of tort law development on insurance: the availability/affordability crisis and its potential solutions, 37 Am. U. L. Rev. 285, 300 (1988) noting that the judiciary has attempted to transform the tort system into a compensation mechanism.

[1390] See Paul H. Rubin, TORT REFORM BY CONTRACT, 49-51, American Enterprise Institute Press (1993) suggesting that deterrence is jointly achieved by tort law and ex ante government regulation and hence there is no need for tortfeasors to bear the full cost of the injuries they cause.

[1391] See generally Michael Faure, ed. Deterrence, insurability and Compensation in Environmental Liability, Future Developments in the European Union, Vol 5 Tort and Insurance Law, European Center of Tort and insurance law, Springer Wien (2003).

[1392] Steven Shavell, FOUNDATIONS OF ECONOMIC ANALYSIS OF LAW, Belknap Press of Harvard University Press, 257-279 (2004). It should be noted that the traditional goal of corrective justice of tort law is not shared by insurance theorists who understand that tort compensation should be based on the individual demand for first-party insurance. So if individuals would not have purchased first-party insurance against certain risks, compensation for accidents in these cases would be inadequate. See Heidi Li Feldman, Harm and Money: Against The Insurance Theory of Tort Compensation, 75 Tex. L. Rev. 1567, 1596 (1997). See

The effectiveness of tort awards in compensating injured victims and making them whole turns on whether the accident modified the victim's utility function after the accident.[1393] Whenever the injured victim's utility function after the accident is not modified and just decreased to a lower utility level,[1394] the tort system can and should perfectly compensate the victim and the two simultaneous goals of tort liability may be achieved: on one side, victims receive compensation that places them back in the same position as they were before the accident took place and on the other, tortfeasors have incentives to optimally invest in care -- or safety -- given that they would fully internalize the victim's losses.[1395] If this outcome was achieved, the investment in care would be optimal and at the same time the level of accidents would be minimized.[1396]

But whenever the utility function of the injured victim is modified as a consequence of the accident,[1397] as for example in cases where the victim suffers serious injuries, the tort system does not provide perfect compensation and the injured victim is generally under-compensated[1398] given that it is not possible to leave the injured victim in

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also Gary T. Schwartz, The Ethics and the Economics of Tort Liability Insurance, 75 Cornell L. Rev. 313, 363 (1990) arguing that compensatory justice provide the rational basis of the tort law.

[1393] See generally Richard A. Posner, ECONOMIC ANALYSIS OF LAW, 219, Aspen eds. (5th ed. 1998). See also Beatrice A. Beltran, Posner and tort law as insurance, 7 Conn. Ins. L. J. 153, 180 (2000) noting that the impact of the accident on the victim's utility function and whether she can truly be made whole by the damage award is directly related on the issue of whether tort law can effectively perform its compensation function.

[1394] This would be cases where the shape of the injured victim's utility function would not change but would decrease and the new utility function of the injured victim after the accident would be parallel to original utility function the victim had before the accident took place. See Hal R. Varian, INTERMEDIATE MICROECONOMICS: A MODERN APPROACH, 55-72, 6W W Norton & Co Inc (Np); 5th ed. (1999).

[1395] See Richard A. Posner, ECONOMIC ANALYSIS OF LAW, 185, Aspen eds. (5th ed. 1998) noting that even if compensation was imperfect, the liability threat would be a way of deterring risky and undesirable behavior.

[1396] Steven Shavell, FOUNDATIONS OF ECONOMIC ANALYSIS OF LAW, Belknap Press of Harvard University Press, 177- 220 (2004).

[1397] See Mitchell Polinsky and Steven Shavell, The uneasy case for product liability, 123 Harv. L. Rev. 1437, 1465 (2010) noting that in cases where the victim's utility function changed, damage awards are incremental in nature, especially when they compensate for pain and suffering.

[1398] In fact, in cases where victims suffered serious injuries, the tort system under-compensates victims. See Richard A. Posner, ECONOMIC ANALYSIS OF LAW, 285 and 214-215, Aspen Eds. (5th ed. 1998) noting that despite the supposed generous damage awards given to injured victims, whenever these victims have suffered serious injuries and are crippled, tort law significantly under-compensates them. See also Kenneth S. Abraham, Private Insurance, Social Insurance, and Tort Reform: Toward A New Vision of Compensation for Illness And Injury, 93 Colum. L. Rev. 75, 108 (1993) arguing that tort law is a highly

the same position it was before the accident took place in light of the change of her utility function.[1399]

In addition to the impact and effect of the accident on the victim's utility function, the effectiveness of the tort system as a compensation mechanism is strongly conditioned on the nature and scope of the system and the victim's ability to successfully bring a claim.[1400] First, compensation under tort is not universally available for any kind of injury and for any amount of loss given that the tort system provides compensation for a limited amount of injuries. For example, European product liability provides a tort remedy for victims of defective products only when the damage suffered is higher than 500 euros.[1401] Victims suffering damages below this amount are not provided any remedy under the European product liability system.[1402]

Second, the prima facie case of an accident victim requires meeting a high burden of proof. Proving the damages is often difficult, especially when these damages include latent harm, continuous harm, or pain and suffering. Proving causation between the tortfeasor's conduct and the victim's damages can also be difficult.[1403] Additionally, in product liability cases, injured victims are required to prove product defect, and this is often a difficult task regardless of the defectiveness test used.[1404]

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unsatisfactory compensation system.

[1399] See W. Kip Viscusi, Toward a diminished role of tort liability: social insurance, government regulation, and contemporary risks to health and safety, 6 Yale J. on Reg. 65, 97-98 (1989) arguing that compensation under tort does not make inured victim's whole given that the actual value of court awards and settlements is often less than the actual losses suffered by the victim.

[1400] See W. Kip Viscusi, Toward a diminished role of tort liability: social insurance, government regulation, and contemporary risks to health and safety, 6 Yale J. on Reg. 65, 69 (1989).

[1401] Article 9 b) of the product liability directive.

[1402] See Lucille M. Ponte, Guilt By Association In United States Products Liability Cases: Are The European Community And Japan Likely To Develop Similar Cause-In-Fact Approaches To Defendant Identification?, 15 Loy. L.A. Int'l & Comp. L.J. 629, 659 (1993) noting that social insurance programs allow victims not entitled to a compensation remedy under tort to receive benefits.

[1403] See W. Kip Viscusi, Toward a diminished role of tort liability: social insurance, government regulation, and contemporary risks to health and safety, 6 Yale J. on Reg. 65, 70 (1989) noting that the tort system can adequately handle risks that have traceable causes but has an extreme difficulty to handle cases with multiple potential causes as well as risks that are new and might have unknown causes when the tort claim is filed.

[1404] As explained in Section 6 of Chapter 2, there are two major defectiveness tests: the consumer expectations test and the reasonable alternative design test. The product liability directive, in its article 6,

Third, even when victims pursue their claims and meet the required burden of proof, they are unable to receive compensation when tortfeasors turn out to be judgment-proof, uninsured, or underinsured.[1405] Whenever tortfeasors do not compensate injured victims the liability system fails both from the compensation perspective, as the victim is left without full relief, and from the deterrence perspective, as the tortfeasor does not fully internalize the victim's losses and hence is not given efficient incentives for care.[1406]

In addition to the challenges presented above, compensating injured victims through the tort system is very expensive,[1407] both privately and socially.[1408] The private costs of the tort system result from the cost of litigation. It is well settled that damage awards received by injured victims represent only a fraction of the funds awarded by courts.[1409] On top of these private costs, administrative costs of the court system necessary to adjudicate tort claims are borne largely by the society as a whole.[1410]

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establishes the consumer expectations test as the defectiveness test applicable in Europe. Some U.S. states apply the consumer expectations test while others apply the reasonable alternative design test for defect. See Geraint G. Howells & Mark Mildred, Is European Products Liability More Protective Than The Restatement (Third) Of Torts: Products Liability?, 65 Tenn. L. Rev. 985, 994 (1998) comparing the tests for defect applied in Europe and in the Restatement (Third).

[1405] See generally Stephen D. Sugarman, The New Zeland Experience and Alternative Compensation Schemes, 15 U. Haw. L. Rev. 659 (1993) analyzing the experience of no-fault compensation in New Zeland and pointing out the challenges presented by the U.S. tort system as a compensation mechanism.

[1406] See generally Steven Shavell, Minimum Asset Requirements And Compulsory Liability Insurance as Solutions to the Judgment-Proof Problem, Rand Journal of Economics, vol 36, num. 1, 63-77, 64 (2005) suggesting the use of asset and liability insurance requirements as mechanisms to ensure victim's compensation instead of using the legal system in light of its costly way of providing compensation to victims.

[1407] See Jeffrey O'Connell, A Correct Diagnosis Of The Ills Of Liability Insurance -- And A False Cure: A Comment On The Reports Of The Federal Tort Policy Working Group, 63 Notre Dame L. Rev. 161, 178 (1988) arguing that the problem of liability under tort is not its costs but how these costs are distributed among the different parties involved.

[1408] Stephen D. Sugarman, The New Zeland Experience and Alternative Compensation Schemes, 15 U. Haw. L. Rev. 659, 664 (1993). See also Beatrice A. Beltran, Posner and tort law as insurance, 7 Conn. Ins. L. J. 153, 159 (2000) concluding that the tort system does not effectively perform its compensation function.

[1409] Kenneth S. Abraham, Private Insurance, Social Insurance, and Tort Reform: Toward A New Vision of Compensation for Illness And Injury, 93 Colum. L. Rev. 75, 108 (1993) noting that a significant fraction of the tort awards are for the injured victim's lawyers instead for compensating victim.

[1410] Richard W. Wright, The principles of product liability, 26 Rev. Litig. 1067, 1096 (2007) noting the high costs involved in using the tort system as a compensation mechanism.

These challenges and imperfections of tort law as a compensation mechanism[1411] does not mean that tort law should be discarded as an instrument for compensation.[1412] Liability under tort can and does play a valuable role in compensating injured parties.[1413] Alternative compensation systems, however, should be considered to complement and supplement tort liability.[1414] When victims' compensation is analyzed from a broad perspective, the role and effects of alternative compensation systems such as private and public insurance should be taken into account given that when injured victims receive insurance compensation, tort compensation becomes incremental[1415] to the compensation already received or in certain cases even superfluous.[1416] From an economic perspective, the role and effects of tort liability in compensating injured victims are strongly influenced by the benefits victims might have previously received from alternative sources.[1417] When injured victims receive compensation from insurance, such compensation often addresses their most necessary and urgent needs. If, after receiving insurance compensation, the victim decides to pursue a product liability claim, the compensation awarded under tort does not provide the same utility as if the victim would

[1411] Kenneth S. Abraham, Private Insurance, Social Insurance, and Tort Reform: Toward A New Vision of Compensation for Illness And Injury, 93 Colum. L. Rev. 75, 108 (1993). See also Michael G. Faure, Ton Hartlief and Niels J. Philipsen, Funding of personal injury litigation and claims culture, Evidence from the Netherlands, Utrecht Law Review, Volume 2, issue 2, 20 (2006) considering the tort system victim unfriendly and arguing in favor of moving away from tort law towards an alternative insurance based compensation system.

[1412] Robert G. Berger, The impact of tort law development on insurance: the availability/affordability crisis and its potential solutions, 37 Am. U. L. Rev. 285, 307-308 (1988).

[1413] W. Kip Viscusi, Toward A Diminished Role For Tort Liability: Social Insurance, Government Regulation, And Contemporary Risks To Health And Safety, 6 Yale J. on Reg. 65, 103 (1989).

[1414] Kenneth S. Abraham, Private Insurance, Social Insurance, and Tort Reform: Toward A New Vision of Compensation for Illness And Injury, 93 Colum. L. Rev. 75, 108 (1993) arguing that tort law is an unsatisfactory system of compensation and hence alternative systems such as private and social insurance systems should be contemplated while leaving the corrective justice and deterring function to tort law.

[1415] Mitchell Polinsky and Steven Shavell, The uneasy case for product liability, 123 Harv. L. Rev. 1437, 1462-1469 (2010).

[1416] Beatrice A. Beltran, Posner and tort law as insurance, 7 Conn. Ins. L. J. 153, 158 (2000).

[1417] See Mitchell Polinsky and Steven Shavell, The uneasy case for product liability, 123 Harv. L. Rev. 1437, 1465 (2010).

only be compensated under tort.[1418] So the utility of tort liability is only incremental to the utility of the benefits previously provided by the collateral source.

So if these alternative compensation instruments are accessible to victims -- either because the tortfeasor purchased insurance coverage or because she is entitled to social insurance benefits, -- coordination between the different sources of compensation will be necessary in order to preserve the parties' incentives and reach a socially optimal outcome.

2 Private insurance as an instrument to compensate injured victims

Whenever tortfeasors are involved in risky activities and hence exposed to liability they can buy insurance coverage in exchange for an insurance premium.[1419] Insurance coverage allows individuals to smooth the amount of money available to them over the diverse states of the world -- before and after the accident takes place -- and hence in situations in which the victim has not suffered any loss or where there are losses.[1420]

Private insurance can play a role in reconciling the two goals of tort: minimizing accidents and compensating victims through spreading the costs of accidents.[1421]

[1418] If individuals are assumed to have a decreasing marginal utility of money, the marginal utility of the award received from the insurance coverage is higher than the marginal utility of the monetary damages awarded under tort. See Mitchell Polinsky and Steven Shavell, The uneasy case for product liability, 123 Harv. L. Rev. 1437, 1465 (2010).

[1419] See in general Tom Baker, Risk, Insurance and (the social construction of) Responsibility, University of Connecticut School of Law Working Paper Series 8 (2002). This article is available at http://lsr.nellco.org/uconn/ucwps/papers/8 considering that insurance is not only a loss spreading instrument but is also a form of social responsibility.

[1420] Steven Shavell, FOUNDATIONS OF ECONOMIC ANALYSIS OF LAW, Belknap Press of Harvard University Press, 257-280 (2004).

[1421] See Guido Calabresi, THE COSTS OF ACCIDENTS: A LEGAL AND ECONOMIC ANALYSIS, 46-54, Yale University Press (1970). See also Richard W. Wright, The principles of product liability, 26 Rev. Litig. 1067, 1096 (2007) noting that the risk spreading rationale conflict with efficient deterrence to the extent that a loss can be shifted or spread the incentives to avoid it decrease.

From a compensation perspective, liability insurance is highly desirable because it ensures that victims receive compensation regardless of the financial condition of the tortfeasor.[1422] At the same time, insurance ensures that the manufacturer is financially viable, even after the accident takes place and liability is established.[1423] In addition of the advantages that the tortfeasor's insurance coverage provides for the victims, it also has serious benefits for potential tortfeasors given that they are able to transfer the risk to an insurer who spreads the risk and cost of the loss.[1424]

But the existence and availability of private insurance also undermines corrective justice and deterrence rationales of tort law in a certain way. When a tortfeasor purchases insurance coverage the tortfeasor does not internalize the cost of the damages he caused[1425] and optimal deterrence is undermined whenever a tortfeasor externalizes the expected liability costs through purchasing private insurance coverage.[1426]

In order for private insurance coverage to be viable two requirements must be met: The risk faced by the insured must be predictable -- with a positive probability but

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[1422] But if the goal is corrective justice, liability insurance would be inadequate. See Gary T. Schwartz, The Ethics and the Economics of Tort Liability Insurance, 75 Cornell L. Rev. 313, 363 (1990). See also Tom Baker, Liability Insurance as Tort Regulation: Six Ways that Liability Insurance Shapes Tort Law in Action, Connecticut Insurance Law Journal, Vol. 12:1, 4 (2006) noting that insurance has a fundamental effect on the victim's collectibility. However, often potential tortfeasfors locate risk in entities with no assets and place their assets in entities with no risks and hence leave injured victims with not compensated. See Lynn Lopucki, The Death of Liability, 106 Yale L. J. 1 (1996). See also Al H. Ringleb and Steven N. Wiggins, Liability and Large-Scale, Long-Term Hazards, The Journal of Political Economy, Vol. 98, No. 3, 574-595 (1990) studying the trade offs presented by the costly decision of reorganizing vertically in order to allocate risk and avoid liability payments and maintaining the same firm's structure but being exposed to liability payments and concluding that large integrated firms working in hazardous sectors of the economy -- especially in latent hazard -- have an incentive to locate risky activities and minimize the exposure of assets to potential liability claims.

[1423] Beatrice A. Beltran, Posner and tort law as insurance, 7 Conn. Ins. L. J. 153, 175 (2000).

[1424] Calabresi offered three main justifications for risk distribution: spreading the risk of loss; placing the risk on the party who is in a better position to bear it and requiring tortfeasors to bear the burden of the loss. See Guido Calabresi, Some Thoughts on Risk Distribution and the Law of Torts, 70 Yale Law Journal 4, 499-553 (1961).

[1425] The corrective justice function of tort law is even more diluted when the insurance premiums do not reflect the amount of the harm caused by the tortfeasor. See Kenneth S. Abraham, Private Insurance, Social Insurance, and Tort Reform: Toward A New Vision of Compensation for Illness And Injury, 93 Colum. L. Rev. 75, 86 (1993).

[1426] Kenneth S. Abraham, Private Insurance, Social Insurance, and Tort Reform: Toward A New Vision Of Compensation For Illness And Injury, 93 Colum. L. Rev. 75, 86 (1993).

lower than one -- and the probability of each harmful event occuring must be independent.[1427] When both of these conditions are met, it is possible to spread risk among a large and homogeneous group of insured parties.

If the undesired outcome and hence the losses would occur with certainty, they would not be insurable[1428] and if the probability of the harmful event -- that is, the risk of harm -- was not predictable, such risk would be very difficult to insure.[1429]

The risk of each potential loss must independent so that insurers can create risk pools of independent risks.[1430] This is a crucial assumption given that when the probability of the different events causing losses is independent, insurance companies are able to compensate the victim who suffered the loss with the premiums paid by the others who purchased insurance. If the different events causing losses would occur at the same time, there could not be insurance offered given that compensation could not be paid to all the insured at the same time.

The degree to which insurance functions as a risk spreading mechanism depends on the capacity of differentiating among different categories of insured when setting premium rates. The lower the differentiation between risk premiums, the more the risk is spread and the more differentiation in risk premiums, the lower loss spreading there is.[1431]

[1427] Robert G. Berger, The impact of tort law development on insurance: the availability/affordability crisis and its potential solutions, 37 Am. U. L. Rev. 285, 288 (1988).

[1428] If losses were certain, the decision would be either saving the cost of insurance before losses occurred or being compensated once losses take place.

[1429] See Robert G. Berger, The impact of tort law development on insurance: the availability/affordability crisis and its potential solutions, 37 Am. U. L. Rev. 285, 288 (1988) noting that if risks are not predictable, insurers would have to increase significantly insurance premiums in order to cover unknown risks or not offer insurance.

[1430] Independent risks are risks the probability of which of occurring is independent from each other. See Steven Shavell, FOUNDATIONS OF ECONOMIC ANALYSIS OF LAW, Belknap Press of Harvard University Press, 257-280 (2004).

[1431] See Guido Calabresi, THE COSTS OF ACCIDENTS: A LEGAL AND ECONOMIC ANALYSIS, 47, Yale University Press (1970).

In order for insurance coverage to be offered, the risk premium must reflect the level of risk engaged in by the potential tortfeasor seeking to be insured.[1432] So it is necessary that the insurance premium is higher or equal to the expected value of the damages suffered by the insured plus administrative costs of running the insurance system.[1433]

So in order for private insurance systems to be able to work efficiently, two information parameters will be necessary: the insured's level of risk -- probability and amount of losses -- and the amount of administrative costs necessary to manage the insurance system. Additionally, information regarding the insured's level of care is of crucial importance given that insurance premiums should be linked to the expected level of accident losses and such losses might depend on the insured's level of care adopted.[1434]

The interests of tortfeasors in insuring risks of losses they may cause are directly related to their exposure to liability under tort.[1435] The literature on insurance has broadly discussed whether insurance coverage should be mandatory or voluntary for potential tortfeasors. Mandatory insurance for tort accidents is often considered to present

[1432] See in general Gary T. Schwartz, The Ethics and the Economics of Tort Liability Insurance, 75 Cornell L. Rev. 313 (1990) noting that insurance premiums somehow adjusted to the risk engaged by the insured would allow achieving simultaneously compensatory and corrective justice goals. See also Robert G. Berger, The impact of tort law development on insurance: the availability/affordability crisis and its potential solutions, 37 Am. U. L. Rev. 285, 288 (1988).

[1433] It should be noted that this way of calculating the insurance premium assumes a neutral attitude towards risk by the insured. If the insured was adverse to risk or risk lover, the premium would be differently calculated and would reflect the insured's attitude towards risk. See Hal R. Varian, INTERMEDIATE MICROECONOMICS: A MODERN APPROACH, 213-227, 6W W Norton & Co Inc (Np); 5th ed. (1999) and Robert S. Pindyck and Daniel L. Rubinfeld, MICROECONOMICS, 163, Prentice Hall, New Jersey, 5th ed. (2001). See also Jürg Spühler, Swiss Re Liability and liability insurance: yesterday – today – tomorrow, 19 (2001).

[1434] Steven Shavell, Minimum Asset Requirements And Compulsory Liability Insurance As Solutions To The Judgment-Proof Problem, Rand Journal of Economics, vol 36, num. 1, 63-77, 64 (2005) noting that when the insured's level of care is not observable, purchasing insurance coverage might dilute the incentives to take care because of moral hazard problems that would arise.

[1435] See Seth J. Chandler, The Interaction Of The Tort System And Liability Insurance Regulation: Understanding Moral Hazard, 2 Conn. Ins. L.J. 91, 153 (1996). See also Robert G. Berger, The impact of tort law development on insurance: the availability/affordability crisis and its potential solutions, 37 Am. U. L. Rev. 285, 288 (1988) noting that the legal transformation of tort law changed the expectations of manufacturers, consumers and insurers.

significant advantages given that it is cheaper to administer and manage than a system of liability under tort.[1436] Insurance policies allow injured victims to know who will bear the cost of the damages they suffered as well as avoid the need to go to court and hence avoid the litigation and the administrative costs involved in a court proceeding. It should be noted that in certain contexts, potential victims might also have incentives to buy insurance coverage and receive compensation in case the accident occurred.[1437] This is less true in Europe, however, given the strong social insurance systems, and so it will not be addressed in detail here.

2.1 The role and positive effects of private insurance coverage in compensating injured victims of tort accidents

Whenever the incentives to reduce risk created by the tort system are not optimal, purchasing insurance coverage for expected losses is socially desirable. Incentives to reduce risk are inadequate mostly in two situations: when the tortfeasor's assets might not be sufficient to compensate the injured victim for the damages caused -- the judgment proof problem -- and when the victim might not pursue her tort claim and hence the tortfeasor could avoid liability.[1438] In these cases, incentives to reduce risk are not efficient.

[1436] Göran Skogh, Mandatory insurance: Transaction Cost Analysis of Insurance, Encyclopedia of Law and Economics, 521-527 (2000). See also Steven Shavell, ECONOMIC ANALYSIS OF ACCIDENT LAW, Cambridge: Harvard University Press, 263 (1987) discussing the relative costs of the liability and the insurance system as compensation mechanisms.

[1437] See Richard A. Epstein, Products Liability as an Insurance Market, 14 J. Legal Stud. 645 (1985) arguing that the tort system -- specifically, product liability -- was not a good insurance system given that the tortfeasor's liability would be more efficiently insured by victims.

[1438] Steven Shavell, On the Social Function and the Regulation of Liability Insurance, Geneva papers on risk and insurance, 25(2), 166-179 (2000).

Whenever tortfeasors have limited assets compared to the damages they may cause, liability rules are not efficient for deterrence and or victim compensation[1439] and tortfeasors may not take cost-justified precautions because they may be aware that their liability exposure is limited to their assets.[1440]

In such cases, tortfeasors do not fully internalize the costs of their actions, instead internalize liability costs only up to their assets. This means they will have suboptimal incentives for care, will engage in too much harmful activity[1441] and the resulting outcome will then be inefficient.[1442]

At the same time, whenever injured victims do not pursue their claims under tort, tortfeasors may escape from liability and hence not have incentives to adopt efficient levels of care.[1443]

Insurance coverage is socially desirable in these cases because it compensates injured victims regardless of the tortfeasor's financial circumstances and regardless of the victims' incentives and abilities to pursue tort claims.[1444]

[1439] The use of insurance coverage as a mechanism to reduce the impact of the judgment proof problem has been widely discussed in the literature. See Mattias K. Polborn, Mandatory Insurance and the Judgment-Proof Problem, International Review of Law and Economics, 18: 141-146 (1998), Peter J. Jost, Limited Liability and the Requirement to Purchase Insurance, International Review of Law and Economics 16: 259-276 (1996) and Steven Shavell, The Judgment Proof Problem, 6 International Review of Law and Economics 47-50 (1986).

[1440] Steven Shavell, The Judgment Proof Problem, 6 International Review of Law and Economics, 45-58, 46 (1986) and Shavell, Steven, FOUNDATIONS OF ECONOMIC ANALYSIS OF LAW, 275-280, Belknap Press of Harvard University Press (2004).

[1441] Steven Shavell, Minimum Asset Requirements And Compulsory Liability Insurance As Solutions To The Judgment-Proof Problem, Rand Journal of Economics, 36 (1), 63-77, 64 (2005) suggesting that requiring a minimum level of assets to engage in a certain activity may prevent individuals with limited assets from engaging too often in it. However Shavell also noted that requiring a minimum level of assets would also have a disadvantageous effect given that it would exclude individuals with assets below the required level that would engage in the activity because the benefits involved in it would outweigh the costs they would cause to others but they would but they would not be able to engage in that activity because of the lack of minimum assets.

[1442] Steven Shavell, The Judgment Proof Problem, 6 International Review of Law and Economics 45-58, 46 (1986).

[1443] Steven Shavell, On the Social Function and the Regulation of Liability Insurance, Geneva papers on Risk and Insurance, 25(2), 166-179 (2000).

[1444] Steven Shavell, The Judgment Proof Problem, 6 International Review of Law and Economics 45-58 (1986).

2.2 Imperfect private insurance markets

Markets of risk are often imperfect for several reasons. First, insurance companies in some cases sell policies at premiums that are not actuarially fair, especially in cases where risk cannot be properly valued.[1445] Second, adverse selection results in high risk individuals being the ones buying insurance coverage. Third, moral hazard problems affect the risk involved in the actions of the insured, increasing the number of injuries. Fourth, the profits of insurance companies are included in their premiums, resulting in excessively high premiums. Fifth, victims' limited perceptions of risk often affect the functioning of private insurance markets. Sixth, tortfeasors have reduced incentives to take care when they are judgment proof. Finally, there is variation in the involved parties' abilities to insure.[1446]

As for the problem of actuarial fairness, in order for insurance premiums to be adequately determined, information must be known regarding the probability of accidents and their costs, as well as of associated administrative costs. But this information is often difficult to obtain and its absence or imperfection results in distorted premiums and the payment of suboptimal benefits.[1447]

The second and third issues, adverse selection and moral hazard, are of special importance when talking about private insurance coverage. Adverse selection refers to the tendency for low risk individuals to avoid voluntary insurance pools and hence leave insurance pools with a disproportionately high percentage of high-risk individuals.[1448]

[1445] W. Kip Viscusi, Toward a diminished role of tort liability: social insurance, government regulation, and contemporary risks to health and safety, 6 Yale J. on Reg. 65 (1989).

[1446] See Guido Calabresi, THE COSTS OF ACCIDENTS: A LEGAL AND ECONOMIC ANALYSIS, 59-60, Yale University Press (1970).

[1447] Evidence suggests that often, insurers tend to over-compensate small losses and under-compensate large losses. See W. Kip Viscusi, Toward a diminished role of tort liability: social insurance, government regulation, and contemporary risks to health and safety, 6 Yale J. on Reg. 65, 97 (1989).

[1448] See Michael Rothschild and Joseph Stiglitz, Equilibrium in Competitive Insurance Markets: An Essay on the Economics of Imperfect Information, Quarterly Journal of Econ. 90:629-49 (1976) noting that one of

Whenever insurance premiums cannot be individualized in order to reflect the individual's level of risk,[1449] it is often economically worth purchasing insurance coverage for high-risk individuals given that the level of risk they present is higher than the premium they have to pay.[1450] Consequently, low-risk individuals do not purchase insurance coverage at the price offered to them given that they find insurance premiums too expensive and insurance pools contain a disproportionate percentage of high-risk individuals.

A response often used to address the adverse selection problem has been risk classification and the possibility of binding risks to the insurance pool. Insurance risk classification aims at matching insurance policies with respect to the level of expected risk presented by the insured individual through charging different insurance premiums or defining different insurance contract provisions depending on the expected level of risk of the insured individual.[1451] Risk classification reduces the risk-spreading element inherent to insurance pools because it aims at having risk premiums reflect as much as possible the level of risk individuals are exposed to. If risk can be classified, low-risk individuals of the risk-pool do not financially contribute to finance the losses experienced by high-risk individuals.[1452]

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the most important problems facing insurance markets is the asymmetry between insurers and insured regarding the level of risk involved.

[1449] See Tom Baker, Containing the Promise of Insurance: Adverse Selection and Risk Classification, University of Connecticut School of Law Working Paper Series 3 (2001) arguing that insurers create and shape adverse selection. This article is available at http://lsr.nellco.org/uconn/ucwps/papers/3.

[1450] See in general Priest, George, The Current Insurance Crisis and Modern Tort Law, 96 Yale L. J. 1521 (1987) analyzing the impact of adverse selection effects on the insurance crisis experienced by the United States during the 1980s.

[1451] See Tom Baker, Containing the Promise of Insurance: Adverse Selection and Risk Classification, University of Connecticut School of Law Working Paper Series 3 (2001). This article is available at http://lsr.nellco.org/uconn/ucwps/papers/3 offering examples of risk classification such as sorting life insurance applicants by age, health insurance applicants by health status, workers compensation insurance applicants by type of industry, or by the nature of the construction of the property to be insured.

[1452] The possibility of risk classification has often been referred to as adverse selection on the insured' side given that this mechanism allows insurers to select risks in an adverse way to the insurance pool. At the extreme, if risk classification is perfect, the ability of the insurance pool to spread risk would be eliminated. Both adverse selection problems -- from the insured and from the insurers are collective action problems given that they inhibit the risk spreading nature of insurance contracts. See Tom Baker, Containing the

An additional and frequently used solution to the adverse selection problem is mandatory insurance policies provided by a single insurer such as for example the state. Even though mandatory insurance significantly reduces adverse selection problems, it increases moral hazard given that the risk of all potential tortfeasors is transferred to the insurer. Against the increase of the probability of the accident resulting from moral hazard problems, the literature has proposed two possible remedies: incomplete insurance coverage for victims so that they continue to bear part of the risk and hence have incentives to avoid accidents, and the possibility of insurers observing insured parties' behavior to determine their level of care.[1453]

The moral hazard problem may arise ex ante or ex post.[1454] Ex ante moral hazard refers to the change in victims' incentives to avoid accidents that can result from insurance protection.[1455] Whenever victims have purchased insurance coverage against a certain risk, the incentives to avoid the accident diminish and hence the likelihood of the accident increases. Ex post moral hazard refers to the increase in claims against the insurance policy beyond what the victims would claim if uninsured.[1456]

Despite these challenges that private insurance faces, private insurers take measures to align individual incentives with the goal of minimizing the probability and amount of insured losses and they have created mechanisms to respond to adverse

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Promise of Insurance: Adverse Selection and Risk Classification, University of Connecticut School of Law Working Paper Series 3 (2001). This article is available at http://lsr.nellco.org/uconn/ucwps/papers/3

[1453] See generally, Shavell, Steven, FOUNDATIONS OF ECONOMIC ANALYSIS OF LAW, 257-280, Belknap Press of Harvard University Press (2004) and Steven Shavell, On moral hazard and insurance, The Quarterly Journal of Economics 93(4), 541-562 (1979).

[1454] See Mark V. Pauly, The Economics of Moral Hazard: Comment, 58 Am. Econ. Rev. 531-537, 535 (1968).

[1455] The moral hazard problem has been widely discussed in the literature. See, for example, Wondon Lee, James A. Ligon, Moral Hazard in Risk Pooling Arrangements, The Journal of Risk and Insurance, 68 (1), 175-190 (2001); Tom Baker, On the Genealogy of Moral Hazard, Texas Law Review 75: 237-92 (1996), Carol Heimer, REACTIVE RISK AND RATIONAL ACTION: MANAGING MORAL HAZARD IN INSURANCE CONTRACTS (1985), (Berkeley: University of California Press) and Steven Shavell, On moral hazard and insurance, The Quarterly Journal of Economics 93(4), 541-562 (1979).

[1456] Mark V. Pauly, The Economics of Moral Hazard: Comment, 58 Am. Econ. Rev. 531-537, 535 (1968). See Kenneth S. Abraham, Private Insurance, Social Insurance, and Tort Reform: Toward A New Vision of Compensation for Illness and Injury, 93 Colum. L. Rev. 75, 88 (1993) noting that ex post moral hazard is also present under tort whenever compensation is not subject to deductibles or coinsurance.

selection and moral hazard problems. For example, in light of the fact that the probability of the loss occurring can be influenced by the insured parties' ex ante behavior and ex post claim decisions, private insurance policies include deductibles and coinsurance provisions in order to dilute the insured parties' potential incentives to increase the likelihood of the loss from occurring as well as their incentives to excessively seek compensation under the insurance policy.[1457] Deductibles limit the amount the insured may recover under the insurance policy and require the insured to bear a share of the amount of the loss. Coinsurance requires the insured to pay a share of the amount of each claim against the insurance.

It should be noted that even if adverse selection and moral hazard were not present in a certain insurance market, the insurance premiums charged to potential victims should be slightly higher than their exact level of risk given that they should include a certain profit for the insurance company to function.

Finally, the limitation of the victim's risk perception also influences the efficiency of insurance markets. Whenever victims do not adequately percieve the risks they are exposed to, their decisions to purchase insurance are distorted and hence inefficient.[1458]

3 Mixing tort law and insurance: Finding the adequate role for each instrument

Tort law and insurance are conceptually distinct, respond to different objectives and function in different ways. At the same time, however, their functions and performance overlap when it comes to acting as compensation mechanisms for injured

[1457] For an application of deductibles and coinsurance in the automobile insurance market and in hospital insurance policies see Catherine S. Elliott, Implications of Uncollectibles for Hospitalization Coinsurance Rates, The Journal of Risk and Insurance, Vol. 58 (4), 616-641 (1991) and Chu-Shiu Li, Chwen-Chi Liu, Jia-Hsing Yeh, The Incentive Effects of Increasing Per-Claim Deductible Contracts in Automobile Insurance, The Journal of Risk and Insurance, 74 (2), 441-459 (2007).

[1458] Jeffrey J. Rachlinski, A positive Psychological Theory of Judging in Hindsight, 95-115, in BEHAVIORAL LAW AND ECONOMICS, Cass R. Susntein (ed.), Cambridge University Press (2000).

victims of accidents. The scope of compensation under tort law and the conditions under which it is granted directly affects incentives to offer and purchase insurance; at the same time, the availability and coverage of private insurance directly affects the incentives injured victims may have to pursue their tort claims.[1459]

As mentioned earlier, facilitating victims' compensation and providing them with some form of insurance[1460] were arguments often presented in order to justify the adoption of strict liability in the product liability directive. Product manufacturers were considered effective and efficient insurers of potential injured victims given that they were considered to be able to pool the risks their products presented and spread the costs of these risks through product prices.[1461] As a result, under strict product liability injured victims were considered to be insured against product accidents.[1462]

[1459] See Heidi Li Feldman, Harm and Money: Against The Insurance Theory of Tort Compensation, 75 Tex. L. Rev. 1567, 1596 (1997) noting that the compensation role of tort law was one of the major arguments suggested in favor of the introduction of strict product liability.

[1460] See the preamble of the product liability directive and James A. Henderson, Why Negligence Dominates Tort, 50 UCLA L. Rev. 377, 392 (2002), noting that the main objectives of strict enterprise liability are loss shifting and spreading. See also Oliver Holmes, THE COMMON LAW, 94-98 (M. Howe ed. 1963) arguing that the only difference between negligence and strict liability was that strict liability provided a form of accident insurance and opposing this role of tort law on the basis that the State has no role in providing insurance. See also Heidi Li Feldman, Harm and Money: Against The Insurance Theory Of Tort Compensation, 75 Tex. L. Rev. 1567, 1575 (1997) noting that strict product liability – even tort liability in general – was seen as an insurance mechanism for early legal economists. For an opposite view see Landes & Posner The Positive Economic Theory of Tort Law, 15 Ga. L. Rev. 851, 852-53 (1981) arguing that tort law should provide insurance to those who fail to insure themselves for injuries caused by accidents and Steven Shavell, On the Social Function and the Regulation of Liability Insurance, Geneva papers on Risk and Insurance, 25(2), 166-179 (2000) arguing that it is much more expensive to insure victims via the legal system than directly through insurance coverage.

[1461] See W. Kip Viscusi, Product Liability and Regulation: Establishing the Appropriate Institutional Division of Labor, The American Economic Review, Vol. 78, No. 2, 300-304 (1988) noting that the emergence of strict liability was due in part to the belief that firms could act as insurers through spreading these risks and incorporating the cost of insurance in the product price, that would be spread among all consumers buying the product. See also Heidi Li Feldman, Harm and Money: Against The Insurance Theory Of Tort Compensation, 75 Tex. L. Rev. 1567, 1575, 1595 (1997) describing the evolution of the role of strict product liability and arguing that product manufacturers are in a better position to create a risk pool and transfer the costs of this risk. See also Richard A. Posner, ECONOMIC ANALYSIS OF LAW, 196, Aspen eds., 5th ed. (1998) discussing generally strict liability.

[1462] Strict product liability represents then an insurance system for injured victims even for unavoidable accidents and for accidents for which it would be inefficient to avoid them. See Richard W. Wright, The principles of product liability, 26 Rev. Litig. 1067, 1096 (2007) arguing that risk spreading through the tort system is a remarkably expensive solution and that risk spreading would be more efficient if done through a universal and publicly funded system such as a no-fault social insurance program.

When the product liability directive was introduced in 1985, the debate was focused on ensuring the efficient functioning of the common internal market, and the strict product liability then in force in the United States[1463] seemed the most adequate rule and the one that could be most easily implemented in the different member states to achieve a harmonized law.[1464]

As mentioned earlier, in order for insurance to function, it is necessary for the risks of insured parties to be ascertainable and quantifiable and for insurance costs to be capable of being transfered through product prices.[1465] Assuming these conditions are met, the use of tort law as an insurance mechanism would be desirable as long as the cost of insurance through the tort system is lower than the victim's cost of buying insurance coverage in the insurance market.[1466] Evidence shows, however, that providing insurance under tort is significantly more expensive than purchasing private insurance coverage.[1467]

Additionally, insuring victims through the tort system might affect the amount of private insurance offered in the market. An example of the effect of using tort liability as an insurance mechanism on the supply of insurance coverage may be found in the insurance crisis that took place in the United States during the 1980s. As George Priest noted at the time,[1468] insuring injured victims through expanding liability under tort had a

[1463] § 402A of the Restatement (Second) of Torts.
[1464] The discussion in Europe regarding the product liability rule that should be adopted was not focused on the evidentiary advantages of strict liability compared to the burden of proof required under negligence liability. See Mark A. Geistfeld, PRINCIPLES OF PRODUCTS LIABILITY, 23-26, Foundation Press, New York (2006) comparing the evidentiary requirements of both liability rules.
[1465] James A. Henderson, Why Negligence Dominates Tort, 50 UCLA L. Rev. 377, 392 (2002). See also W. Kip Viscusi, Toward a diminished role of tort liability: social insurance, government regulation, and contemporary risks to health and safety, 6 Yale J. on Reg. 65, 97-98 (1989) noting that when a product involves some risk and the chance of a damage award, the product price incorporates the expected award or the firm's liability insurance premium. In this sense, Viscusi concludes, through the product price consumers purchase a product-specific insurance within the limits established by the tort system. These product specific insurance are less efficient than broader policies of multiple risks.
[1466] See Richard A. Posner, ECONOMIC ANALYSIS OF LAW, 196, Aspen eds., 5th ed. (1998).
[1467] Steven Shavell, On the Social Function and the Regulation of Liability Insurance, Geneva papers on Risk and Insurance, 25(2), 166-179 (2000) noting that it is much more expensive to insure victims via the legal system than directly through insurance coverage.
[1468] See George L. Priest, The current insurance crisis and modern tort law, 96 Yale L. J. 1521 (1987) discussing the role of liability under tort on the market of private insurance coverage.

profound effect on the decision of supplying and demanding liability insurance coverage.[1469]

During the 1980s, the liability exposure of potential tortfeasors increased[1470] based on an increase in tort awards.[1471] Because of the high expected liability costs manufacturers were exposed to, the demand of insurance coverage increased[1472] but at the same time, the risk of having to pay such claims increased as well.[1473] As a result, the joint effect of an increase in liability exposure and the uncertainty involved in the outcome of product liability claims resulted in an increase in insurance premiums.[1474]

These phenomena had two major effects: first, even though the goal of the increase of tort exposure was increasing the insurance coverage of potential injured victims, there was actually a reduction of the insurance coverage available to society as a whole.[1475] Consequently, despite using tort law as an insurance mechanism, the expansion of its scope resulted in undermining the function and role of private coverage

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[1469] George L. Priest, The current insurance crisis and modern tort law, 96 Yale L. J. 1521, 1526 (1987).
[1470] George L. Priest, The current insurance crisis and modern tort law, 96 Yale L. J. 1521, 1525 (1987).
[1471] Ralph A. Winter, The Liability Insurance Market, The Journal of Economic Perspectives, vol. 5, no 3, 115-136, 134 (1991).
[1472] See George L. Priest, The current insurance crisis and modern tort law, 96 Yale L. J. 1521, 1522-1524 (1987) explaining the crisis of the insurance industry in the U.S. during the mid 1980s and noting that the U.S. Justice Department attributed such crisis to the expansion of corporate liability exposure.
[1473] Ralph A. Winter, The Liability Insurance Market, The Journal of Economic Perspectives, vol. 5, no 3, 115-136, 134 (1991).
[1474] This was especially important when comparing the liability insurance premiums paid by U.S. manufacturers during the 80s when compared with European manufacturers, who bore significantly lower insurance costs. See Robert G. Berger, The impact of tort law development on insurance: the availability/affordability crisis and its potential solutions, 37 Am. U. L. Rev. 285, 313 (1988) arguing that the different insurance costs for U.S. and European manufacturers directly affected their competitive advantage. However, see Douglas A. Kysar, Thomas O. Mcgarity, and Karen Sokol, Medical Malpractice Myths And Realities: Why An Insurance Crisis Is Not A Lawsuit Crisis, 39 Loy. Law Rev. 2, 785-818, 794 - 796(2006) noting that in some cases, an insurance crisis is not due to a liability crisis as for example, in the context of malpractice insurance, and hence liability under tort should not be reconsidered in order to solve a potential insurance crisis. Instead, Kysar et al. argue that the insurance crisis such as the malpractice insurance crisis were mostly due to the management and investment decisions of the insurance industry and not to their exposure to malpractice liability.
[1475] See Robert G. Berger, The impact of tort law development on insurance: the availability/affordability crisis and its potential solutions, 37 Am. U. L. Rev. 285, 288-289 (1988) noting that the increase of the scope of liability exposure, together with the shift from fault-based negligence to strict liability and with high punitive damages awarded, was one of the major factors that contributed to the a crisis of availability and affordability of insurance.

and hence resulted in a reduction of private insurance being offered and available in the market.[1476] Second, based on the fear of high losses, product manufacturers could have been deterred from introducing potentially useful products in the market.[1477]

The potential of tort liability to act as an effective insurance mechanism is remarkably limited[1478] given that neither product manufacturers nor insurers have the ability to pool the risks and spread them indefinitely.[1479] Moreover, as Priest noted, using tort liability as an insurance mechanism can have the unintended effect of reducing the amount of insurance coverage available to society.[1480]

Conversely, the scope and availability of insurance coverage also has effects on tort law at different levels. Tom Baker points out six major areas where insurance coverage influences liability under tort. First, private insurance coverage allows for the compensation of individuals regardless of their financial abilities to pursue tort claims; second, liability insurance represents a de facto cap on tort damages; third, liability under tort is limited as a consequence of insurance exclusions; fourth, lawsuits against individuals and organizations often become a cost for defendants instead of becoming a legal claim focused on the tortfeasor's fault; fifth, liability insurance affects tort rules in

[1476] George L. Priest, The current insurance crisis and modern tort law, 96 Yale L. J. 1521, 1550 - 1551 (1987).
[1477] Victor E. Schwartz & Thomas C. Means, The Need for Federal Product Liability-- and Toxic Tort Legislation: A Current Assessment, 28 Vill L. Rev. 1088, 1110 (1982-83) noting that exposure of high liability costs might result in not marketing potentially useful products.
[1478] Jeffrey O'Connell, A Correct Diagnosis Of The Ills Of Liability Insurance -- And A False Cure: A Comment On The Reports Of The Federal Tort Policy Working Group, 63 Notre Dame L. Rev. 161, 178 (1988).
[1479] Robert G. Berger, The impact of tort law development on insurance: the availability/affordability crisis and its potential solutions, 37 Am. U. L. Rev. 285, 288 (1988)
[1480] See generally George L. Priest, The Modern Expansion of Tort Liability: Its Sources, Its Effects, and Its Reform, 5 J. Econ. Persp. 31 (1991) noting the reduction of the availability of insurance did not have a uniform effect across injured victims and had an asymmetric effect that the mostly affected were the low-income and the poor, who precisely were the ones who were intended to protect. See generally George L. Priest, The current insurance crisis and modern tort law, 96 Yale L. J. 1521 (1987) noting that some of the effects derived from the insurance crisis might have become permanent.

that fault becomes less relevant; and sixth, negotiations over insurance coverage are directly related to the scope and content of the tort claim.[1481]

Despite the interaction, effects and the overlap of tort liability and private insurance as compensation mechanisms, there are also important differences in the nature and functioning of each of them.[1482]

First, under tort law, both pecuniary and non-pecuniary losses, such as pain and suffering, are compensable. In contrast, non-pecuniary losses are not compensated under private insurance policies because individuals would not privately insure against this kind of loss.[1483] Second, under tort law there are no such things as deductibles or coinsurance provisions and hence tort law does not include ex ante provisions to dilute victims' moral hazard incentives. There may be comparative and contributory negligence considerations but these do not specifically address moral hazard given that they are based on the victim's negligent behavior and not on the victim's incentives to increase the probability of the accident to occur. Third, the scope of victims' compensation under tort has also evolved based on insurance considerations. Tort compensation has evolved from its initial goal of placing the victim in the same position as if the accident had not taken place, to a situation in which the victim's demand for insurance coverage should be a key parameter when determining the scope of the damages to be compensated under tort.[1484]

[1481] See Tom Baker, Liability Insurance as Tort Regulation: Six Ways that Liability Insurance Shapes Tort Law in Action, Connecticut Insurance L. J., Vol. 12:1, 3-4 (2006).

[1482] See W. Kip Viscusi, Tort Reform and insurance markets, John M. Olin Center for Law, Economics and Business, Discussion Paper No. 440. 10/2003 (2003) noting that there is a role for both instruments in that there is a tradeoff between optimal insurance and optimal deterrence in that optimal insurance provides for little deterrence while optimal deterrence provides for excessive levels of insurance.

[1483] It should be noted that when victims suffer pain and suffering, ex ante they would not insure given that their utility function would be modified as a consequence of these non-pecuniary losses and hence the value of money ex post would be lower than its value ex ante. Consequently, if victims would act rationally, they would not buy insurance for non-pecuniary losses. See Steven Shavell, FOUNDATIONS OF ECONOMIC ANALYSIS OF LAW, Belknap Press of Harvard University Press, 257-280 (2004).

[1484] See W. Kip Viscusi, Toward a diminished role of tort liability: social insurance, government regulation, and contemporary risks to health and safety, 6 Yale J. on Reg. 65 (1989) arguing that in order to provide appropriate levels of compensation, the amount of insurance an individual would purchase at fair prices should determine the compensation the injured victim should be entitles to. Following the same argument see Heidi Li Feldman, Harm and Money: Against the Insurance Theory of Tort Compensation, 75 Tex. L. Rev. 1567, 1595 (1997).

Consequently, in light of the different nature, goals and performance of insurance and tort liability as compensation systems and as incentive creation mechanisms, each regime should be focused on the role it performs best: insurance as compensation and tort liability as deterrence. [1485]

4 Product liability insurance coverage in Europe: the importance of the phenomenon

One of the major fears generated by the adoption of the product liability directive was its impact on insurance rates and, consequently, on the prices of European products to which increased insurance costs would be transferred. In particular, it was feared that European products would suffer a competitive disadvantage compared to other products produced in countries without strict product liability regimes. The business community feared that the Directive's strict liability regime and its resulting increase on the liability exposure of product manufacturers, would significantly increase insurance premiums and reduce insurance availability, leading to the type of insurance crisis experience in the United States during the 1980s.[1486] The European Commission[1487] also considered these risks but concluded that the insurance industry would be able to provide the necessary coverage without a significant increase on product prices.

[1485] See A. Mitchell Polinsky & Yeon-Koo Che, Decoupling Liability: Optimal Incentives for Care and Litigation, Rand Journal 22 (4), 562-570 (1993) arguing in favor of limiting tort liability to deterrence and relying on insurance for compensation.
[1486] R. Patrick Thomas, Risk Management in the New Europe: Insurance and Financial Management Issues, 139, 148, in THE EUROPEAN ECONOMIC COMMUNITY: PRODUCTS LIABILITY RULES AND ENVIRONMENTAL POLICY (Patrick Thieffry & G. Marc Whitehead eds. 1990).
[1487] Report on the proposal from the Commission of the European Communities to the Council for a directive relating to the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products, 1979-1980. EUR PARL. Doc. (DOC 71/79) 4 (1979).

In fact, the business community's fears appear to have been misplaced.[1488] Insurance premiums may have slightly increased in some member states but at a significantly lower rate than expected.[1489] Explanations for this result can be found in the particularities of the European system discussed in previous chapters. European legal rules and procedures, for instance, operate in a way that keeps litigation costs and damage awards significantly lower than in the United States, and this keeps insurance costs within a reasonable range.[1490] Other explanations include the design of product liability insurance policies in Europe,[1491] the scope of the insurance coverage provided, the important role of settlements in product cases that result in few cases reaching the courts,[1492] and the low incentives of tortfeasors to purchase private insurance coverage.

The regulation of insurance contracts in Europe is not harmonized. Member states tend to place domestic insurance regulation in special insurance laws or in their civil codes. In the United Kingdom, the regulation of insurance contracts finds its basis in the common law. In states with statutory regulation of insurance contracts, provisions are in some cases mandatory and in others semi-mandatory.[1493] Whenever a contract provision

[1488] See Dana Kerr, Ma, Yu-Len and Schmit, Joan T., Is liability a substitute for social insurance?, Proceedings of the International Insurance Society, New York (2004) analyzing the relationship between private insurance premiums and the existence, scope and role of the social insurance and suggesting that there was a negative relationship between liability insurance premiums and the scope of social insurance programs. For an opposite conclusion see G. Wagner, TORT LIABILITY AND INSURANCE: COMPARATIVE REPORT AND FINAL CONCLUSIONS, in Gerhard Wagner (ed) Tort Law and Liability Insurance, Wien: Springer (2005).

[1489] Alberto Cavaliere, Product Liability in the European Union: Compensation and Deterrence Issues, European Journal of Law and Economics, 18: 299–318, 304 (2004) noting that Austria is an example of member state where the product liability directive has had no effect because Austrian manufacturers, based on internal Austrian regulation, already had private liability insurance before the product liability directive entered into force.

[1490] Sandra N. Hurd and Frances E. Zollers, Product Liability in the European Community: Implications for United States Business, 31 American Business Law Journal 245, 261 (1993).

[1491] Some have argued that in light of the poor design of product liability insurance policies, they are a defective product themselves. See Daniel Schwarcz, A Products Liability Theory for the Judicial Regulation of Insurance Policies, 48 William and Mary Law Review 1389 (2007). This article is available at http://ssrn.com/abstract=923423

[1492] Susan Narita, Product Liability Claims in Europe, Swiss Reinsurance Company, Zurich, 37 (1996).

[1493] Susan Narita, Product Liability Claims in Europe, Swiss Reinsurance Company, Zurich, 31 (1996) noting that departure from mandatory provisions might be possible as long as the provisions included in the insurance contract are to the advantage of the insured.

is ambiguous, it is generally interpreted according to the general principles of law in the country where the contract is entered into and if the ambiguity remains, the contract is interpreted in favor of the insured or claimant.[1494]

Typical European insurance policies do not only cover the potential liability a product manufacturer might be exposed to for the harm caused by a defective product but extend to include product safety obligations as well. As explained in Chapters 5 and 6, European product manufacturers are subject to ex ante safety regulations that also include post-marketing obligations.[1495] Insurance policies for European manufacturers aim at creating incentives for loss prevention -- through safety measures before a product causes harm -- and through loss reduction once a product has been marketed and whenever possible, before it caused harm.[1496]

Product liability insurance policies in Europe, as in the United States, are usually integrated in the general insurance conditions of a comprehensive general liability policy.[1497] This formal uniformity is due not to any specific harmonized regulation but to the market standards established by professional associations.[1498]

Insuring damage caused by defective products is not easy given that the time frame between when a product is manufactured and when it is put into circulation in the market and causes harm may be very long. Moreover, the product liability directive includes a three-year period in which a victim may file a product claim after suffering

[1494] Susan Narita, Product Liability Claims in Europe, Swiss Reinsurance Company, Zurich, 32 (1996) noting that the regulation and interpretation of insurance contracts is a consumer friendly regulation.
[1495] Jürg Spühler, Swiss re Product recall and product tampering insurance, Swiss Reinsurance Company, 6 (1998) noting that this is a way to keep companies linked with the products they sell from the manufacturing process to the liability phase.
[1496] Jürg Spühler, Swiss re Product recall and product tampering insurance, Swiss Reinsurance Company, 10 (1998) noting that costs in prevention are often lower than costs for compensation of losses caused.
[1497] Susan Narita, Product Liability Claims in Europe, Swiss Reinsurance Company, Zurich, 28 (1996) noting that product liability provisions are either included in the special provisions or defined in special articles. An exception of this general design is Germany, the U.K. and Italy that use separate standard product liability policies independent from the comprehensive general liability provisions.
[1498] This does not mean the insurance policies are uniform across the different member states given that they might provide coverage for different geographical area. See Susan Narita, Product Liability Claims in Europe, Swiss Reinsurance Company, Zurich, 28 (1996) explaining the different geographical coverage included in Spanish and Portugal insurance policies.

harm[1499] as well as a ten-year repose period[1500] from when a product is put into circulation after which any liability claim is extinguished.

General coverage includes personal property, consequential damages and any interest applicable to the amount insured.[1501] Insurance coverage also includes the primary costs incurred for product recall or, when necessary, product withdrawal.[1502] These costs include the costs of notifying the affected consumers, transporting the recalled or withdrawn products back to the producer, importer or distributor, any cost for storing the recalled products and any expenses for repairing, replacing the defective products or even for reimbursing consumers for the defective products.[1503] Additionally, European product liability insurance policies include a serial claims clause so that all damages that can be traced to the same cause or the same product defect are regarded as a single loss and hence entitled to a single claim.[1504] In these cases, the insurer of a serial claim compensates these serials claims as if there was only one claim for damage losses.

But there are also important exclusions. Pure financial losses are not covered in the general provisions but in certain cases they might be included through supplementary coverage purchased.[1505] Similarly, recall costs, beyond the costs of notifying consumers and transporting recalled or withdrawn products,[1506] and guarantee and warranty claims are generally excluded.[1507]

[1499] Article 10 (1) of the product liability directive.
[1500] Article 11 of the product liability directive.
[1501] Susan Narita, Product Liability Claims in Europe, Swiss Reinsurance Company, Zurich, 28 (1996).
[1502] Jürg Spühler, Swiss re Product recall and product tampering insurance, Swiss Reinsurance Company, 25 (1998).
[1503] Jürg Spühler, Swiss re Product recall and product tampering insurance, Swiss Reinsurance Company, 25 (1998) noting that insurance coverage has evolved towards including what often might be considered as uninsurable entrepreneurial risk.
[1504] Susan Narita, Product Liability Claims in Europe, Swiss Reinsurance Company, Zurich, 30 (1996) noting that product liability insurance policies provide coverage for serial claims.
[1505] Susan Narita, Product Liability Claims in Europe, Swiss Reinsurance Company, Zurich, 28 (1996).
[1506] As mentioned earlier, insurance coverage for product recall and withdrawal is very limited. See Jürg Spühler, Swiss re Product recall and product tampering insurance, Swiss Reinsurance Company, 25 (1998).
[1507] Susan Narita, Product Liability Claims in Europe, Swiss Reinsurance Company, Zurich, 29-30 (1996) noting that Spain covers recall costs in the context of loss prevention.

Regarding the geographical coverage of private insurance policies, standard policies in Europe are not exclusively limited to the territory of the party subscribing the insurance coverage. Coverage might be offered in countries different to the one where the manufacturer has its headquarters at an additional premium.[1508]

Regarding legal provisions included in insurance policies, two major issues might be highlighted. First is the issue of clauses regarding choice of jurisdiction and applicable law. The introduction of clauses regarding jurisdiction and applicable law are used mostly in France and Switzerland.[1509] Insurance policies in Italy, Poland and Spain include a clause on jurisdiction but none on applicable law.[1510] Second is the issue of provisions regarding who will bear the potential litigation costs involved in product claims. When admitted under the domestic insurance contract law of a certain state, coverage for defense costs is generally specified in the general insurance conditions of the insurance policy.[1511]

Even though it is possible to draw certain general characteristics shared by insurance contract law across the different European member states, it should be noted that insurance contract law, including the regulation of product liability insurance coverage, is subject to the domestic legislation of each member state. Consequently, while liability exposure is harmonized to a certain degree across the different European member states, many other aspects of product liability such as the economic consequences derived from the violation of post-sale duties, the calculation of damage awards and the admissibility and determination of damages for pain and suffering, are left

[1508] Susan Narita, Product Liability Claims in Europe, Swiss Reinsurance Company, Zurich, 30 (1996) noting that this is an important difference with private insurance coverage in the United States, where obtaining coverage in foreign markets is often difficult.
[1509] Susan Narita, Product Liability Claims in Europe, Swiss Reinsurance Company, Zurich, 31 (1996).
[1510] Susan Narita, Product Liability Claims in Europe, Swiss Reinsurance Company, Zurich, 31 (1996).
[1511] Susan Narita, Product Liability Claims in Europe, Swiss Reinsurance Company, Zurich, 33 (1996) noting that German insurance contract law is the only law of an EU member state that explicitly allows for the introduction of a provision regarding defense costs. In Germany, the insurer is liable for defense costs as long as such defense costs together with the losses insured do not exceed the total amount insured. In contrast, defense costs are limited under a liability insurance policy in Spain.

to domestic regulation. Hence, it is difficult to draw general characteristics of insurance coverage of the different European member states in light of the different coverage provided to the potential tortfeasors as a consequence of the different expected damages and liability tortfeasors might demand coverage for.[1512]

Since the adoption of the product liability directive in 1985, product liability cases have rarely reached courts and are instead mostly settled out of court by insurance companies.[1513] Product claims brought by insured victims have been rare but insurance coverage litigation is even rarer.[1514] Hence, the increase in the product liability insurance premiums that was feared when the product liability directive was introduced has not taken place. In fact, despite of manufacturers being exposed to strict product liability and product safety regulations, Spanish firms have tended to reduce the level of insurance coverage they purchased.[1515] Although it is not possible to conclude that this is the general tendency in all European member states, of all industry sectors and for all firm sizes, the Spanish case is instructive.[1516]

It seems fair to conclude that the adoption and implementation of the European product liability directive in the different member states and the subsequent adoption of ex ante product safety regulation has not resulted in an increase in product liability insurance premiums or in an increase of product liability insurance coverage purchased by the firms exposed to liability. The feared insurance crisis and significant price

[1512] Susan Narita, Product Liability Claims in Europe, Swiss Reinsurance Company, Zurich, 36 (1996).
[1513] Susan Narita, Product Liability Claims in Europe, Swiss Reinsurance Company, Zurich, 37-38 (1996).
[1514] Susan Narita, Product Liability Claims in Europe, Swiss Reinsurance Company, Zurich, 38 (1996).
[1515] Luis Ramírez, RC alerta roja: sanidad y productos son los dos sectores más sensibles: el nivel de cobertura se ha reducido notablemente, Mercado previsor, núm. 400, 32-33 (2004).
[1516] It should be noted that Southern European firms tend to purchase a lower level of insurance coverage than compared with northern European firms. The amount of insurance coverage purchased also depends on the industry sector the firm is in. In this sense, pharmaceutical and chemical firms buy the highest insurance policies. Finally, the insurance coverage purchased also depends on the size of the firm. Bigger firms tend to buy more insurance coverage than smaller firms. See Luis Ramírez, RC alerta roja : sanidad y productos son los dos sectores más sensibles: el nivel de cobertura se ha reducido notablemente, Mercado previsor, núm. 400, 32-33 (2004).

increases have not taken place and the effect of the product liability directive on the private insurance coverage purchased has been remarkably limited.

4.1 Product liability insurance coverage in Spain

The product liability directive does not require product manufacturers to purchase mandatory insurance for the harm caused by defective products, nor does it require the creation and administration of a compensation fund. The Spanish law of insurance contracts[1517] allows the government to introduce mandatory insurance coverage for liability for harm caused by defective products.[1518] Further, the transposition of the product liability directive into Spanish law -- with law 22/1994[1519] and the current law 1/2007[1520] -- requires mandatory insurance coverage depending on the kind of damage the defective product can cause. For damages resulting in death, intoxication and personal harm, a warranty fund for compensating victims is required,[1521] and for any other kind of

[1517] Law 50/1980, of October 8, of Insurance Contracts (BOE-A-1980-22501, available at http://www.boe.es/aeboe/consultas/bases_datos/doc.php?id=BOE-A-1980-22501)

[1518] Article 75 of Law 50/1980, of October 8, of Insurance Contracts provides that

> *Artículo 75.*
> *Será obligatorio el seguro de responsabilidad civil para el ejercicio de aquéllas actividades que por el Gobierno se determinen. La Administración no autorizará el ejercicio de tales actividades sin que previamente se acredite por el interesado la existencia del seguro. La falta de seguro, en los casos en que sea obligatorio, será sancionada administrativamente.*
>
> *Article 75.*
> *Liability insurnace will be mandatory for exercising the activites established by the Government. Public authorities will not authorize the exercise of such activities without first showing insurance coverage has been purchased. Proving the existence of insurance. Lacking insurance coverage in cases where it is compulsory will be sanctioned through an administrative fine.*

[1519] Law No. 22/1994 of July 6, 1994 de Responsabilidad Civil por los Daños Causados por Productos Defectuosos transposed the product liability directive into Spanish law.

[1520] Royal Law Decree 1/2007 of November 16, 2007 approving the merged text of the General Law for the Defense of Consumers and users and other complementary laws (BOE núm. 287, de 30-11-2007, pp. 49181-49215) overruled law 22/1994. RDL 1/2007, in its article 131, maintains the different insurance requirements depending on whether damages are caused for defective products or services, where mandatory insurance could be required, or where damages resulted in death, intoxication or personal harm in which cases they would still be compensated through funds from mandatory insurance.

[1521] See article 131 of the RDL 1/2007.

damages caused by defective products, the injured victim will have seek a remedy under tort based on the product liability directive and its transposition laws.[1522]

5 Public insurance in Europe: a safety net

5.1 The origin and evolution of welfare systems in European countries

One of the defining characteristics of European countries is the shared understanding of the role of the state in ensuring and providing a certain level of welfare to its citizens.[1523] The welfare systems in place across the different European states include a variety of programs aimed at integrating economically disfavored social groups into the social structure and offering citizens similar possibilities regardless of their levels of income. European states try to reduce social inequalities by balancing market-oriented efficiency with solidarity-based state intervention.[1524]

Initial attempts to provide social security in Europe were focused on those who were economically poor, and particularly industrial sector workers.[1525] After the Second World War there was an increase in the scope of state intervention and social schemes, which expanded to include additional social groups and more types of subsidies such as unemployment.[1526]

[1522] See article 135 and following of the RDL 1/2007.
[1523] Niels Ploug and Jon Kvist, Kluwer Sovac, SOCIAL SECURITY IN EUROPE: DEVELOPMENT OR DISMANTELMENT?, 1 (Series on Social Security, (1996)) noting that the welfare state has often been defined as a "national compromise."
[1524] Thomas Wilhemlsson, SOCIAL CONTRACT LAW AND EUROPEAN INTEGRATION, Darmouth, 33-34 (1995).
[1525] Niels Ploug and Jon Kvist, Kluwer Sovac, SOCIAL SECURITY IN EUROPE: DEVELOPMENT OR DISMANTELMENT? , Series on Social Security, 3 (1996).
[1526] Social security included income maintenance in cases of unemployment, sickness and the elderly. Niels Ploug and Jon Kvist, Kluwer Sovac, SOCIAL SECURITY IN EUROPE: DEVELOPMENT OR DISMANTELMENT?, Series on Social Security, 16 (1996).

Through their introduction and development, social welfare programs became one of the major pillars of the growth of the modern European welfare states[1527] based on the idea of the need for solidarity between citizens and social groups and social cohesion. Welfare programs not only provided income in cases of unemployment but incorporated additional public services such as education, health, and pensions.[1528]

The introduction, existence, and development of welfare programs in the different European countries have not always had support. In the early 1980s many European social programs were questioned and from the 1990s until today many concerns about the sustainability and future of the systems have been raised.[1529] Up to today, many European countries have seriously questioned the role of social programs based on the costs they entail and the different social composition and evolution of the societies of the different countries.[1530]

European countries have gone through a variety of social changes that can be classified into three major categories: First are changes in the labor market. During the last twenty years, European labor markets have become less stable, with higher rates unemployment and with increasing part-time and temporary jobs. Second, family structures have also gone through significant changes that often have not been reflected in social programs. The traditional family structure, under which the man had a paid job for which the woman and the children were beneficiaries, no longer reflects the diversity of today's European family structures. The rise in the participation of women in the labor market and in the number of single-parent families has upended the traditional structure

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[1527] Welfare state is a vague concept that for the purpose of this research will be used as the frame of social policies where social security is integrated in. Professor LAWRENCE FRIEDMAN, LEGAL CULTURE AND THE WELFARE STATE, 13 (Gunther Teubner ed., Dilemmas of Law in the Welfare State, Walter de Gruyter, Berlin New York, (1986).

[1528] Jochen Clasen & Wim Van Oorschot, CHANGING PRINCIPLES IN EUROPEAN SOCIAL SECURITY, EUROPEAN JOURNAL OF SOCIAL SECURITY, volume 4/2, 97 (2002).

[1529] Jochen Clasen and Wim Van Oorschot, CHANGING PRINCIPLES IN EUROPEAN SOCIAL SECURITY, EUROPEAN JOURNAL OF SOCIAL SECURITY, volume 4/2, 90 (2002).

[1530] Ulrich Magnus, THE IMPACT OF SOCIAL SECURITY LAW ON TORT LAW, vol. 3 (Tort and Insurance Law), Springer ed. (2003).

of benefits and beneficiaries.[1531] Finally, Europe has experienced a significant demographic change, with an increase in life expectancy and decrease in fertility that has put pressure on pay-as-you-go pension systems by creating an imbalance between contributors and beneficiaries.[1532]

These changes have been taking place over the course of the past decades framed in a context of increasing challenges to the role of the state and to government spending from both economic and political perspectives.

Currently, European welfare systems are not moving in the direction of covering new risks or expanding benefits. Instead, the major concern of policy makers is costs, level of expenditure of social insurance programs and their viability and sustainability in the future.[1533] There is a general impression that the expenditure on social insurance programs needs to be reconsidered and somehow reduced. However, there is also strong public support for such programs and Europeans view these programs as inherent rights as citizens.[1534] Therefore, talk of reductions or termination is very unpopular.[1535]

The goals, nature and challenges of welfare systems are mostly shared -- albeit with slight differences -- in the different European countries.[1536] However, the design and roles of welfare programs, the programs included in the welfare systems, the scope of beneficiaries, and the benefits provided vary across Europe.

[1531] European Commission (1994), Employment in Europe, Luxembourg: Office for Official Publications of the European Communities and Webb, S. Social Security Policy in a changing Labor market, Oxford Review of Economic Policy, vol. 11, num. 3, 11-24 (1995).
[1532] See van Ginneken W., Finding the balance: Financing and coverage of social protection in Europe, in OCCASIONAL PAPERS ON SOCIAL SECURITY, van Ginneken W. ed., International Social Security Association, Geneva (1996).
[1533] See generally Gösta Esping-Andersen, WELFARE STATES IN TRANSITION, London: Sage (1996).
[1534] Jochen Clasen, WHAT FUTURE FOR SOCIAL SECURITY? DEBATES AND REFORMS IN NATIONAL AND CROSS-NATIONAL PERSPECTIVE, Policy Press, 34 (2002).
[1535] Jochen Clasen, WHAT FUTURE FOR SOCIAL SECURITY? DEBATES AND REFORMS IN NATIONAL AND CROSS-NATIONAL PERSPECTIVE, Policy Press, 34 (2002).
[1536] See generally Ulrich Magnus, THE IMPACT OF SOCIAL SECURITY LAW ON TORT LAW, vol. 3 (Tort and Insurance Law), Springer ed. (2003).

5.2 European Social Insurance Systems: a unique concept with different implementations, structures and functioning

European countries do not present a uniform concept and implementation of social insurance. Their differences, instead, reflect different understandings of what welfare state programs should encompass.[1537] For example, the U.K. provides a comprehensive system of income protection and flat-rate benefits to the poor through a program designed by statute and managed by the government. Germany and France base their systems on the direct relationship between benefits and contributions.[1538] At the same time, in Sweden and Denmark,[1539] earnings-related social insurance programs, such as basic pensions, are universal. Other differences between member states regarding social insurance programs include, among other things, the scope of coverage, the levels of contributions, qualification criteria and the existence and amount of benefit ceilings.[1540]

While all European countries are advanced welfare states, they are structured differently and require different funding and economic resources.[1541] European authorities have been considering whether social insurance programs and more broadly, welfare programs generally, should be harmonized. The Lisbon Labor and Social Affairs

[1537] See Table 7.2 in this chapter for an overview of the content of the social welfare programs of the different European Union countries. See also generally Thierry Warin and Peter Hannessy, One welfare state for Europe: a Costly utopia?, Middlebury college economics discussion paper no. 03-25 (2003) for a description of the different content and social programs of the welfare state in the different European countries.

[1538] Both Germany and France have adopted a selective welfare system under which benefits are limited to workers and assistance is given to individuals without other resources. Thus, participation to the labor market is the central precondition for coverage by social security even though often benefits are extended to the whole family. See Council of Europe, Social Affairs, Rationalization and simplification of social security systems, Strasbourg, p. 45 (1987).

[1539] Nordic states have adopted comprehensive welfare systems under which population, both national or resident has the right to benefits and to social security regardless of their occupation. Council of Europe, Social Affairs, Rationalization and simplification of social security systems, Strasbourg, 1987. P. 45.

[1540] See Table 7.2. See also Jochen Clasen and Wim Van Oorschot, Changing Principles in European Social Security, European Journal of Social Security, volume 4/2, 98 (2002).

[1541] Thierry Warin and Peter Hannessy, One welfare state for Europe: a Costly utopia?, Middlebury college economics discussion paper no. 03-25 (2003)

Councils have issued recommendations on convergence of social protection since 1992,[1542] but up until today such harmonization has not taken place and member states have approached the issue through the coordination of their programs instead of through harmonization.

Despite of the existing differences between the social programs of the different European states, it is possible to conclude that there is a reasonably high level of protection through medical care, income maintenance and disability protection shared across all of them.[1543] The different social insurance systems share a number of common features that distinguish them from other forms of social protection.[1544] First is their function. In all member states, social insurance is a risk pooling mechanisms -- like private insurance -- under which individuals' contributions are not related to their personal exposure to risk or to the risk they impose on third parties.[1545] European social security systems are funded through the so-called "solidarity contract" between generations under which those gainfully employed today contribute from their wages to social security while the elderly receive social security funds in order to maintain their living standards.[1546] At the same time, the contributions for minimum coverage are not

[1542] See European Council, Fight against poverty and social exclusion - Definition of appropriate objectives (2000). The report is available at http://ec.europa.eu/index_en.htm. For a follow up report of the provisions subsequently included in the Nice Treaty (2001) see The Social Protection Committee Coreper/Council (Employment, Social Policy, Health and Consumer Affairs), Fight against poverty and social exclusion: common objectives for the second round of National Action Plans (2002). The report is available at ec.europa.eu/employment_social/social_inclusion/docs/counciltext_en.pdf. See also Thierry Warin and Peter Hannessy, One welfare state for Europe: a Costly utopia?, Middlebury college economics discussion paper no. 03-25 (2003) considering whether, in light of the harmonized monetary policy and increasingly harmonized economic policies, social policy should be harmonized in the European Union concluding that he did not find evidence to support policy harmonization on the European welfare programs.

[1543] Anita Bernstein, L'harmonie Dissonante: Strict Products Liability Attempted In The European Community, 31 Va. J. Int'l L. 673, 689-690 (1991).

[1544] Jochen Clasen, SOCIAL INSURANCE IN EUROPE, 241, Bristol: Policy Press, ed. (1997).

[1545] From pyramid to pillar, Population Change And Social Security In Europe, International Labor organization Working paper, 81 (1989) See also van Ginneken W., Finding the balance: Financing and coverage of social protection in Europe, in OCCASIONAL PAPERS ON SOCIAL SECURITY, 16, van Ginneken W. ed., International Social Security Association, Geneva (1996) for a discussion of alternatives to improve the deteriorated pay-as-you-go pension system.

[1546] For example, European pensions are based on the pay-as-go principle under which productive population of today has to provide the resources required to cover the current cost of pensions while future

determined by the extent of the coverage provided, but are either flat-rate (the same for all contributors) or related to the income of contributors up to a ceiling.[1547] In most countries, some benefits, such as pensions, may have a second complementary contribution, which increases the basic minimum provision. However, the extent of coverage is usually not determined by the contributors' decision to complement their benefits.

Second, in all member states the state has an active role in establishing the minimum standards for contributions and benefits and in regulating social insurance schemes.[1548] Social insurance schemes are generally of a compulsory nature for the majority of wage earners, which enhances their redistributive impact.[1549] For that reason, the entitlement to benefits depends upon contribution and not upon causation or non-faulty conduct, as would be the case under tort. The risks or contingencies that social insurance typically covers, such as old age, ill, health, occupational injuries and unemployment, are generally those associated with contributions paid through salaries.[1550]

5.3 European welfare state programs: the joint role of social assistance and social insurance

The concept of welfare programs provided by the different European countries is often related to the concept of social insurance programs. However, a shared

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generations will have to finance the pensions of the ones who are working today. RECENT TRENDS IN CASH BENEFITS IN EUROPE, Niels Ploug & Jon Kvist, eds. (1994).

[1547] See generally COMPENSATION FOR PERSONAL INJURY IN A COMPARATIVE PERSPECTIVE, Bernhard A. Koch and Helmut Koziol (eds.), Tort and Insurance Law vol 4 (2003).

[1548] COMPENSATION FOR PERSONAL INJURY IN A COMPARATIVE PERSPECTIVE, Bernhard A. Koch and Helmut Koziol (eds.), Tort and Insurance Law vol 4, 406 (2003).

[1549] Jochen Clasen, SOCIAL INSURANCE IN EUROPE, Bristol: Policy Press, ed. (1997).

[1550] Jochen Clasen, SOCIAL INSURANCE IN EUROPE, Bristol: Policy Press, ed. (1997).

characteristic of the European welfare programs is the difference between social assistance and social insurance.

Social assistance programs aim to support individuals who are in economic need due to their personal and social situations -- for example, those who are unemployed or permanently disabled. In contrast, social insurance aims to compensate individuals for economic losses they suffer as a consequence of certain contingencies -- for example, those who suffer product-related accidents.[1551] The assistance relevant for the compensation of victims of product related accidents is social insurance, which includes disability payments, employment compensation and lost earnings,[1552] medical care and economic benefits resulting from having suffered personal injuries.[1553] Victims rely on social insurance programs for compensation,[1554] and so these programs will be the focus of this section.

Social insurance functions as a risk-pooling mechanism. In this sense, it can be considered a special type of insurance system. The major goal of social insurance is not efficiency, as can be seen from the fact that insurance premiums do not reflect

[1551] Social insurance will refer to the part of social security that provides for cash in order to compensate the loss incurred by an individual even though it is not an equivalent concept of the New Zealand social insurance system that provides no-fault compensation and functions as a truly insurance system but run by the government.

[1552] Sandra N. Hurd and Frances E. Zollers, Product Liability in the European Community: Implications for United States Business, 31 American Business Law Journal 245, 254 (1993).

[1553] See Lucille M. Ponte, Guilt By Association In United States Products Liability Cases: Are The European Community And Japan Likely To Develop Similar Cause-In-Fact Approaches To Defendant Identification?, 15 Loy. L.A. Int'l & Comp. L.J. 629, 659 (1993) noting that the availability of social insurance programs in Europe is one of the major differences between Europe and the United States and further arguing that part of the driving force behind the reforms of product liability in the United States has been the lack of regulation and social insurance necessary for providing a high level of consumer protection.

[1554] See Anita Bernstein, L'harmonie Dissonante: Strict Products Liability Attempted In The European Community, 31 Va. J. Int'l L. 673, 688-690, 714-715 (1991) and Patrick Thieffry et al., Strict product liability in the EEC: Implementation, Practice and Impact on U.S. Manufacturers of Directive 85/374, 25 Tort & Ins. Law Journal 65, 65-66 (1989) noting that the product liability directive, despite intending to shift the costs of product-related accidents from private and public insurance systems to tortfeasors, it was unlikely to change the fact that Europeans would continue to use the social health and welfare programs rather than utilizing the limited course of litigation as their safety net as found in the United States.

individuals' risk.[1555] Instead, the goal is one of distributive justice:[1556] the solidarity and reciprocity between individuals who participate in the system by providing benefits whenever contingencies occur.[1557] Because of this social function based on solidarity and reciprocity, participation in social insurance is compulsory.[1558] At the same time, there is variation in levels of participation, with contributions sometimes based on labor market participation, citizenship or residence, or economic need.[1559] For example, cash benefits are directed to citizens and in some cases also to residents, but other benefits are attached to participation in the labor market.[1560]

Another factor that leads social insurance programs to depart from efficiency parameters is the determination of individuals' contributions. The contributions to social insurance programs, known as social insurance premiums, do not depend upon the risk posed but instead on the individual's level of income.[1561] Given the lack of individual differentiation of risk, the premium does not reflect the risk posed, and this leads to problems of moral hazard and adverse selection.[1562]

[1555] See Michael Moore and W. Kip Viscusi, Promoting Safety through Workers' Compensation: The Effcacy and Net Wage Costs of Injury Insurance, Working Paper, Northwestern University (1988). See also W. Kip Viscusi, Toward a diminished role of tort liability: social insurance, government regulation, and contemporary risks to health and safety, 6 Yale J. on Reg. 65 (1989).

[1556] Alberto Cavaliere, Product Liability in the European Union: Compensation and Deterrence Issues, European Journal of Law and Economics, 18: 299–318, 307-308 (2004).

[1557] Jochen Clasen, SOCIAL INSURANCE IN EUROPE, Bristol: Policy Press, ed. (1997).

[1558] Jochen Clasen, SOCIAL INSURANCE IN EUROPE, Bristol: Policy Press, ed. (1997).

[1559] RECENT TRENDS IN CASH BENEFITS IN EUROPE, Niels Ploug & Jon Kvist, eds. (1994).

[1560] Arrow pointed out that the demand for health care increases as soon as full insurance coverage is provided. See Kenneth J. Arrow, Uncertainty and the Welfare Economics of Medical Care, American Economic Review, vol. LIII, number 5, 941-973 (1963).

[1561] Ulrich Magnus, THE IMPACT OF SOCIAL SECURITY LAW ON TORT LAW, vol. 3 (Tort and Insurance Law), Springer ed. (2003). See also Michael Moore and W. Kip Viscusi, Promoting Safety through Workers' Compensation: The Efficacy and Net Wage Costs of Injury Insurance, Working Paper, Northwestern University (1988) noting that if insurance premiums are not merit based and hence do not reflect the tortfeasor's level of risk, there is a problem of inefficient incentives for risk-reduction. An example of social insurance with contributions regardless of the level of risk is the Spanish insurance system regulated in the Royal Law Decree RDL 1/1994 of June 20, approving the General Law on Social insurance (BOE 154, p. 20658 of June 29, 1994). The text of the Royal Decree is available at http://www.boe.es/aeboe/consultas/bases_datos/doc.php?id=BOE-A-1994-14960

[1562] Steven Shavell, On moral hazard and insurance, The Quarterly Journal of Economics 93(4), 541-562 (1979). See also W. Kip Viscusi, Toward a diminished role of tort liability: social insurance, government regulation, and contemporary risks to health and safety, 6 Yale J. on Reg. 65 (1989) noting that when

Sometimes, although not often, social insurance systems use risk classification techniques to determine social insurance contributions linked to insured parties' individual levels of risk instead of setting premiums based on income.[1563] Whenever social insurance systems use risk classification, the premiums are experience-rated and are established based on the past level of risk presented by the insured party.[1564]

The state is crucial to the functioning of the social insurance system.[1565] Social insurance is generally financed through contributions paid by employees and employers and through taxes.[1566] Therefore, the public agencies play important roles in managing the system, and public funds are used to cover whatever deficit the system ends up in.

In terms of benefits, the systems of the different European countries differ but the general principles are similar and include guaranteed access to health care and to cash benefits, sometimes dependent on the amount contributed,[1567] sometimes not. It is possible to differentiate between three types of benefits (1) earnings and contribution-related benefits, such as retirement pensions, (2) means-tested benefits, which are adjusted to the particular circumstances of the individual, and (3) flat-rate benefits, which

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premiums are not determined with respect to the level of risk presented, tortfeasors have no incentives to reduce the risks their activity or product involves.

[1563] Experience rating refers to the mechanism by which insurance premiums are determined based on the past risk experience of the insured. It is, thus, a form of risk classification because past risks are used to establish future premiums. See Tom Baker, Containing the Promise of Insurance: Adverse Selection and Risk Classification, University of Connecticut School of Law Working Paper Series 3, 10 (2001). This article is available at http://lsr.nellco.org/uconn/ucwps/papers/3. See also W. Kip Viscusi, Toward a diminished role of tort liability: social insurance, government regulation, and contemporary risks to health and safety, 6 Yale J. on Reg. 65 (1989) noting that when social insurance contributions are related to the risk presented, tortfeasors have incentives to minimize the risks of their activity or product and hence social insurance systems have an effect on ex ante accident minimization and deterrence.

[1564] For an empirical analysis of the different impact of the different compensation mechanisms and the different impact of flat rate and experience rated contributions in job related accidents see Michael J. Moore and W. Kip Viscusi, COMPENSATION MECHANISMS FOR JOB RISKS: WAGES, WORKERS COMPENSATION AND PRODUCT LIABILITY, Princeton University Press (1990).

[1565] Ulrich Magnus, THE IMPACT OF SOCIAL SECURITY LAW ON TORT LAW, vol. 3 (Tort and Insurance Law), Springer ed. (2003).

[1566] W. Kip Viscusi, Toward a diminished role of tort liability: social insurance, government regulation, and contemporary risks to health and safety, 6 Yale J. on Reg. 65, 70 (1989).

[1567] Ulrich Magnus, THE IMPACT OF SOCIAL SECURITY LAW ON TORT LAW, vol. 3 (Tort and Insurance Law), 232, Springer ed. (2003).

provide a minimum level of income irrespective of the individual's present or past income.[1568]

The importance and impact of the benefits provided by European social insurance systems[1569] to victims of product-related accidents cannot be understated. Such benefits are the major source of compensation for these victims.[1570] In a way, social insurance programs provide compensation for damages similar to the damages provided by tort litigation.[1571] So the role of a public no-fault system in providing benefits to victims is of special importance for the overall performance of the product liability system.[1572] Injured victims are entitled to no-fault social insurance benefits and such compensation has a direct effect on the victim's incentives on either buying private insurance coverage or on eventually pursuing a liability claim under tort as well as on the tortfeasor's incentives on whether to purchase private insurance liability coverage.[1573]

6 Tort law and social insurance: finding the adequate role of each instrument

[1568] RECENT TRENDS IN CASH BENEFITS IN EUROPE, Niels Ploug & Jon Kvist, eds. (1994).
[1569] This is a remarkable difference form U.S. social insurance programs that are significantly more restricted compared to the European programs implemented in the different member states. See Silva, F. & Cavaliere, A. The Economic Impact of Product Liability: Lessons from the US and the EU Experience, in G. Galli and J. Pelkmans (Eds.), REGULATORY REFORM AND COMPETITIVENESS IN EUROPE. Cheltenham, UK: Edward Elgar (2000).
[1570] Commission of the European Communities, Grenn Paper on Product Liability, COM (1999) 396 final, 8 (1999).
[1571] Joan T. Schmit, Factors Likely to Influence Tort Litigation in the European Union, The Geneva Papers 31, 304–313, 311 (2006).
[1572] In light of the limited funds available for social insurance programs there are voices who argue that, in cases where the injurer can be identified, compensation paid by social insurance should be borne by private insurance so that the viability of the system is ensured. See W. Kip Viscusi, Toward A Diminished Role For Tort Liability: Social Insurance, Government Regulation, And Contemporary Risks to Health and Safety, 6 Yale J. on Reg. 65, 103 (1989).
[1573] Ulrich Magnus, THE IMPACT OF SOCIAL SECURITY LAW ON TORT LAW, vol. 3 (Tort and Insurance Law), 241, Springer ed. (2003).

As mentioned above, tort law may in some senses be considered a system of social insurance.[1574] Tort law is similar to social insurance in that it performs an insurance function based on the compensation it provides to injured victims and in that it has the general purpose of providing broad-based compensation for accident risks.[1575]

At the same time, however, tort law and social insurance are significantly different in terms of underlying principles, eligibility criteria, process, and amount and content of the compensation itself.

6.1 Public v. Private concerns

Tort law and social insurance are compensation systems based on different underlying ideas about interactions between individuals and justice. When focusing on the compensation goal of tort law, corrective justice is the element to determine the interactions between individuals.[1576] In contrast, social insurance responds to distributive justice considerations.[1577]

Despite of their emphasis on compensation, tort law also aims to create the adequate incentives to deter accidents.[1578] In fact, tort law is often deemed a better

[1574] W. Kip Viscusi, Toward a diminished role of tort liability: social insurance, government regulation, and contemporary risks to health and safety, 6 Yale J. on Reg. 65, 97-98 (1989)

[1575] The social function of tort law is exacerbated when strict liability is the liability system in place. See W. Kip Viscusi, Product Liability and Regulation: Establishing the Appropriate Institutional Division of Labor, The American Economic Review, Vol. 78, No. 2, pp. 300-304 (1988) noting that the emergence of strict liability was partly based on the belief that firms could act as consumers' insurers. See also Heidi Li Feldman, Harm and Money: Against The Insurance Theory Of Tort Compensation, 75 Tex. L. Rev. 1567, 1575, 1595 (1997) and Richard A. Posner, ECONOMIC ANALYSIS OF LAW, 196, Aspen eds., 5th ed. (1998).

[1576] See generally Gary T. Schwartz, Mixed Theories of Tort Law: Affirming Both Deterrence and Corrective Justice, 75 Tex. L. Rev. 1801 (1997).

[1577] Hassan El Menyawi, Public Tort Liability: Recommending an Alternative to Tort Liability and No-Fault Compensation, Global Jurist Advances, Volume 3, Issue 1, article 1, 8 (2003).

[1578] Richard Posner, ECONOMIC ANALYSIS OF LAW, Aspen Eds. 201-214 (6th ed.) (2003). See also W. Kip Viscusi, Toward a diminished role of tort liability: social insurance, government regulation, and contemporary risks to health and safety, 6 Yale J. on Reg. 65 (1989) noting that in addition to its compensation goal, tort law aims also at creating incentives to potential tortfeasors to invest in safety whereas social insurance has no role in creating ex ante incentives to minimize accidents.

deterrence instrument than a compensation system.[1579] Social insurance, in contrast, is a compensation mechanism based on solidarity and reciprocity between individuals[1580] that provides benefits to injured victims (albeit not full compensation) immediately -- without their needing to file legal claims -- regardless of the cause of the accident and regardless of the level of care adopted.[1581] Social insurance does not have, as one of its goals, the creation of incentives to deter or minimize accidents. The tortfeasor's incentives to minimize accidents and invest in care derive from the internalization of accident costs. Under social insurance, injured victims are under-compensated and the costs of this compensation are not internalized by tortfeasors unless social insurance systems seek reimbursement from them.[1582] Although this type of reimbursement is an option in many European countries, the administrators of their social insurance systems rarely pursue it.

6.2 The individuals entitled to compensation under tort versus social insurance

The set of individuals entitled to compensation under tort law -- and, more specifically, under product liability -- differs from that covered by social insurance. Under product liability, for example, only individuals injured by a defective product may seek compensation from the tortfeasor. To the extent that compensation creates efficient risk-reduction incentives, restricting eligibility for compensation to individuals injured by the risky product is economically efficient.[1583]

[1579] Richard Posner, ECONOMIC ANALYSIS OF LAW, Aspen Eds., 201-214 (6th ed.) (2003).
[1580] Ulrich Magnus, THE IMPACT OF SOCIAL SECURITY LAW ON TORT LAW, vol. 3 (Tort and Insurance Law), 225, Springer ed. (2003).
[1581] COMPENSATION FOR PERSONAL INJURY IN A COMPARATIVE PERSPECTIVE, Bernhard A. Koch and Helmut Koziol (eds.), Tort and Insurance Law vol 4, 407 (2003).
[1582] W. Kip Viscusi, Tort Reform and Insurance Markets 3, Discussion Paper No. 440, 10/2003, Harvard Law School (2003).
[1583] W. Kip Viscusi, Toward a diminished role of tort liability: social insurance, government regulation, and contemporary risks to health and safety, 6 Yale J. on Reg. 65 (1989).

In contrast, social insurance constitutes an egalitarian compensation scheme because victims who suffer personal injury are compensated regardless of the cause of the harm.[1584] Entitlement is determined based on the individual's status in the system -- as a participant of the labor market, as a citizen or as a resident -- and on the existence of the damage suffered. It does not depend on issues of causation or contributory or comparative negligence. Consequently, the range of individuals entitled to compensation under a social insurance system is significantly broader than that of individuals entitled to compensation under tort.

6.3 Seeking compensation under tort versus social insurance: The story of two different processes

Another important difference between tort law and social insurance is the process injured victims must follow to seek compensation. The procedural differences between the two systems can be seen at different levels: the nature of the process, its costs and length, the standard of proof, and the uncertainty of whether compensation will be awarded.

Tort processes are often lengthy[1585] and entail significant private and public expenses. This is particularly true of the process and judicial systems involved in adjudicating product liability claims.[1586] Compensation under tort is awarded once the

[1584] COMPENSATION FOR PERSONAL INJURY IN A COMPARATIVE PERSPECTIVE, Bernhard A. Koch and Helmut Koziol (eds.), Tort and Insurance Law vol 4, 407 (2003).
[1585] Stephen D. Sugarman, Personal Injury and Social Policy – Institutional and Ideological Alternatives, 302, in Nicholas Mullany and Allen Linden, ed., TORTS TOMORROW, Australia: LBC Information Services, (1998).
[1586] Additionally, the private value of litigation is different than the public cost of it, which internalizes the deterrence created by the information gained from the trial and the public exposure of the defendant's misbehavior. Therefore, too much litigation from private parties could also lead to an inefficient outcome from a social perspective. See Steven Shavell, The Fundamental Divergence Between The Private And The Social Motive To Use The Legal System, 26 J. Legal Stud. 2, 575-612, 579 (1997). See also W. Kip

victim has filed a claim, met the required burden of proof and received the court-determined compensation from the injurer. This process, when successful may take a significant length of time. In contrast, compensation under social insurance is given relatively shortly after the accident has taken place. This is possible because only entitlement to compensation, instead of fault or causation, must be proved.[1587] In this sense, the information requirements of social insurance programs are much lower than those under tort.

Universal compensation regardless of causation is advantageous for victims because they do not have to meet any standard of proof and thus avoid having to prove the prima facie product liability claim.[1588] Meeting the burden of proof under tort can sometimes be very difficult and can discourage victims from seeking compensation.[1589]

Universal and immediate compensation under social insurance systems also allows government agencies and public hospitals to capture economies of scale and information regarding product risks and types of product-related harm suffered by individuals. This places these institutions in a better position to manage these risks.[1590]

Viscusi, Toward a diminished role of tort liability: social insurance, government regulation, and contemporary risks to health and safety, 6 Yale J. on Reg. 65 (1989).

[1587] The no-fault benefits provided by social insurance systems imply that some victims entitled and receiving benefits from social insurance would not be compensated under tort. Hence, the scope of victims compensated under social insurance is broader than the scope of victims compensated under tort. See Ulrich Magnus, THE IMPACT OF SOCIAL SECURITY LAW ON TORT LAW, vol. 3 (Tort and Insurance Law), 230, Springer ed. (2003).

[1588] Hassan El Menyawi, Public Tort Liability: Recommending an Alternative to Tort Liability and No-Fault Compensation, Global Jurist Advances, Volume 3, Issue 1, Article 1, 10 (2003).

[1589] For example, the asymmetry of information between victim and injurer and the lack of discovery rules in most of the European member states may become the key parameter when deciding the outcome of a case when the victim tries to overcome the defendant's defenses under the product liability directive but does not have access to the state of the art and the scientific knowledge regarding product risks. Thus, the lack of access to information necessary to grant a symmetric defense can become the factor that may decide a case.

[1590] The savings derived from these economies of scale could even compensate the decreased efficiency that could result from the absence of a competitive insurance environment but due to the lack of data, it is not possible to conduct this assessment in the European context. See Steven Shavell, The Fundamental Divergence Between The Private And The Social Motive To Use The Legal System, 26 J. Legal Stud. 2, 575-612, 578-579 (1997) and Kenneth S. Abraham and Lance Liebman, Private Insurance, Social Insurance, and Tort Reform: Toward A New Vision Of Compensation For Illness And Injury, 93 Colum. L. Rev. 75, 107 (1993).

Another relevant aspect is the risk of injured victims encountering judgment proof defendants.[1591] The tortfeasor's financial capacity is a crucial parameter that strongly conditions whether potential tortfeasors have incentives to purchase private insurance. If potential tortfeasors are judgment proof or do not have enough financial means to afford the full damages they cause to others, they may not have incentives to buy private insurance and injured victims may be left without compensation. Social insurance eliminates such uncertainty for injured victims given that it compensates them regardless of the financial situation of their injurer.

Finally, under social insurance, injured victims are not exposed to the uncertainty of the outcome of the case given that compensation is immediate. Social insurance systems potentially cover all risk to which the individual is exposed as long as there are available funds.[1592] This allows victims, who often need immediate funds, to recover their financial means.

From a procedural standpoint, social insurance presents remarkable advantages for injured victims. Overall, the combination of immediate compensation, greater certainty, and avoidance of the judgment-proof-defendant problem makes social insurance in many ways a better system for compensation than tort.[1593]

[1591] Hassan El Menyawi, Public Tort Liability: Recommending an Alternative to Tort Liability and No-Fault Compensation, Global Jurist Advances, Volume 3, Issue 1, Article 1, 9 (2003).

[1592] W. Kip Viscusi, Toward a diminished role of tort liability: social insurance, government regulation, and contemporary risks to health and safety, 6 Yale J. on Reg. 65, 70 (1989) noting that there is no barrier to risk coverage under social insurance systems.

[1593] See W. Kip Viscusi, Toward a diminished role of tort liability: social insurance, government regulation, and contemporary risks to health and safety, 6 Yale J. on Reg. 65 (1989) noting that social insurance systems generally provide more appropriate compensation to the injured. See also COMPENSATION FOR PERSONAL INJURY IN A COMPARATIVE PERSPECTIVE, Bernhard A. Koch and Helmut Koziol (eds.), Tort and Insurance Law vol 4, 408 (2003). See also Alf Erling Risa, The Welfare State as provider of accident insurance in the workplace: efficiency and distribution in equilibrium, The Economic Journal, Vo. 105, no. 458, 129-144 (1995).

6.4 Immediate but incomplete: The compensation trade-off

The compensation awarded to injured victims under tort and social insurance is remarkably different in terms of the amount to which injured victims are entitled and the range of eligible victims.

Regarding the compensation amount, tort law and social insurance aim at different goals: While social insurance programs aim at compensating those who need such compensation the most, tort law aims at making the injured victim whole. The universal entitlement and the immediate payment of benefits represent a trade-off, with social insurance compensation limited in time and amount and tort compensation offering undertain but potentially full compensation.[1594] Social insurance benefits are often lower than private insurance payments because the programs cover a broad range of individuals and injuries. Often, social insurance does not include compensation for certain types of harm,[1595] such as mental distress or pain and suffering.[1596] In addition, the amounts paid under social insurance are often limited by caps and statutory ceilings.

In theory, a victim who manages to succeed in a tort claim will be fully compensated, whereas a victim who seeks social insurance under a no-fault system will not.[1597] However, this does not seem to be a problem in Europe, where victims appear to prefer immediate compensation, even if incomplete, under social insurance.[1598]

[1594] The capacity of tort law to provide full compensation to victims is also arguable given that there is evidence that only about 10-15 percent of costs of the tort system go to compensating victims for out-of-pocket medical expenses and for example, lost income and the rest is for lawyers' fees, administrative costs, among others. See Hassan El Menyawi, Public Tort Liability: Recommending an Alternative to Tort Liability and No-Fault Compensation, Global Jurist Advances, Volume 3, Issue 1, article 1, 12 (2003).

[1595] W. Kip Viscusi, Toward a diminished role of tort liability: social insurance, government regulation, and contemporary risks to health and safety, 6 Yale J. on Reg. 65, 97-98 (1989) noting that in light of the diverse range of individuals and injuries presenting different levels of risk, the reduction incentives of the social insurance system result inefficient.

[1596] Hassan El Menyawi, Public Tort Liability: Recommending an Alternative to Tort Liability and No-Fault Compensation, Global Jurist Advances, Volume 3, Issue 1, article 1, 15 (2003).

[1597] Hassan El Menyawi, Public Tort Liability: Recommending an Alternative to Tort Liability and No-Fault Compensation, Global Jurist Advances, Volume 3, Issue 1 article 1, 15 (2003).

[1598] Commission of the European Communities, Green Paper on Product Liability, COM (1999) 396 final, p. 8 (1999). See also Stephen D. Sugarman, DOING AWAY WITH PERSONAL INJURY LAW, Westport,

In terms of the range of victims compensated, there are also differences between social insurance and tort. Some injured victims who are able to receive benefits from social insurance programs would not be entitled to compensation under tort due to their inability to meet the burden of proof.

7 The interaction between social insurance compensation and product liability claims in Europe: Visible and invisible effects

The availability of social insurance as a compensation mechanism for victims of product-related accidents generates three major -- and related -- effects. It directly impacts the incentives of injured victims to pursue their product liability claims and, at the same time, it affects the incentives of tortfeasors -- product manufacturers -- for adopting risk-minimizing measures. Further, social insurance systems bear the costs of accidents that should be borne by tortfeasors.

The existence and availability of compensation -- even if imperfect -- under social insurance dilutes victims' incentives to file product liability claims and seek compensation for their injurers under tort. When injured victims are compensated -- even if imperfectly -- through the public insurance system, they have less reason to incur the litigation costs and face the uncertainty inherent in the judicial process. For this reason, they may choose to forego pursuing product liability claims.

The lack of incentives for injured victims to pursue their product liability claims has a second major effect -- this one on product manufacturers. Tort law aims to induce accident deterrence by making the tortfeasor internalize the cost of accidents through litigation, either by the victim or by a party subrogated in the victim's position. When

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Connecticut: Quorum Books, 56 (1989) discussing the theoretical implications of the compensation trade-off between tort liability and private and public insurance.

injured victims do not pursue their claims for the harm they suffer, product manufacturers are not exposed to the compensation for the harm they cause and do not internalize the cost of the accidents they cause and hence have no incentives to adopt optimal precaution or optimally invest in care -- i.e., product safety.[1599] Similarly, when social insurance systems do not seek reimbursement from tortfeasors -- in this case, product manufacturers -- for the benefits paid to injured victims, the cost of accidents is not internalized and optimal accident deterrence is not achieved.

Further, given that social insurance covers certain types of injuries regardless their cause, whenever social insurance provides compensation to injured victims for the harm caused by tortfeasors, the public system bears these costs and tortfeasors do not internalize the costs of the accidents they cause.[1600] This implicit subsidy that social insurance provides to tortfeasors and, specifically, product manufacturers, has been cricized as resulting in moral hazard.[1601] This seems to be the structure of compensation of victims of product-related accidents in Europe where victims are being under-compensated by social insurance and tortfeasors, while complying with product safety regulations, are not reacting to the incentives that the product liability directive's strict liability regime aims to create.

7.1 The need for coordination mechanisms between compensation systems

As presented in this chapter, victims of product-related accidents in Europe have three major compensation mechanisms available to them: First, they can rely on tort law, which entitles them to bring claims against tortfeasors for the damages caused by

[1599] Alberto Cavaliere, Product Liability in the European Union: Compensation and Deterrence Issues, European Journal of Law and Economics, 18: 299–318, 300 (2004).
[1600] Richard Posner, ECONOMIC ANALYSIS OF LAW, Aspen eds. 201-214 (6th ed.) (2003).
[1601] Alf Erling Risa, The Welfare State as provider of accident insurance in the workplace: efficiency and distribution in equilibrium, The Economic Journal, Vo. 105, no. 458, 129-144 (1995).

defective products under strict liability. Second, they can rely on social insurance, which plays an important role by avoiding some of the downsides of tort litigation. Third, they can rely on private insurance. In the beginning of this chapter we noted that private insurance coverage and social insurance have important differences but share a common goal: providing benefits to accident victims regardless of fault.

In light of the different compensation mechanisms available to victims, their individual roles and their effects on one another, there are good reasons to introduce coordination mechanisms between them. A mechanism to coordinate between tort law -- and, more specifically, product liability, -- and public and private insurance is necessary to avoid distortions.

Without such coordination, the availability of alternative compensation systems for injured victims could result in inefficiencies for tortfeasors, for injured victims, and for society as a whole. Injured victims could eventually receive compensation under tort, private insurance and social insurance.[1602] Hence, if accumulation of benefits were possible, victims would be over-compensated and thus would profit from the harm they suffer. At the same time, victims' overcompensation could result in torfeasors' over-deterrence and thus in an inefficient investment in care. If the different compensation mechanisms were properly coordinated, however, victims' over-compensation and tortfeasors' over-deterrence would be avoided and the incentives for risk minimization would be efficient. If, instead, victims would receive social insurance benefits and decide not to pursue their product claims, victims would end up under-compensated, tortfeasors would be under-deterred and social insurance systems would bear costs that should not be borne by the public system.

[1602] See W. Kip Viscusi, Toward a Diminished Role for Tort Liability: Social Insurance, Government Regulation, and Contemporary Risks to Health and Safety, 6 Yale J. on Reg. 65, 103 (1989) arguing for the need of coordination mechanisms between alternative compensation systems in the context of worker's compensation.

This section will present the mechanics and effects of the coordination mechanisms between the different compensation systems in Europe. It will focus on the current regulations in force in the different European states and will discuss measures that could be adopted at the European Union level to enhance the effectiveness of product regulation and victim compensation while preserving optimal accident deterrence and a cost-effective social insurance system.

7.2 Coordination mechanisms between social insurance and product liability

It is possible for tort and insurance to work together to encourage product manufacturers to adopt optimal care while also compensating accident victims for harm that occurs. Even if the two systems are structurally and conceptually different, there is a strong relationship in practice between tort law and insurance, both private and publicly funded.[1603] Given the interaction between insurance and tort liability, and more specifically, product liability, the efficiency of a compensation system depends on the overall performance of the deterrence/compensation goals in the prevention of product-related accidents by both systems. In light of the different compensation mechanisms available, the question is how they should be coordinated so that each party involved has adequate incentives and the outcome is socially desirable. The optimal situation would be one in which injurers pay for the victims' loss -- which is necessary in order to maintain the injurers' incentive to adopt care[1604] -- and the victim would be fully compensated for

[1603] See Seth J. Chandler, The Interaction of the Tort System and Liability Insurance Regulation: Understanding Moral Hazard, 2 Conn. Ins. L.J. 91, 1996, P 93, Jon D. Hanson & Kyle D. Logue, The First-Party Insurance Externality: An Economic Justification for Enterprise Liability, 76 Cornell L. Rev. 129 (1990) and Richard J. Pierce, Jr., Encouraging Safety: The Limits of Tort Law and Government Regulation, 33 Vand. L. Rev. 1281, 1298-1300 (1980)).

[1604] Richard Posner, ECONOMIC ANALYSIS OF LAW, Aspen Eds., 201-214, (6th ed.) (2003)

the harm suffered while social insurance systems would not bear the costs of the damages suffered by the injured victim as the consequence of the tortfeasor's actions.

Coordination between tort and insurance would not be necessary in a world where the tort system would function perfectly.[1605] For example, under a perfect negligence system, injurers would know the optimal standard of care and, therefore, would not deviate from it. Under strict liability, victims would not care about collateral benefits[1606] because they would be fully compensated by their injurers.[1607] Unfortunately it is well known that the tort system does not operate perfectly and is subject to limitations such as insufficient enforcement, the plaintiffs' difficulty in meeting the burden of proof, the possibility of judgment proof defendants, and the possibility of misassessment of damages. As a result, coordination systems are necessary. [1608]

The European case is quite peculiar given that social insurance provides immediate benefits (albeit not full compensation) regardless of fault and, consequently, reduces victims' incentives to seek damages from tortfeasors.[1609]

The legal systems of the member states[1610] include mechanisms to coordinate their alternative compensation systems in order to correct this distortion, by encouraging reimbursement claims against tortfeasors for the benefits already paid by insurance,[1611]

[1605] See Fernando Gomez and Jose Penalva, Insurance and Tort: Coordination Mechanisms and Imperfect Liability Rules, 217-237, in INTERNALISIERUNGS DES RECHTS UND SEINE ÖKONOMISCHE ANALYSE. FESTSCHRIFT FÜR HANS-BERND SCHÄFER ZUM 65 GEBURTSTAGS, Jochen Bigus, Tomas Eger, and Georg von Wangenheim (eds.) Gabler Verlag, Wiesbaden (2008).

[1606] And therefore would not buy insurance coverage because they would be insured by the injurer.

[1607] Fernando Gomez and Jose Penalva, Insurance and Tort: Coordination Mechanisms and Imperfect Liability Rules, 217-237, 224, in INTERNALISIERUNGS DES RECHTS UND SEINE ÖKONOMISCHE ANALYSE. FESTSCHRIFT FÜR HANS-BERND SCHÄFER ZUM 65 GEBURTSTAGS, Jochen Bigus, Tomas Eger, and Georg von Wangenheim (eds.) Gabler Verlag, Wiesbaden (2008).

[1608] For an analysis of the conditions of the optimal interaction between insurance and tort see Steven Shavell, On Liability and Insurance, The Bell Journal of Economics 13(1), 120-132 (1982) and Steven Shavell, ECONOMIC ANALYSIS OF ACCIDENT LAW, 215 (1987) Cambridge (Mass.) where optimal insurance is defined as the level of coverage that provides identical marginal utility of income in the absence or in the presence of an accident.

[1609] COMPENSATION FOR PERSONAL INJURY IN A COMPARATIVE PERSPECTIVE, Bernhard A. Koch and Helmut Koziol (eds.), Tort and Insurance Law vol 4 (2003).

[1610] See Table 7.2 of this chapter.

[1611] See generally Ulrich Magnus, THE IMPACT OF SOCIAL SECURITY LAW ON TORT LAW, vol. 3 (Tort and Insurance Law), Springer ed. (2003).

and by trying to ensure that victims are compensated for the harm they suffered. This coordination improves the situation but still does not create optimal incentives for tortfeasors given that social insurance only provides compensation for personal injury,[1612] and thus without liability claims under the product liability directive tortfeasors avoid liability for property damage.[1613]

There are three major coordination mechanisms at work in the member states: First, insurers are allowed to seek reimbursement from tortfeasors for the benefits paid to the injured victims. Second, there is a collateral source rule, and third, there is a collateral benefit offset.[1614]

In principle, injured victims should have no preferences with respect to the mechanism providing compensation to them.[1615] However, as explained above, each compensation system presents different trade-offs -- time, compensation amount, uncertainty, possibility of judicial error -- and these may result in the victim preferring one compensation system over another.

7.2.1 The insurer's right of reimbursement for the benefits paid to the injured victim

The first coordination mechanism, the insurers' right of reimbursement, may be implemented in different ways: a direct cause of action from the insurance -- either

[1612] COMPENSATION FOR PERSONAL INJURY IN A COMPARATIVE PERSPECTIVE, Bernhard A. Koch and Helmut Koziol (eds.), Tort and Insurance Law vol 4 (2003).
[1613] But non-material damage is not covered. See article 9 of the product liability directive.
[1614] See Tung Yin, Nailing Jello to a Wall: A Uniform Approach for Adjudicating Insurance Coverage Disputes in Products Liability Cases with Delayed Manifestation Injuries and Damages, 83 Calif. L. Rev. 1243, 1302 (1995) suggesting that the existence of simultaneously applicable coordination mechanisms generates negative externalities on society.
[1615] See Kenneth S. Abraham and Lance Liebman, Private Insurance, Social Insurance, and Tort Reform: Toward A New Vision Of Compensation For Illness And Injury, 93 Colum. L. Rev. 75 (1993) for a general overview of the different compensation systems interacting in the U.S.

private or public, referred to as collateral source -- against the tortfeasor, an insurer's subrogation right, or a cession of the victim's tort claim against the tortfeasor in favor of the insurer.[1616] Under the first system, the insurer is entitled to seek reimbursement of the benefits already paid to the injured victims, but the victims may still seek damages from the tortfeasor beyond this amount. In contrast, under subrogation or cession rules, victims are not entitled to seek damages from the tortfeasor at all once they have been compensated by an insurer.

The right of reimbursement does not rule out the implementation of either of the other two coordination mechanisms -- the collateral source rule and the collateral benefit offset. If liability under tort is awarded, the insurance benefits already received by the victim from the insurer might be either added to the tort award -- if the collateral source rule is applicable -- or deducted from the tort award -- if the collateral benefit offset rule is applicable.

The reimbursement of the benefits provided by the insurance system may come from either the tortfeasor or from the victim depending on whether damages were reduced by the compensation received from other sources or not. In cases where the compensation from the collateral sources was deducted from the victim's damage award, the victim would be fully compensated but the tortfeasor would only pay the difference between the damage award and the compensation from other sources. In this case the tortfeasor would reimburse the collateral compensation scheme. If the tort award would not be reduced by the amount of the benefits already received, the tortfeasor as well as the alternative compensation scheme would compensate the injured victim and hence the victim would be overcompensated. In order to avoid overcompensation, the victim has to reimburse the collateral source for the benefits paid.

[1616] Fernando Gomez and Jose Penalva, Insurance and Tort: Coordination Mechanisms and Imperfect Liability Rules, 217-237, in INTERNALISIERUNGS DES RECHTS UND SEINE ÖKONOMISCHE ANALYSE. FESTSCHRIFT FÜR HANS-BERND SCHÄFER ZUM 65 GEBURTSTAGS, Jochen Bigus, Tomas Eger, and Georg von Wangenheim (eds.) Gabler Verlag, Wiesbaden (2008).

It should be noted that when the collateral source is a social insurance agency, the claim against the tortfeasor mostly adopts two different forms: first, a direct cause of action against the injurer or a subrogation to step in the shoes of the injured victim when seeking damages from the tortfeasor under tort.[1617]

a. The insurer's direct cause of action against the liable tortfeasor

One of the major goals of enabling insurers to seek reimbursement from the tortfeasor for the benefits paid to the injured victim is leaving the victim whole while avoiding any dislocation of accident costs and minimizing the administrative costs involved in the compensation process.[1618] If the administrative costs involved in the reimbursement claim would be relatively low, this would appear as an attractive solution.[1619]

In order to ensure that insurance systems -- private or public -- are reimbursed for the benefits paid to injured victims, they are often entitled to a direct cause of action against the tortfeasor in order to be able to seek reimbursement for the benefits already paid.[1620]

[1617] Fernando Gomez and Jose Penalva, Insurance and Tort: Coordination Mechanisms and Imperfect Liability Rules, 217-237, in INTERNALISIERUNGS DES RECHTS UND SEINE ÖKONOMISCHE ANALYSE. FESTSCHRIFT FÜR HANS-BERND SCHÄFER ZUM 65 GEBURTSTAGS, Jochen Bigus, Tomas Eger, and Georg von Wangenheim (eds.) Gabler Verlag, Wiesbaden (2008).

[1618] Ulrich Magnus, THE IMPACT OF SOCIAL SECURITY LAW ON TORT LAW, vol. 3 (Tort and Insurance Law), 306, Springer ed. (2003).

[1619] Guido Calabresi, THE COSTS OF ACCIDENTS: A LEGAL AND ECONOMIC ANALYSIS, Yale University Press (1970) and Calabresi, Some thoughts on risk distribution and the law of torts, 70 Yale Law Journal 4, 499-553 (1961). Given that in some member states such administrative costs are significantly high, the Netherlands, Germany and France exercise a collective right of recourse, which means that part of the compensation paid by social security agencies is shifted to liability insurers. See Ulrich Magnus, THE IMPACT OF SOCIAL SECURITY LAW ON TORT LAW, vol. 3 (Tort and Insurance Law), 258, Springer ed. (2003).

[1620] Fernando Gómez Pomar, Tort Liability and Other Means of Redress: "Collateral Source Rule" and Related Topics, www.Indret.com 1/00 (2000) noting that excluding the right of recourse would result in the tortfeasor's under-deterrence.

From an economic perspective this system seems rational and efficient given that each party has efficient incentives.[1621] But it also presents some implementation problems given that it may be difficult to bring all the parties into the judicial reimbursement proceedings, the collateral payments need to be assessed and doing so can be expensive, and there needs to be a mechanism under which either the tortfeasor or the victim will have to reimburse the collateral source. In some cases, exercising the reimbursement claim may not be cost-effective when compared to the amount to be recovered.[1622]

As mentioned earlier, social insurance agencies are often given a direct cause of action against the injurer.[1623] Once the social insurance system is reimbursed for the benefits paid to the victim there is a perfect allocation of costs given that the tortfeasor has paid full compensation to the victim under tort, the victim has been fully compensated under tort, and the collateral source has been reimbursed for the benefits paid.[1624]

Therefore, allowing a direct action from social insurance systems against the tortfeasor results in an optimal outcome.

b. Subrogation right for the tort claim to the insurer against the injurer

[1621] Hassan El Menyawi, Public Tort Liability: Recommending an Alternative to Tort Liability and No-Fault Compensation, Global Jurist Advances, Volume 3, Issue 1, Article 1, P. 18 (2003).
[1622] Richard Lewis, DEDUCTING BENEFITS FROM DAMAGES FOR PERSONAL INJURY, 37, Oxford University Press (2000).
[1623] Fernando Gomez and Jose Penalva, Insurance and Tort: Coordination Mechanisms and Imperfect Liability Rules, 217-237, in INTERNALISIERUNGS DES RECHTS UND SEINE ÖKONOMISCHE ANALYSE. FESTSCHRIFT FÜR HANS-BERND SCHÄFER ZUM 65 GEBURTSTAGS, Jochen Bigus, Tomas Eger, and Georg von Wangenheim (eds.) Gabler Verlag, Wiesbaden (2008).
[1624] Richard Lewis, DEDUCTING BENEFITS FROM DAMAGES FOR PERSONAL INJURY, Oxford University Press (2000).

Subrogation is generally defined as "stepping into someone else's shoes" for the purpose of making a legal claim.[1625] When a victim suffers a loss, the insurance system will provide benefits according to the insurance coverage. Once the victim receives these benefits from the insurer, the victim may or may not claim damages under tort from the tortfeasor. The victim's decision to pursue a claim under tort after receiving insurance benefits has overall consequences for the parties involved as already discussed.

If the victim pursues a tort claim, any insurance benefit would either be cumulated to the tort award if the coordination rule is a collateral source rule or would be deducted from the tort award in order to avoid the victim of being over-compensated under a collateral benefit offset rule. This latter case would lead to the optimal outcome regarding both deterrence and compensation given that the collateral source would break even, the victim would be compensated under tort and the tortfeasor would bear the full accident costs.[1626]

If the victim does not pursue a claim and the collateral source -- the insurance system -- declines to seek reimbursement from the tortfeasor, the collateral source will end up paying benefits to the victim and the tortfeasor will not bear any accident costs. But if subrogation rights are available, the collateral source could step into the shoes of the injured victim and seek compensation in full, including compensation for damages potentially not covered and hence not compensated under insurance and for damages exceeding the insurance benefits received by the insured.[1627] Whenever the collateral source exercises the subrogation right and hence pursues a tort claim on behalf of the victim, two additional conditions are necessary so that the injurer does not have to pay

[1625] On insurance subrogation, see Robert E. Keeton & Alan I. Widiss, INSURANCE LAW, §3.10(a)(1), 220 West Group (1988).
[1626] Richard Lewis, DEDUCTING BENEFITS FROM DAMAGES FOR PERSONAL INJURY, 41, Oxford University Press (2000).
[1627] See generally David Rosenberg, Deregulating Insurance Subrogation: Towards an Ex Ante Market in Tort Claims. Harvard Law School, Public Law Research Paper No. 43; Harvard Law and Economics Discussion Paper No. 395. Available at SSRN: http://ssrn.com/abstract=350940 or doi:10.2139/ssrn.350940 (2002).

damages to both the injured victim and the collateral source:[1628] First, injured victims must be barred from pursuing tort claims whenever they have been compensated in full by the collateral source. Second, if injured victims have been only partly compensated by the collateral source and pursue their tort claim against their injurers, their damages must be reduced accordingly. As a result, whenever subrogation rights are available, the collateral benefit offset is essential for the optimal performance of the overall system and for the optimal incentives of each of the parties' involved.[1629]

This structure is equivalent (in terms of its result) to one in which insured parties transfer any tort award to their insurers. If the insurer prevails under subrogation, it may retain all or part of the judgment or settlement up to the amount paid to the insured,[1630] while paying to the victim anything over this amount.[1631] Hence, the collateral source will have incentives to settle for amounts lower than the ones the victims might have settled for.[1632]

The transfer of a tort claim from the injured victim to the insurer can have three major positive effects:[1633] First, insurance premiums may be reduced so as to take into

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[1628] Fernando Gomez and Jose Penalva, Insurance and Tort: Coordination Mechanisms and Imperfect Liability Rules, 217-237, in INTERNALISIERUNGS DES RECHTS UND SEINE ÖKONOMISCHE ANALYSE. FESTSCHRIFT FÜR HANS-BERND SCHÄFER ZUM 65 GEBURTSTAGS, Jochen Bigus, Tomas Eger, and Georg von Wangenheim (eds.) Gabler Verlag, Wiesbaden (2008).

[1629] See Fernando Gomez and Jose Penalva, Insurance and Tort: Coordination Mechanisms and Imperfect Liability Rules, 217-237, in INTERNALISIERUNGS DES RECHTS UND SEINE ÖKONOMISCHE ANALYSE. FESTSCHRIFT FÜR HANS-BERND SCHÄFER ZUM 65 GEBURTSTAGS, Jochen Bigus, Tomas Eger, and Georg von Wangenheim (eds.) Gabler Verlag, Wiesbaden (2008) noting that the collateral benefit offset is an essential part of the performance of the insurance subrogation structure.

[1630] Tom Baker, INSURANCE LAW AND POLICY: CASES, MATERIALS AND PROBLEMS, 391-407 (2003)

[1631] It is also possible to distinguish between limited and unlimited subrogation. See David Rosenberg, Deregulating Insurance Subrogation: Towards an Ex Ante Market in Tort Claims. Harvard Law School, Public Law Research Paper No. 43; Harvard Law and Economics Discussion Paper No. 395. Available at SSRN: http://ssrn.com/abstract=350940 or doi:10.2139/ssrn.350940 (2002).

[1632] Mitchell Polinsky and Steven Shavell, The uneasy case for product liability, 123 Harv. L. Rev. 1437, 1463 (2010).

[1633] David Rosenberg, Deregulating Insurance Subrogation: Towards an Ex Ante Market in Tort Claims, 10, Harvard Law School, Public Law Research Paper No. 43; Harvard Law and Economics Discussion Paper No. 395. Available at SSRN: http://ssrn.com/abstract=350940 or doi:10.2139/ssrn.350940 (2002) presenting these positive effects of introducing subrogation rights in tort claims but also noting that the potential existence of an ex ante market of claims could have long term positive effects in terms of the parties' incentives, deterrence and policy making.

account the subrogation right and the damages the insurer may potentially recover. Second, the deterrence effects of tort law may be preserved, as tortfeasors will internalize the damage caused and will be exposed to greater liability than they would without a subrogation system. If subrogation rights are not available, tortfeasors are exposed to liability only in cases in which injured victims pursue their tort claims. Under subrogation, tortfeasors are exposed to liability in those cases, but also in cases where insurers pursue tort claims in the shoes of injured victims. Consequently, deterrence effects will be higher.[1634] Finally, administration costs may be reduced given that insurers have access to better information due to the number of claims they pursue on behalf of insured parties, and this allows them to manage the litigation more efficiently.

As can be seen, giving the collateral source a subrogation right is in the best interest in the victim.[1635]

An important disadvantage of subrogation rights is that the functioning of the system involves high costs[1636] -- both in administration and in litigation -- given that it increases the volume of suits and entails also subsequent payments to victims whenever insurers are able to collect more than they have already paid out.[1637]

There is an important difference between the subrogation right and the direct action explained above. Whenever the collateral source stands in the position of the injured victim through subrogation, the amount of damages awarded is not limited to the benefits amount previously paid; instead, the insurer may collect the total amount of the

[1634] See Alan O. Sykes, Subrogation and Insolvency, 30 Journal of Legal Studies 2, 383-399 (2001) available at http://ideas.repec.org/a/ucp/jlstud/v30y2001i2p383-99.html analyzing the positive effect of subrogation provisions in insurance contracts in cases of tortfeasor's insolvency.
[1635] See Steven Shavell, ECONOMIC ANALYSIS OF ACCIDENT LAW, 235-255, Cambridge: Harvard University Press (1987) and Patricia M. Danzon, Tort Reform and the Role of Government in Private Insurance Markets, 13 Journal of Legal Studies 3, 517–549 (1984).
[1636] Fernando Gomez and Jose Penalva, Insurance and Tort: Coordination Mechanisms and Imperfect Liability Rules, 217-237, in INTERNALISIERUNGS DES RECHTS UND SEINE ÖKONOMISCHE ANALYSE. FESTSCHRIFT FÜR HANS-BERND SCHÄFER ZUM 65 GEBURTSTAGS, Jochen Bigus, Tomas Eger, and Georg von Wangenheim (eds.) Gabler Verlag, Wiesbaden (2008).
[1637] John G. Fleming, The collateral source rule and loss allocation in tort, 54 Cal. L. Rev. 1478, 1556 (1966) suggests that the cost of subrogation in less serious accidents could amount to half of the amount of money claimed.

victim's damages. Furthermore, the insurance agency has to return the difference between the insurance benefits and the tort award. Under direct action, whenever the insurance agency seeks reimbursement from the tortfeasor, the tort award is limited to the amount of benefits already paid and therefore there is under-deterrence. The advantage presented by giving insurers the right of subrogation[1638] is due to the position of the parties under each structure: under the direct action, insurers claim reimbursement in their own names and are therefore entitled only to what they have paid out; under subrogation, they stand in the victim's shoes and so can recover everything the victim was entitled to.

c. Compulsory cession of the victim's tort claim in favor of the insurer

Under the compulsory cession system, the victim cedes their claim under tort to the collateral source, in this case, social insurance agencies. The compulsory cession of the victim's claim under tort in favor of the insurer is quite rare in European legal systems. Germany and Austria are the only member states that allow an action by social insurance agencies in the form of a cession. Germany provides social insurance with a right of recourse against the person who caused the injury in the form of a *cession legis,*[1639] but only under certain conditions:[1640] The victim's claim cannot be based on social insurance law and it must not be likely that social insurance systems would have to provide additional benefits to the victim due to an identical event, for identical purposes and occurring within the same period of time.[1641]

[1638] See Steven Shavell, ECONOMIC ANALYSIS OF ACCIDENT LAW, 235-36, Cambridge: Harvard University Press (1987). In addition, as Shavell points out, subrogation eliminates the moral hazard problem of double indemnity. Unlimited insurance subrogation would effectively solve the conflict between deterrence and compensation created by the collateral source rule.

[1639] See art I §116 I SGB X of the German Social Security Law.

[1640] Martha Warren Neocelous, PERSONAL INJURY, PRACTICE AND PROCEDURE IN EUROPE, Cavendish Publishing Limited, 65 (1997).

[1641] Ulrich Magnus, THE IMPACT OF SOCIAL SECURITY LAW ON TORT LAW, vol. 3 (Tort and Insurance Law), 106, Springer ed. (2003).

Given that the exercise of the right is derived from a cession, social insurance agencies have the same limitations as the victims' when exercising the right. So if the victim's claim against the tortfeasor was limited by law, social insurance agencies would only be able to exercise the cession as long as social insurance benefits would have covered the damages subsequently awarded under tort.[1642] Similarly, whenever the victim was contributory negligent, the social insurance recourse would be limited to the tortfeasor's share.

Austria also provides a legal cession[1643] under which the victim's claim against the tortfeasor passes to the social insurance agency as long as social insurance has previously paid benefits to the injured victim.[1644] As in the case for Germany, there are certain pre-requisites that evolve around the concept of "congruence." Social insurance agencies can exercise the ceded right as long as the claims are equivalent to the social benefits in a factual, personal and temporal manner.[1645] As soon as the claim is ceded to the social insurance agency, the injured person loses his or her right to file a claim for compensation under tort arising out of the same accident.

This system has some advocates[1646] even though it is a relatively less frequent structure of subrogation rights in Europe.

7.2.2 Collateral Source Rule

[1642] Ulrich Magnus, THE IMPACT OF SOCIAL SECURITY LAW ON TORT LAW, vol. 3 (Tort and Insurance Law), 207, Springer ed. (2003).
[1643] See §332 ASVG.
[1644] Ulrich Magnus, THE IMPACT OF SOCIAL SECURITY LAW ON TORT LAW, vol. 3 (Tort and Insurance Law), 17, Springer ed. (2003).
[1645] Ulrich Magnus, THE IMPACT OF SOCIAL SECURITY LAW ON TORT LAW, vol. 3 (Tort and Insurance Law), 17, Springer ed. (2003).
[1646] David Rosenberg, Deregulating Insurance Subrogation: Towards an Ex Ante Market in Tort Claims. Harvard Law School, Public Law Research Paper No. 43; Harvard Law and Economics Discussion Paper No. 395. Available at SSRN: http://ssrn.com/abstract=350940 or doi:10.2139/ssrn.350940 (2002).

Under the collateral source rule, injured victims can accumulate insurance benefits -- from private insurance, social insurance, or both collateral sources -- and damage awards under tort in full.[1647] The collateral source rule does not differentiate between the nature and sources of the compensation paid to the victim. Even if the injured victim manages to obtain compensation from alternative private sources (previously purchased private insurance or publicly funded social insurance), the tortfeasor must still pay full damages in any tort suit. The court in the tort action does not take the compensation received from the collateral source into account when determining the damage award to which the victim is entitled.[1648]

From the victims' perspective, this is the best solution because it enables them to receive full compensation for the harm suffered from any compensation system available to them.[1649] This system could even result in the victim being over-compensated (which would obviously be beneficial for the victim).

At the same time, from the tortfeasor's perspective, the tortfeasor is liable for the full damage caused to the victim, regardless of whether the victim has already been compensated for such damage through another source of compensation. Hence, under a

[1647] See Stephen B. Presser, How should the Law of Products Liability be Harmonized? What Americans Can Learn from Europeans, Center for Legal Policy at the Manhattan Institute (2002) noting that the collateral source rule allows for "double recovery" given that it prevents evidence from any benefits already paid to the injured victim to be taken into account when determining the damage award under tort. See also Elaine W. Shoben et al., REMEDIES, CASES AND PROBLEMS, 646, Foundation Press (3rd ed. 2002) and James M. Fischer, UNDERSTANDING REMEDIES, 76, LexisNexis/Matthew Bender; 1st ed (2000) pointing out the double recovery problem of the collateral source rule. For a history of the application of the collateral source rule see Jeremy L. Kidd and Michael I. Krauss, Collateral source and tort's law, George mason university Law and Economics research paper series 08-57, 7-19 (2008).

[1648] Kevin S. Marshall and Patrick W. Fitzgerald, The Collateral Source Rule And Its Abolition: An Economic Perspective, 15 Fall Kan. J. L. & Pub. Pol'y 57, 58-60 (2005) analyzing the effects of the collateral source rule on accident deterrence.

[1649] See Collateral Source Rule Reform, American Tort Reform Association, available at http://www.atra.org/show/7344 (last visited April, 10 2011). See also Fernando Gómez Pomar, Tort Liability and Other Means of Redress: "Collateral Source Rule" and Related Topics, www.Indret.com 1/00 (2000) for an analysis of the functioning, effects and implications of the collateral source rule and Collateral Source Rule Reform, National Association of Mutual Insurance Companies, available at http://www.namic.org/reports/tortReform/CollateralSourceRule.asp (last visited April 10, 2011).

collateral source rule the tortfeasor fully internalizes the damage caused to the victim given that no reduction is allowed.

The main critique of the collateral source rule is that it can result in victims' overcompensation, which is undesirable.[1650] This important challenge might explain why the collateral source rule is not implemented in any of the European member states.[1651] In the states of the United States where the collateral source rule or some form of it is applicable,[1652] the collateral source rule is both a substantive rule of compensation as well as a procedural rule of evidence.[1653] As a substantive rule of compensation, injured victims are entitled to collect full damage awards or benefits from the different sources of compensation available without any compensation system being able to offset or reduce the amount already received from another compensation system. As a rule of evidence, the collateral source rule is a rule that precludes the defendant from introducing evidence of any benefits already paid to the victims through other alternative compensation mechanisms such as private or social insurance.

The accumulation of benefits seems contrary to economic efficiency.[1654] Thus, if the goal of compensation systems is to leave injured victims in the position in which they

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[1650] See Elaine W. Shoben et al., REMEDIES, CASES AND PROBLEMS, 646, Foundation Press (3d ed. 2002) noting that the collateral source rule may result in an injured victim receiving double compensation for a single harm. See also James M. Fischer, Understanding Remedies, 76 (2000) noting that under this rule injured victims might obtain benefits he would not have obtained but for the legal accumulation of remedies.

[1651] See Table 7.2 of this chapter.

[1652] For a list of the different U.S. states where the collateral source rule or some similar rule is in force see Collateral Source Rule Reform, American Tort Reform Association, available at http://www.atra.org/show/7344 (last visited April, 10 2011). See also Collateral Source Rule Reform, National Association of Mutual Insurance Companies, available at http://www.namic.org/reports/tortReform/CollateralSourceRule.asp (last visited April 10, 2011). See also Kevin S. Marshall and Patrick W. Fitzgerald, The Collateral Source Rule And Its Abolition: An Economic Perspective, 15 Fall Kan. J. L. & Pub. Pol'y 57, 66 (2005) noting that many states in the United States have eliminated or minimized the application of the collateral source rule. See also Paul H. Rubin and Joanna M. Shepherd, Tort Reform and Accidental Deaths, Journal of Law & Economics, University of Chicago Press, vol. 50, 221-238 (2007) showing empirically that the shift from the collateral source rule and the collateral benefit offset rule in some U.S. states has resulted in a negative effect on the levels of investment in care and on the accident level.

[1653] See generally James L. Branton, The Collateral Source Rule, 18 St. Mary's L. J. 883 (1987).

[1654] Victor E. Schwartz, Tort law reform: strict liability and the collateral source rule do not mix, 39 Vanderbilt Law Review 569 (1986) discussing the history of the collateral source rule in the different

would have been before the accident occurred, any source and amount of compensation should be arguably taken into account when determining tort awards.[1655] Some justify the accumulation of damages by arguing that the victim is entitled to certain damages under the law as a right granted by the legal system and that receiving other payments from other sources such as insurance should not be relevant given that the these benefits were awarded because the insurance coverage was previously purchased.[1656] However, whenever the additional benefits are provided by the state, the victim's over-compensation is more difficult to justify,[1657] which may explain why this coordination system has not been adopted in any of the European member states.

It should be noted that if accident deterrence was the main goal, the collateral source rule would be the best instrument of corrective justice because it forces potential tortfeasors to fully internalize the economic costs of their risky activity or products.[1658] But if efficient victim compensation was the goal, the collateral source rule would perform sub-optimally.[1659]

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jurisdictions of U.S. states implementing it and arguing that state statutes have misled courts regarding the substantive and evidence component of the rule.

[1655] See David W. Robertson et al., William Powers, Jr., David A. Anderson, and Olin Guy Wellborn, III, CASES AND MATERIALS ON TORTS, 325 (3d ed., 2004) noting that damage compensation under tort aims at leaving the injured victim in the situation he was in before the accident took place. See also Richard Lewis, DEDUCTING BENEFITS FROM DAMAGES FOR PERSONAL INJURY, 12, Oxford University Press (2000).

[1656] See Patricia M. Danzon, Tort Reform and the Role of Government in Private Insurance Markets, 13 Journal of Legal Studies 3, 517-550 (1984) where Danzon stated that in situations where there is a buyer-seller or employee-employer relationship, victims have also indirectly paid for the compulsory insurance provided by the tort system and thus are entitled to what they paid for. See also Fleming, "Collateral benefits" in international encyclopedia of comparative law (Vo, XI)(1983) chapter 11-18. See also Kevin S. Marshall and Patrick W. Fitzgerald, The Collateral Source Rule And Its Abolition: An Economic Perspective, 15 Fall Kan. J. L. & Pub. Pol'y 57, 66 (2005) justifying the potential overcompensation of injured victims based on the fundamental purposes of tort law of compensation, indemnity, restitution and deterrence.

[1657] See Stephen B. Presser, How should the Law of Products Liability be Harmonized? What Americans Can Learn from Europeans, Center for Legal Policy at the Manhattan Institute (2002) noting the difficulty to justify over-compensation when part of the compensation comes from public funds. See also S. Sugarman, Doing away with personal injury law, 79 (1989) suggesting changes in social insurance and employment benefits in order to justify the accumulation of compensation from different sources.

[1658] Kevin S. Marshall and Patrick W. Fitzgerald, The Collateral Source Rule And Its Abolition: An Economic Perspective, 15 Fall Kan. J. L. & Pub. Pol'y 57, 66 (2005).

[1659] Jeremy L. Kidd and Michael I. Krauss, Collateral source and tort's law, George mason university Law and Economics research paper series 08-57 (2008) arguing that the justification of the application of the collateral source rule can be found in the essence of tort law.

7.2.3 Collateral benefits offset (deduction rule)

The collateral benefits offset rule seeks to avoid the victim's overcompensation eventually resulting from allowing the victim to accumulate several compensations, by reducing the damage award in the amount of the benefits already received by the victim from other alternative sources.[1660]

This rule does not provide private or social insurance with a specific right of reimbursement from the tortfeasor. It is the victim, not the insurer, who is able to seek damages under tort for the additional amount not compensated by the social insurance system.

This is the best system for tortfeasors because they are responsible for an amount lower than the full accident cost and have no duty to return the benefits paid by other compensation schemes. Consequently, tortfeasors are under-deterred and, in a way, subsidized.

From an administrative cost perspective, the collateral benefits offset is the simplest system to manage because it avoids the costs associated with reimbursement actions and the duplicity of payments to the victim.[1661]

However, this rule it does not lead to an optimal outcome given that the victim is indifferent between increasing the scope of insurance benefits or receiving tort damages.[1662] The reason why this happens is that the benefits of having more insurance coverage go not only to the victim but also to the injurer, due to offsetting the collateral

[1660] Fernando Gomez and Jose Penalva, Insurance and Tort: Coordination Mechanisms and Imperfect Liability Rules, 217-237, in INTERNALISIERUNGS DES RECHTS UND SEINE ÖKONOMISCHE ANALYSE. FESTSCHRIFT FÜR HANS-BERND SCHÄFER ZUM 65 GEBURTSTAGS, Jochen Bigus, Tomas Eger, and Georg von Wangenheim (eds.) Gabler Verlag, Wiesbaden (2008).
[1661] Richard Lewis, DEDUCTING BENEFITS FROM DAMAGES FOR PERSONAL INJURY, 43, Oxford University Press (2000).
[1662] See generally Fernando Gomez and Jose Penalva, Insurance and Tort: Coordination Mechanisms and Imperfect Liability Rules, 217-237, 226, in INTERNALISIERUNGS DES RECHTS UND SEINE ÖKONOMISCHE ANALYSE. FESTSCHRIFT FÜR HANS-BERND SCHÄFER ZUM 65 GEBURTSTAGS, Jochen Bigus, Tomas Eger, and Georg von Wangenheim (eds.) Gabler Verlag, Wiesbaden (2008).

benefits from the damage awards. However, the costs of the alternative compensation system are born not by tortfeasors but by either victims, if the collateral system is private insurance, or by society as a whole, if the collateral system is social insurance.[1663]

As Table 7.2 shows, Finland provides a right of priority of the state over the plaintiff's damages such that when compensation is paid to the plaintiff in the form of a damage award, the benefits from the state are deducted.[1664] Denmark and France also have set off rules under which social insurance benefits are deducted from victims' tort awards.[1665] The Danish and French systems combine a victim's benefit offset with a direct action of social insurance agencies to seek reimbursement of the compensation benefits already paid.[1666]

7.2.4 No right of recourse

The absence of a right of recourse of collateral sources -- specifically, social insurance agencies -- leaves all the decision to the victim, who is the one entitled to decide whether to pursue the tort claim against the tortfeasor. This system does not lead to an optimal outcome because if the victim does not pursue a tort claim, the social insurance system cannot be reimbursed for the benefits it provides. Victims are not fully compensated because they only receive benefits under social insurance, and tortfeasors

[1663] Fernando Gomez and Jose Penalva, Insurance and Tort: Coordination Mechanisms and Imperfect Liability Rules, 217-237, in INTERNALISIERUNGS DES RECHTS UND SEINE ÖKONOMISCHE ANALYSE. FESTSCHRIFT FÜR HANS-BERND SCHÄFER ZUM 65 GEBURTSTAGS, Jochen Bigus, Tomas Eger, and Georg von Wangenheim (eds.) Gabler Verlag, Wiesbaden (2008).
[1664] Martha Warren Neocelous, PERSONAL INJURY, PRACTICE AND PROCEDURE IN EUROPE, Cavendish Publishing Limited, 41 (1997).
[1665] Martha Warren Neocelous, PERSONAL INJURY, PRACTICE AND PROCEDURE IN EUROPE, Cavendish Publishing Limited, 20 (1997)
[1666] Ulrich Magnus, THE IMPACT OF SOCIAL SECURITY LAW ON TORT LAW, vol. 3 (Tort and Insurance Law), 76, Springer ed. (2003).

do not internalize accident costs because they are neither forced to compensate the victims nor forced to reimburse the social insurance agency.

If the victim decides to pursue a tort claim against the tortfeasor and prevails, the collateral benefit offset rule is often applied and the tort award is reduced by the compensation received from any other source.[1667] This situation does not lead to an optimal outcome either, because even though the victim is fully compensated, the tortfeasor does not internalize the full cost of the accident and the social insurance system is not reimbursed for the benefits paid. Hence, a positive externality for the tortfeasor is generated and part of the cost of the accident is born by society as a whole.

Sweden is the only country where social insurance agencies have no right of recourse against tortfeasors in order to recover the benefits provided to the victim.[1668]

Even though the idea not to provide this right of recourse to social insurance agencies is intended to reduce and avoid transaction costs, this perception is currently changing based on the belief that tortfeasors should be forced to internalize the cost of the accidents they cause.[1669]

8 The difficult balance between ex ante incentives, compensation and low administrative costs of the different coordination systems

In light of the different compensation systems available to victims of product-related accidents, coordination rules are necessary to preserve injurers' incentives while preventing victims' overcompensation. The implementation of the coordination rules

[1667] Ulrich Magnus, THE IMPACT OF SOCIAL SECURITY LAW ON TORT LAW, vol. 3 (Tort and Insurance Law), 181, Springer ed. (2003).
[1668] Ulrich Magnus, THE IMPACT OF SOCIAL SECURITY LAW ON TORT LAW, vol. 3 (Tort and Insurance Law), 183, Springer ed. (2003).
[1669] Ulrich Magnus, THE IMPACT OF SOCIAL SECURITY LAW ON TORT LAW, vol. 3 (Tort and Insurance Law), 183, Springer ed. (2003).

presented above -- the collateral source rule, the collateral benefits offset and the reimbursement action of the collateral source against the torfeasor, specifically the subrogation right -- have different effects on the compensation of victims, on tortfeasors' incentives for care, and on administrative costs (private litigation costs as well as public costs of the court system). Each of these dimensions conditions the efficient performance of each of the coordination rules.[1670]

The coordination mechanisms of the different compensation rules have remarkable effects on victims' compensation. The collateral source rule results in victims' overcompensation given that they are allowed to accumulate the compensation received from any of the available sources. In contrast, the reimbursement action of the insurer against the torfeasor in any of its forms results in victims receiving the same compensation to which they would be entitled to under tort. The result of the collateral benefit offset is different given that victims' tort awards are reduced by the benefits they receive from other compensation sources. Under this rule, as explained above, victims might be fully compensated but tortfeasors do not internalize the full costs of the damages caused and so are under-deterred.

With respect to the victims' incentives for care, the collateral source rule does not create efficient incentives.[1671] This is because the victim can receive compensation from both the collateral source and the tortfeasor. Therefore, both benefits accumulate and the final compensation is higher than the actual damage suffered. Thus, in such situations, the victim has incentives to engage in risky conduct since any resulting harm is overly

[1670] Michael G. Faure, Ton Hartlief and Niels J. Philipsen, Funding of personal injury litigation and claims culture, Evidence from the Netherlands, Utrecht Law Review, Volume 2, issue 2, 18 (2006) arguing that these costs should not be neglected.

[1671] Fernando Gomez and Jose Penalva, Insurance and Tort: Coordination Mechanisms and Imperfect Liability Rules, 217-237, in INTERNALISIERUNGS DES RECHTS UND SEINE ÖKONOMISCHE ANALYSE. FESTSCHRIFT FÜR HANS-BERND SCHÄFER ZUM 65 GEBURTSTAGS, Jochen Bigus, Tomas Eger, and Georg von Wangenheim (eds.) Gabler Verlag, Wiesbaden (2008).

compensated ex post.[1672] Consequently, the collateral source rule may generate the opposite effect than it intends.

From the perspective of the tortfeasor's incentives for care, the collateral source rule and the subrogation or the direct action rules result in efficient care because under any of these rules the tortfeasor faces a damage payment equal to the cost of the injury caused to victim,[1673] which is the socially optimal outcome.[1674] Hence, none of these rules has an impact on accident deterrence. But the outcome is different when the collateral benefit offset rule is in place since it does not result in a socially optimal outcome[1675] because it allows for the victim's full compensation and thus causes an indirect effect through which the compensation under tort is reduced the higher the benefits from the alternative compensation schemes are. Therefore, the injurer's incentives for care are diluted in light of the externality generated by the deduction of the victim's benefits from the tort award that results in tortfeasors being exposed to a lower level of liability than the actual damage they caused.[1676] In contrast, under subrogation

[1672] The marginal utility of money is not equal before and after the accident has taken place and therefore the victim does not have optimal incentives to adopt care. See Fernando Gómez Pomar, Tort Liability and Other means of redress: "collateral source rule" and related topics, Indret 1/00, 6-7 (2000). Available at www.indret.com/code/getPdf.php?id=29&pdf=005_en.pdf

[1673] Fernando Gomez and Jose Penalva, Insurance and Tort: Coordination Mechanisms and Imperfect Liability Rules, 217-237, in INTERNALISIERUNGS DES RECHTS UND SEINE ÖKONOMISCHE ANALYSE. FESTSCHRIFT FÜR HANS-BERND SCHÄFER ZUM 65 GEBURTSTAGS, Jochen Bigus, Tomas Eger, and Georg von Wangenheim (eds.) Gabler Verlag, Wiesbaden (2008).

[1674] Steven Shavell, ECONOMIC ANALYSIS OF ACCIDENT LAW, 256, Cambridge: Harvard University Press (1987) where it showed that insurance subrogation was the preferred by victims and lead to a pareto-optimal outcome. See also Patricia M. Danzon, Tort Reform and the Role of Government in Private Insurance Markets, 13 Journal of Legal Studies 3, 517-532 (1984).

[1675] Fernando Gomez and Jose Penalva, Insurance and Tort: Coordination Mechanisms and Imperfect Liability Rules, 217-237, in INTERNALISIERUNGS DES RECHTS UND SEINE ÖKONOMISCHE ANALYSE. FESTSCHRIFT FÜR HANS-BERND SCHÄFER ZUM 65 GEBURTSTAGS, Jochen Bigus, Tomas Eger, and Georg von Wangenheim (eds.) Gabler Verlag, Wiesbaden (2008).

[1676] See also Paul H. Rubin and Joanna M. Shepherd, Tort Reform and Accidental Deaths, Journal of Law & Economics, University of Chicago Press, vol. 50, 221-238 (2007) for an empirical analysis of the impact of these rules on the torfeasor's incentives for care. See also R. B. Stewart, Liability for Natural Resource Injury: Beyond Tort. Revesz R. L. & Stewart, R. B. (editors). Analyzing Superfund: Economics, Science and Law, Washington, 219-241 (1995) discussing this issue in the context of liability for environmental harm.

and the collateral source rule, the tortfeasor is exposed to the full cost of the harm caused to the victim and this results in optimal incentives for care.

Another important parameter that should be taken into account when evaluating the performance of the different coordination systems is the administrative costs involved in their implementation.[1677] Subrogation is often considered to involve significantly high administrative costs because either the victim or the collateral source -- private or public insurance -- will pursue the liability claim against the tortfeasor and they will have to bear the significant costs of the court system.[1678] Similarly, under the collateral source rule, the victim also has incentives to pursue her claim under tort as long as the expected tort award is significantly high so that she will be fully -- or even overly -- compensated for the damage suffered. As a result, under this rule, administrative and litigation costs, both private and social costs, are significant.

The collateral benefits offset rule, under which the victim's compensation under tort is reduced by the compensation the victim receives from collateral sources, reduces the victim's incentives to pursue her claim under tort.[1679] This rule is the coordination system that involves the lowest administrative and transaction costs given that the collateral source -- public and private insurers -- will not pursue the victim's claim under tort and hence will not incur the costs involved in litigation. In addition, the victims'

[1677] For an analysis of the performance of the different coordination rules see in general Fernando Gomez and Jose Penalva, Insurance and Tort: Coordination Mechanisms and Imperfect Liability Rules, 217-237, in INTERNALISIERUNGS DES RECHTS UND SEINE ÖKONOMISCHE ANALYSE. FESTSCHRIFT FÜR HANS-BERND SCHÄFER ZUM 65 GEBURTSTAGS, Jochen Bigus, Tomas Eger, and Georg von Wangenheim (eds.) Gabler Verlag, Wiesbaden (2008).

[1678] See Steven Shavell, The Fundamental Divergence Between The Private And The Social Motive To Use The Legal System, 26 J. Legal Stud. 2, 575-612, 579 (1997) and Fernando Gomez and Jose Penalva, Insurance and Tort: Coordination Mechanisms and Imperfect Liability Rules, 217-237, in INTERNALISIERUNGS DES RECHTS UND SEINE ÖKONOMISCHE ANALYSE. FESTSCHRIFT FÜR HANS-BERND SCHÄFER ZUM 65 GEBURTSTAGS, Jochen Bigus, Tomas Eger, and Georg von Wangenheim (eds.) Gabler Verlag, Wiesbaden (2008).

[1679] Further, the cost of each trial is also reduced given that only the tort award needs to be determined and the collateral benefits are reduced. See Patricia M. Danzon, The Frequency and Severity of Medical Malpractice Claims, Law and Contemporary Problems 49, 57-72 (1986) where evidence is presented of the effects of the set-off rule inducing reductions in the frequency and amount of claims in medical malpractice.

incentives to pursue claims under tort significantly decrease. Consequently, when compared to the other coordination rules, the administration and litigation costs involved in the implementation of the collateral benefit offset rule are the lowest.

Table 7.1

Performance of the Coordination Systems of Alternative Compensation Schemes with respect to three dimensions

	Victim's compensation	**Tortfeasor's incentives for care**	**Administrative costs**
Collateral source rule	Suboptimal	Optimal	High
Subrogation right	Optimal	Optimal	Highest
Collateral benefit offset	Optimal	Suboptimal	Low

In sum, it is well settled in the literature that when liability under tort operates perfectly, any of the coordination rules result in an efficient outcome. But whenever liability under tort functions imperfectly, only subrogation rights of the insurer against the tortfeasor result in an optimal outcome from both the tortfeasor's and the victim's perspectives.[1680] From the tortfeasor's perspective, the availability of subrogation rights results in optimal incentives for care and hence in the full internalization of the damages caused given that the tortfeasor is exposed to the full liability costs derived from the accident. From the victim's perspective, subrogation allows the victim to be fully compensated, if not from the tortfeasor under tort then from the collateral source. Hence, under subrogation, potential victims have incentives to purchase insurance coverage to

[1680] Steven Shavell, ECONOMIC ANALYSIS OF ACCIDENT LAW, 235-255 Cambridge (Mass.) (1987) and Alan O. Sykes, Subrogation and Insolvency, 30 J. Leg. Stud. 2, 383- 399 (2001) available at http://ideas.repec.org/a/ucp/jlstud/v30y2001i2p383-99.html.

make them whole.[1681] Despite creating efficient incentives for compensation and for deterrence, subrogation rights involve high administrative costs that should also be taken into account when determining the coordination system that would perform best in a certain context.

9 The variability of the coordination systems implemented in the different European member states

In most European countries social insurance authorities bear the financial burden of compensating accident victims -- including victims of product-related accidents -- and are entitled to seek reimbursement from tortfeasors -- in the case of products, against the manufacturers of defective products that cause harm.[1682]A remarkable exception to this general scheme is Sweden, where social insurance agencies have no recourse against the tortfeasor that caused the victim's damages.[1683]

The Mediterranean countries, such as Italy and Greece, have similar systems that include reimbursement rights for social insurance agencies. In Italy, social insurance agencies have a direct right of reimbursement against tortfeasors for personal damages.[1684] This direct right is exercised in an administrative procedure.[1685] If the victim

[1681] The tortfeasor could not fully compensate the injured victim under tort in cases where, for example, the injured victim could not meet the burden of proof; there was judicial error or the tortfeasor was judgment proof and hence did not have sufficient assets to pay the liability award to the victim.

[1682] See generally Ulrich Magnus, THE IMPACT OF SOCIAL SECURITY LAW ON TORT LAW, vol. 3 (Tort and Insurance Law), 106, Springer ed. (2003) for an overview of the different social insurance systems in the different European countries and the different coordination mechanisms adopted when interacting with tort liability. However, could not gather information about Ireland, Luxemburg and Portugal in the different sources consulted.

[1683] Ulrich Magnus, THE IMPACT OF SOCIAL SECURITY LAW ON TORT LAW, vol. 3 (Tort and Insurance Law), 183, Springer ed. (2003). See also Susan Narita, Product Liability Claims in Europe, Swiss Reinsurance Company, Zurich, 32 (1996) noting that in 1996 there was a project to introduce reimbursement right from Swedish social insurance agencies. However, this revision does not seem to have resulted in introducing such claim.

[1684] However, recourse actions do not seem to be "fully coordinated." See Ulrich Magnus, THE IMPACT OF SOCIAL SECURITY LAW ON TORT LAW, vol. 3 (Tort and Insurance Law), 135, Springer ed. (2003). See

instead pursues her tort claim, then the victim must reimburse the Italian social insurance system for the benefits received.[1686] The structure in Greece is quite similar to the one in Italy. Greece allows a reimbursement right for the social insurance agency against the tortfeasor for all benefits the agency has granted to the victim. Greek law aims at avoiding the victim's overcompensation and enables the exercise of the reimbursement right against the tortfeasor -- under negligence or under strict liability -- or under another collateral source such as private insurance.[1687]

Northern European countries also have adopted a right of recourse of social insurance agencies against tortfeasors for the benefits paid. This is the system in force in Denmark, France and Germany. In Denmark, social insurance systems may seek reimbursement for the sickness benefits provided while in France, social insurance agencies may seek reimbursement as long as the benefits provided to the victim are a consequence of the accident and damages caused by the tortfeasor.[1688] Under French, Danish and German law, the reimbursement right of social insurance agencies is independent from the victim's potential tort claim against the tortfeasor.[1689] But in Germany, there is no record of any decision where social insurance agencies have pursued reimbursement.[1690] Under French and Danish law, the social insurance agencies'

Alberto Cavaliere, Product Liability in the European Union: Compensation and Deterrence Issues, European Journal of Law and Economics, 18: 299–318, 307 (2004) noting that the reimbursement right against a product manufacturer has never been exercised in Italy.

[1685] Ulrich Magnus, THE IMPACT OF SOCIAL SECURITY LAW ON TORT LAW, vol. 3 (Tort and Insurance Law), 135, Springer ed. (2003).

[1686] Martha Warren Neocelous, PERSONAL INJURY, PRACTICE AND PROCEDURE IN EUROPE, Cavendish Publishing Limited, 89 (1997).

[1687] The Greek reimbursement right against another collateral source such as private insurance would be limited to the amount of benefits provided under the insurance coverage purchased. This right is granted by the Sickness Benefits Act, Compulsory Health Insurance Act and the Invalidity insurance Act. Ulrich Magnus, THE IMPACT OF SOCIAL SECURITY LAW ON TORT LAW, vol. 3 (Tort and Insurance Law), 129, Springer ed. (2003).

[1688] Martha Warren Neocelous, Personal injury, Practice and Procedure in Europe, Cavendish Publishing Limited, 52 (1997).

[1689] Ulrich Magnus, THE IMPACT OF SOCIAL SECURITY LAW ON TORT LAW, vol. 3 (Tort and Insurance Law), 76, Springer ed. (2003).

[1690] Alberto Cavaliere, Product Liability in the European Union: Compensation and Deterrence Issues, European Journal of Law and Economics, 18: 299–318, 307 (2004).

reimbursement right and the victim's tort claim are combined with a collateral benefit offset rule such that if the injured victim pursues a tort claim, any benefit received from the Danish or French social insurance services is deducted from the victim's tort award.[1691]

Belgian[1692] and Dutch[1693] social insurance agencies are also entitled to reimbursement of the benefits paid to injured victims but such recourse action against the tortfeasor is limited to the amount of benefits payments made by the social insurance, as long as this compensation does not exceed the damages due by the tortfeasor.[1694] It should be noted that under Belgian law, compensation under tort -- including product liability -- is justified whenever social insurance benefits are not sufficient to compensate the victim for the harm suffered.[1695] Dutch law does not give priority to the claim of the social insurance right of reimbursement and the victim's claim under tort even though in practice Dutch social insurance agencies generally give priority to the victim's tort claim against the tortfeasor.[1696]

Finland gives a subrogation right to social insurance agencies to step into the position of injured victims for the purpose of seeking compensation under tort.[1697] Based

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[1691] See Martha Warren Neocelous, PERSONAL INJURY, PRACTICE AND PROCEDURE IN EUROPE, Cavendish Publishing Limited, 20 (1997) noting that Danish social insurance agencies have a right of reimbursement since 1996.

[1692] Ulrich Magnus, THE IMPACT OF SOCIAL SECURITY LAW ON TORT LAW, vol. 3 (Tort and Insurance Law), 38, Springer ed. (2003).

[1693] See Martha Warren Neocelous, PERSONAL INJURY, PRACTICE AND PROCEDURE IN EUROPE, Cavendish Publishing Limited, 111 (1997) and Ulrich Magnus, THE IMPACT OF SOCIAL SECURITY LAW ON TORT LAW, Tort and insurance Law vol. 3, 160 (2003).

[1694] Ulrich Magnus, THE IMPACT OF SOCIAL SECURITY LAW ON TORT LAW, vol. 3 (Tort and Insurance Law), 49, Springer ed. (2003).

[1695] This situation contrasts with regulation in France, Finland and Spain where compensation by social insurance systems does not prevent the injured victim from seeking compensation under tort. See Commission of the European Communities, Green Paper on Product Liability, COM (1999) 396 final, p. 8 (1999).

[1696] See Michael G. Faure, Ton Hartlief and Niels J. Philipsen, Funding of personal injury litigation and claims culture, Evidence from the Netherlands, Utrecht Law Review, Volume 2, issue 2 (2006) noting that Dutch social insurance agencies generally give priority to the victim's tort claim against the tortfeasor even though from a legal perspective, there is no priority between the social insurance right of reimbursement and the victim's claim under tort.

[1697] Martha Warren Neocelous, PERSONAL INJURY, PRACTICE AND PROCEDURE IN EUROPE, Cavendish Publishing Limited, 41 (1997).

on this subrogation right, Finnish social insurance agencies enjoy a right of priority over the victim's claim under tort. When Finnish social insurance agencies do not exercise this right and injured victims instead pursue their tort claims and prevail, the collateral benefit offset rule in force requires deducting the benefits already received from social insurance from the tort award.[1698]

English social security agencies had no right of recourse until 1989.[1699] Today social insurance agencies have a statutory claim against the tortfeasor.[1700] The only precondition for this subrogated right is that the benefits obtained must have been a consequence of the accident caused by the tortfeasor. The agency's recourse claim is independent of whether the victim would sue the tortfeasor. If she does, any social insurance benefit received will be deducted from the damage award.[1701] However, the reimbursement right is hardly ever exercised given that in 1989, a Compensation Recovery Unit was established with the purpose of ensuring that insurers would seek the benefits paid to the injured victim as a result of an accident.[1702] The party responsible for the victim's damages has the duty to reimburse the full amount of benefits to the Compensation Recovery Unit.[1703] Given that social insurance is reimbursed for the benefits paid to injured victims through the Compensation Recovery Unit, the recourse action is very rarely exercised since the economic incentives to litigate are reduced when

[1698] Martha Warren Neocelous, PERSONAL INJURY, PRACTICE AND PROCEDURE IN EUROPE, Cavendish Publishing Limited, 41 (1997).
[1699] Ulrich Magnus, THE IMPACT OF SOCIAL SECURITY LAW ON TORT LAW, vol. 3 (Tort and Insurance Law), 63, Springer ed. (2003).
[1700] Article 30 of the English Social insurance Act of July 5, 1985.
[1701] Martha Warren Neocelous, PERSONAL INJURY, PRACTICE AND PROCEDURE IN EUROPE, Cavendish Publishing Limited, 52 (1997).
[1702] Ulrich Magnus, THE IMPACT OF SOCIAL SECURITY LAW ON TORT LAW, vol. 3 (Tort and Insurance Law), 67, Springer ed. (2003).
[1703] The collection of the Compensation Recovery Unit is a consequence of the duty imposed on the injurer or whoever compensated the victim to inquire about the benefits paid to the victim. See Martha Warren Neocelous, PERSONAL INJURY, PRACTICE AND PROCEDURE IN EUROPE, Cavendish Publishing Limited, 31 (1997).

social insurance agencies recover the expenses they incurred in when they compensated the victim.[1704]

Spain presents a mixed situation where, depending on the context in which the product accident takes place and hence the court with jurisdiction over the issue, different coordination mechanisms are applicable.[1705] The general rule of Spanish civil law does not preclude an injured victim who has already received insurance benefits (regardless whether these benefits are private or public) from seeking compensation under tort. At the same time, Spanish social insurance agencies have a right of recourse against the person who causes the injury with respect only to the victim's medical expenses previously paid by the social insurance system.[1706] This reimbursement right can be exercised judicially against the tortfeasor regardless of the victim's behavior.[1707] The coordination between both compensation sources can be articulated through the collateral source rule[1708] or through the collateral benefits offset rule applied by the third section of the Spanish Supreme Court (the administrative law section),[1709] under which

[1704] Ulrich Magnus, THE IMPACT OF SOCIAL SECURITY LAW ON TORT LAW, vol. 3 (Tort and Insurance Law), 67, Springer ed. (2003).
[1705] See Fernando Gómez Pomar, Responsabilidad extracontractual y otras fuentes de reparación de daños: "Collateral Source Rule" y afines, InDret 1/00, available at www.indret.com presenting an overview of the different coordination mechanisms available under Spanish law and their interpretation and implementation by the different sections of the Spanish Supreme Court.
[1706] See Article 127.3 of the Royal Law Decree RDL 1/1994 of June 20, approving the General Law on Social insurance (BOE 154, p. 20658 of June 29, 1994). The text of the Royal Decree is available at http://www.boe.es/aeboe/consultas/bases_datos/doc.php?id=BOE-A-1994-14960.
[1707] Ulrich Magnus, THE IMPACT OF SOCIAL SECURITY LAW ON TORT LAW, vol. 3 (Tort and Insurance Law), 172, Springer ed. (2003).
[1708] The collateral source rule, followed by the Civil and Labor Law sections of the Spanish Supreme Court, is the rule applied in civil, as well as in labor law cases. See, for example, Judgment of the Spanish Supreme Court (Civil Section), num. 409/1999, of May 18, 1999 (Hon. Ignacio Sierra Gil de la Cuesta) (RJ 1999\4112); Spanish Supreme Court (Civil Section), Auto of April 15, 1997 (RJ 1997\5280); Judgment of the Spanish Supreme Court (Labor Law Section), num. 124/1997, of February 2nd, 1998 (Hon. Pablo Manuel Cachón Villar) (RJ 1998/3250) and Judgment of the Spanish Supreme Court (Labor Law section), num. 1663/2002, of February 7th, 2003 (Hon. José María Botana López)(RJ 2004\1828).
[1709] The collateral benefit offset rule is the coordination mechanism used for compensating victims of product-related accidents. See articles 132 and 133 of the Royal Law Decree 1/2007 of November 16, for which approved the merged text of the General Law for the Defense of Consumers and users and other complementary laws (BOE núm. 287, de 30-11-2007, pp. 49181-49215).

compensation received by the injured victim from different sources such as public and private insurance are deducted from liability awards obtained under tort.[1710]

The third possibility, the subrogation right, is also contemplated by Spanish legislation even though this is not the solution generally implemented when coordinating compensation awards received from different sources.[1711] As mentioned earlier, this solution is the most efficient one given that the tortfeasor internalizes the full cost of the damage caused to the injured victim, the victim is made whole and is not over-compensated, and the insurer -- private or public -- is reimbursed for the amount of benefits paid to the injured victim.[1712]

The subrogation right of the insurer against the tortfeasor is the coordination rule contemplated by the Spanish transposition law of the product liability directive[1713] within certain limits.[1714] Additionally, social insurance law also gives social insurance agencies a direct claim against the tortfeasor under tort to seek reimbursement of the amount already paid to the injured victim.[1715]

[1710] See for example, Judgment of the Spanish Supreme Court (Administrative law section), num. 1770/1994, of March 27, 1998 (Hon. Francisco José Hernando Santiago) (RJ 1998/2942) and Judgment of the Spanish Supreme Court (Administrative law section), num 2694/1995, of April 17, 1998 (Hon. José Manuel Sieira Míguez)(RJ 1998\3832).

[1711] Fernando Gomez and Jose Penalva, Insurance and Tort: Coordination Mechanisms and Imperfect Liability Rules, 217-237, in INTERNALISIERUNGS DES RECHTS UND SEINE ÖKONOMISCHE ANALYSE. FESTSCHRIFT FÜR HANS-BERND SCHÄFER ZUM 65 GEBURTSTAGS, Jochen Bigus, Tomas Eger, and Georg von Wangenheim (eds.) Gabler Verlag, Wiesbaden (2008).

[1712] See Alan O. Sykes, Subrogation and Insolvency, 30 J. Leg. Stud. 383, 388 (2001) available at http://ideas.repec.org/a/ucp/jlstud/v30y2001i2p383-99.html. See also Fernando Gomez and Jose Penalva, Insurance and Tort: Coordination Mechanisms and Imperfect Liability Rules, 217-237, in INTERNALISIERUNGS DES RECHTS UND SEINE ÖKONOMISCHE ANALYSE. FESTSCHRIFT FÜR HANS-BERND SCHÄFER ZUM 65 GEBURTSTAGS, Jochen Bigus, Tomas Eger, and Georg von Wangenheim (eds.) Gabler Verlag, Wiesbaden (2008).

[1713] Articles 132 and 133 of the Royal Law Decree 1/2007 of November 16, for which approved the merged text of the General Law for the Defense of Consumers and users and other complementary laws (BOE núm. 287, de 30-11-2007, pp. 49181-49215).

[1714] The liability limits are established in article 141 (a), that provides for a deductible of 390.66 euros, and 141 (b) that provides for a maximum liability of 63 106 270.66 euros.

[1715] See article 127.3 of the Royal Law Decree RDL 1/1994 of June 20, approving the General Law on Social insurance (BOE 154, p. 20658 of June 29, 1994). The text of the Royal Decree is available at http://www.boe.es/aeboe/consultas/bases_datos/doc.php?id=BOE-A-1994-14960.

10 The collision of alternative compensation systems in Europe: reaching an equilibrium between product liability and struggling social insurance systems

All coordination systems present advantages and disadvantages that have different effects on victims' compensation, tortfeasors' incentives for care, and administrative and litigation costs. The choice of one coordination system over another should turn on the priority given to compensation, deterrence or on the reduction of administrative costs in a given situation.

One of the parameters of special importance when discussing the efficiency and effects of the different coordination systems in European product liability is the public nature of the most important collateral source in compensating victims of product-related accidents: social insurance.

As explained in Chapter 2, the European product liability directive intended to provide a high level of protection to victims of product-related accidents and to make it easier for them to seek compensation for the harm suffered.[1716] The adoption of strict product liability was expected to increase the number of product liability claims in Europe but as shown earlier, the number of judgments as well as the amount of the damage awards is still significantly low, especially when compared to those in the United States.[1717]

In addition to liability under tort, victims of product related accidents also have collateral sources of compensation such as private insurance coverage and public insurance benefits.

[1716] Paula Giliker, Strict Liability for Defective Products: The Ongoing Debate, 24 Business Law Review 4, 87-90 (2003).
[1717] Green Paper: Access of consumers to justice and the settlement of consumer disputes in the Single market, COM/93/576FINAL, 56, November 16 (1993). Available at http://europa.eu/legislation_summaries/other/l32023_en.htm

The introduction of the product liability directive has not had a significant effect on the private insurance coverage purchased,[1718] and in some cases such as in Spain, it may have even resulted in lower levels of insurance coverage of potential tortfeasors subject to the different transposition laws of the member states.[1719] Considering the role of social insurance systems in European countries, private insurance coverage for product-related accidents might not have been necessary. Social insurance programs provide a comprehensive safety net for victims of product related accidents through a system of no-fault,[1720] incomplete, but immediate compensation to injured victims. Hence, the incentives to purchase private insurance coverage as well as the incentives to pursue a product liability claim are diluted.[1721]

In light of the different compensation systems available and the importance of social insurance benefits for compensating victims of product related accidents, it becomes necessary to coordinate the different systems involved in order to align the incentives of the different parties involved and ensure optimal outcomes. If European product liability would prioritize the compensation of victims over accident deterrence, a collateral source rule would be preferred to the collateral benefits offset solution because it would ensure that the victim was fully -- or even overly -- compensated both from the tort system and from the collateral source. The questionable issue would be whether it is

[1718] See Dana Kerr, Yu-Len Ma, and Joan T. Schmit, Is liability a substitute for social insurance?, Proceedings of the International Insurance Society, New York. (2004) arguing for the existence of a negative relationship between liability insurance premiums and the scope of social insurance programs. For an opposite conclusion see G. Wagner, Tort liability and insurance: Comparative report and final conclusions, in Gerhard Wagner (ed) Tort Law and Liability Insurance, Wien: Springer (2005).

[1719] See Luis Ramírez, RC alerta roja: sanidad y productos son los dos sectores más sensibles: el nivel de cobertura se ha reducido notablemente, Mercado previsor, núm. 400, 32-33 (2004) noting that since the product liability directive was introduced the level of insurance coverage purchased by potential tortfeasors in Spain has decreased.

[1720] Ulrich Magnus, THE IMPACT OF SOCIAL SECURITY LAW ON TORT LAW, vol. 3 (Tort and Insurance Law), 230, Springer ed. (2003).

[1721] Lawrence C. Mann and Peter R. Rodrigues, The European Directive on PL: the promise or progress ?, 18 Ga. J. Int'l & Comp. L. 391, 415 (1988) arguing that there is a lower need to use product liability litigation in order to have access to necessary and sufficient medical, rehabilitative and living assistance in Europe. However, empirical support for this conclusion is not available. See Lawrence C. Mann and Peter R. Rodrigues, The European Directive on PL: the promise or progress?, 18 Ga. J. Int'l & Comp. L. 391, fn 115 (1988).

reasonable for part of that overcompensation to come from public funds.[1722] If accident deterrence was the major goal of the system, again a collateral source rule or a reimbursement right would achieve the efficient outcome.

The special question arising in the compensation of victims of product-related accidents in Europe is the existence, role and importance of a publicly funded collateral source such as the no-fault social insurance system.[1723] The existence of the welfare state provides basic benefits to injured victims that are necessary right after these victims have been injured without having to go through an often lengthy litigation process of pursuing the claim for damages.[1724] Under this structure a collateral benefit offset rule combined with a subrogation right could arguably be preferred to the collateral source rule.[1725] However, one of the potential problems of this solution is the certainly high private and public costs of combining two compensation mechanisms like social insurance and tort with their significant administrative costs.[1726]

One of the basic assumptions entailed when analyzing the differences in all these coordination systems and their outcomes is that the collateral source -- either private or publicly funded -- will seek reimbursement from the tortfeasor for the benefits already paid. But private and public insurers do not have the same incentives to do so and practical evidence suggests that neither of them do it frequently. As explained earlier, most European member states provide for a reimbursement right in favor of social

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[1722] Richard Lewis, DEDUCTING BENEFITS FROM DAMAGES FOR PERSONAL INJURY, 113, Oxford University Press (2000).

[1723] See Alfred E. Mottur, The European Product Liability Directive: A Comparison With U.S. Law, An Analysis Of Its Impact On Trade, And A Recommendation For Reform So As To Accomplish Harmonization And Consumer Protection, 25 Law & Pol'y Int'l Bus. 983, 1006-1007 (1994) arguing that the existence and availability of mandatory health care coverage dilutes the victim's incentives to bring a product liability claim and hence seek compensation under tort.

[1724] Richard Lewis, DEDUCTING BENEFITS FROM DAMAGES FOR PERSONAL INJURY, 116, Oxford University Press (2000).

[1725] Shavell has shown that this solution leads to the Pareto-optimal outcome. Steven Shavell, ECONOMIC ANALYSIS OF ACCIDENT LAW, 235-255, Cambridge (Mass.) (1987).

[1726] See Richard W. Wright, The principles of product liability, 26 Rev. Litig. 1067, 1096 (2007) suggesting the use of a universal and publicly funded compensation system of victims of product-related accidents in order to avoid the high administrative costs involved in the tort system.

insurance systems against the tortfeasor for the benefits already paid to the injured victim. However, such action is hardly ever pursued by social insurance systems.

The product liability directive was adopted over twenty years ago and the level of product liability litigation initiated by either injured victims,[1727] private insurance companies or social insurance agencies, has been and still today remains remarkably low.[1728] From a litigation perspective, the product liability directive has not had a significant impact.[1729] It is difficult to provide quantitative evidence of this situation in light of the lack of a systematic collection of information regarding the identity of the tortfeasor or the product that might have caused damages to the victim and the benefits paid to the victim.[1730] The lack of a systematic collection of information about product liability accidents, health care provided to injured victims and the benefits received by them might explain why, in light of the difficulty of meeting the required burden of proof, social insurance systems hesitate and do not exercise their subrogation right against tortfeasors in order to seek reimbursement for the benefits already paid to the victim.[1731] Considering the new technologies available today, the lack of collection of information seems a poor explanation of this situation but up to today, the information available on product accidents in the different European states is scarce.[1732] Regardless of its cause,

[1727] Eleonora Rajneri, Interaction Between the European Directive on Product Liability and the Former Liability Regime in Italy, Global Jurist Topics, Vol. 4, Issue 1 num. 3, 8 (2004).
[1728] Jane Stapleton, Bugs in Anglo-American Products Liability, 295, in PRODUCT LIABILITY IN COMPARATIVE PERSPECTIVE, edited by Duncan Fairgrieve, Cambridge (2005).
[1729] Eleonora Rajneri, Interaction Between the European Directive on Product Liability and the Former Liability Regime in Italy, Global Jurist Topics, Vol. 4, Issue 1 num. 3, 8 (2004).
[1730] The European Commission has initiated different projects -- the IPP-project "A surveillance based model to calculate the direct medical costs in Europe: Eurocost;" the ECOSA European Working Group and the EHLASS project on Collection of data on Home and Leisure Accidents (former EHLASS) -- in order to be able to assess and compare the direct medical costs afforded by public hospitals in the different member states as well as identify which of these costs are caused by product-related accidents. Their success has been quite limited.
[1731] Willem H. van Boom/ Michael G. Faure, Concluding Remarks to the book Shifts in Compensation between Private and Public Systems, in Tort and Insurance Law in Shifts in Compensation between Private and Public Systems, Willem H. van Boom/ Michael G. Faure (eds.), Tort and Insurance Law, vol. 22, 219-235 (2007) noting that information on medical costs and benefits as well as their variation among the different member states is a necessary step in the economic assessment of injury measures in Europe.
[1732] Richard Lewis, DEDUCTING BENEFITS FROM DAMAGES FOR PERSONAL INJURY, 114, Oxford University Press (2000).

practical evidence shows that social insurance systems do not seek reimbursement from the tortfeasor for the benefits paid to the victim.[1733]

In addition to the reimbursement right to which social insurance systems are entitled, injured victims are not precluded from seeking compensation through the tort system for damages not covered by their social insurance benefits.[1734] The legal regimes of the different European member states provide coordination systems between damage awards a victim may receive through tort and the compensation received from social insurance.

Injured victims, however, often lack incentives to pursue their product liability claims[1735] due to several factors that have been aleady explained: the negligence elements of the Directive,[1736] procedural rules that become procedural barriers to claims, substantive legal aspects of product liability regulation that do not contribute to make litigation attractive for injured victims, and the general cultural attitudes of Europeans against the idea of litigating.[1737]

But the most important factor that may dissuade Europeans from litigating is the availability of immediate compensation regardless of fault through social insurance.[1738]

[1733] See Alberto Cavaliere, Product Liability in the European Union: Compensation and Deterrence Issues, European Journal of Law and Economics, 18: 299–318, 307 (2004) noting that there is no record showing social insurance agencies in Germany, Italy or Spain pursuing the reimbursement action they are entitled to.
[1734] Alfred E. Mottur, The European Product Liability Directive: A Comparison With U.S. Law, An Analysis Of Its Impact On Trade, And A Recommendation For Reform So As To Accomplish Harmonization And Consumer Protection, 25 Law & Pol'y Int'l Bus. 983, 1006-1007 (1994).
[1735] Ulrich Magnus, THE IMPACT OF SOCIAL SECURITY LAW ON TORT LAW, vol. 3 (Tort and Insurance Law), 242, Springer ed. (2003) arguing that injured victims do not have incentives to bring their product claims.
[1736] Mark Mildred, Litigation Rules and Culture: The European Perspective, 23 N.Y.U. Rev. L. & Soc. Change 433, 435 (1997) noting that the standard of liability under the Directive is complicated to determine based on the vagueness of defining important terms such as producer and defect.
[1737] Mark Mildred, Litigation Rules and Culture: The European Perspective, 23 N.Y.U. Rev. L. & Soc. Change 433, 441 (1997). See also J.G. Fleming, Mass Torts, 42 Am. J. Comp. L. 507, 519 (1994) noting that Europeans do not rely on the judicial process as much as U.S. citizens do.
[1738] Alfred E. Mottur, The European Product Liability Directive: A Comparison With U.S. Law, An Analysis Of Its Impact On Trade, And A Recommendation For Reform So As To Accomplish Harmonization And Consumer Protection, 25 Law & Pol'y Int'l Bus. 983, 1006-1007 (1994). See also Ulrich Magnus, THE IMPACT OF SOCIAL SECURITY LAW ON TORT LAW, vol. 3 (Tort and Insurance Law), 241, Springer ed. (2003) noting that a large part of the costs of the victim's personal injuries is compensated via social security and not under tort law.

Victims of product-related accidents in Europe turn to social insurance programs to seek remedies for their personal and economic injuries[1739] and they appear to accept the trade-off between the immediate but incomplete compensation they receive under this system instead of full compensation they could receive under tort, with its costly and uncertain litigation.[1740] Even though social insurance agencies could exercise their reimbursement right against the tortfeasor, they do not seem to do so either.

The fact that injured victims do not pursue their product liability claims only partially explains the lack of effectiveness of product liability in the different European member states. Deterrence could also be achieved through social insurance, if insurance agencies would pursue reimbursement actions against tortfeasors for the benefits paid to victims for the personal injuries suffered.[1741] However, social insurance systems do not seem to do so and hence do not exercise the subrogation action available to them.[1742] In light of the scarce number of product liability decisions and the parties involved, it seems that neither injured victims nor social insurance systems have incentives to pursue their product liability claims under tort.[1743]

[1739] See Anita Bernstein, L'harmonie Dissonante: Strict Products Liability Attempted In The European Community, 31 Va. J. Int'l L. 673, 688-689 (1991) and Patrick Thieffry et al., Strict product liability in the EEC: Implementation, Practice and Impact on U.S. Manufacturers of Directive 85/374, 25 Tort & Ins. Law Journal 65, 90 (1989).

[1740] This is a well settled view in the literature. See Alfred E. Mottur, The European Product Liability Directive: A Comparison With U.S. Law, An Analysis Of Its Impact On Trade, And A Recommendation For Reform So As To Accomplish Harmonization And Consumer Protection, 25 Law & Pol'y Int'l Bus. 983, 1006-1007 (1994) and Anita Bernstein, L'harmonie Dissonante: Strict Products Liability Attempted In The European Community, 31 Va. J. Int'l L. 673, 688-689, 714-715 (1991) noting that seeking compensation under tort involves a more expensive and uncertain process than receiving social insurance benefits.

[1741] See Table 7.2 at the end of this chapter. See generally Ulrich Magnus, THE IMPACT OF SOCIAL SECURITY LAW ON TORT LAW, vol. 3 (Tort and Insurance Law), 288, Springer ed. (2003). See also Alf Erling Risa, The Welfare State as provider of accident insurance in the workplace: efficiency and distribution in equilibrium, The Economic Journal, Vol. 105, no. 458, 129-144 (1995).

[1742] See Table 7.2 at the end of this chapter.

[1743] Andrew C. Spacone, Strict Liability in the European Union - Not a United States Analog, 5 Roger Williams U. L. Rev. 341,. 373-374 (2000) noting that some suggest that because of the respect Europeans have for businesses, the lack of tort litigation would be a result of a conscious decision to give a free pass to manufacturers.

The outcome of this situation in product liability accidents in Europe is remarkably inefficient: Victims are under-compensated through being compensated by social insurance benefits and have no incentives to pursue their claims under tort and social insurance programs bear the cost of the benefits provided to injured victims and do not have incentives to exercise their subrogation rights.[1744] As a result, tortfeasors do not fully internalize the cost of the accidents they cause and consequently are not effectively deterred given that they are not fully exposed to the full costs of the damages they cause and social insurance systems bear most of the product-related accident costs.

The low impact of the product liability directive together with the existing dislocation of product-related accidents costs result in a lack of an effective product liability regime in Europe. Even though this situation and its outcome have come to be accepted, they generate a significant amount of waste in terms of incentive creation, damage internalization and administrative costs.

Over the last three decades, European welfare states have experienced development and economic pressures[1745] with many years of economic crisis, demographic pressures[1746] including the need of long-term care and the drop in birth rates,[1747] recent labor market changes and changes in family structures with the participation of married women in the labor market and the emergence of new family forms.[1748] All these parameters together have lead to a debate on welfare systems and

[1744] Göran Skogh, Public insurance and accident prevention, The international review of law and economics, vol 2, 67-80 (1982). See also James A. Henderson, Jr., Coping With the Time Dimension in Products Liability, 69 Cal. L. Rev. 919, 935-38 (1981) noting that when products liability functions adequately, compensation, deterrence and shifting the social costs of risky activities to tortfeasors are goals achieved by products liability.
[1745] Joan T. Schmit, Factors Likely to Influence Tort Litigation in the European Union, The Geneva Papers 31, 304–313, 311 (2006) noting that the role of social insurance in compensating victims of product-related accidents is of crucial importance considering the debate that has taken place during the last years concerning the reduction of the coverage of social insurance programs in Europe.
[1746] For an analysis of the social security reforms regarding the aging population process in Europe see "Social Security in Europe: the impact of an aging population: and information paper prepared for use by the Special Committee on aging, United States Senate," 38 (1981).
[1747] See From pyramid to pillar, population change and social security in Europe, International Labor organization, 85 (1989) for an analysis of the influence of demographic changes on pension policies.
[1748] Jochen Clasen, SOCIAL INSURANCE IN EUROPE, The policy press, 244 (1997).

questions about the sustainability of social insurance systems.[1749] From different perspectives, sociologists, economists, political scientists and social policy analysts are discussing the normative foundations of the existing welfare state and are suggesting new principles of social protection and the development of new systems that may improve the capacity to adapt to changing environments.[1750]

There seems to be a broad social consensus that social insurance systems should not disappear (as this would change the entire European social model) but should adapt to the new reality in many European societies.[1751] These issues have generated a remarkable amount of research regarding the reforms that should be made. However, surprisingly enough, most of the reforms and changes that have been made to address the financial problems of the social insurance systems are neither substantial nor fundamental, and have often increased the resources used by the systems or restructured the existing ones. Thus, the tendency has been to make relatively minor changes and to avoid any radical restructuring of programs, which seems urgent.

Compensation of victims of product-related accidents in Europe can be seen as a case study for considering whether the objectives of the European welfare state and its interaction with tort law should be redefined. The costs of product-related accidents born by social insurance systems might be partially contributing to the financial crisis of social insurance and more generally, welfare states in Europe.[1752] If, instead, it is determined that the costs of the product liability system should be absorbed by social insurance systems, it would then become necessary to determine what the social cost of such

[1749] Social Security in Europe: Development or Dismantelment?, Niels Ploug and Jon Kvist, Kluwer Sovac, Series on Social Security, 25 (1996).
[1750] Jochen Clasen, WHAT FUTURE FOR SOCIAL SECURITY? DEBATES AND REFORMS IN NATIONAL AND CROSS-NATIONAL PERSPECTIVE, Policy Press, 1-10 (2002).
[1751] G. Bagdy, Policies for national consensus and reform, in OCCASIONAL PAPERS ON SOCIAL SECURITY: FINDING THE BALANCE: FINANCING AND COVERAGE OF SOCIAL PROTECTION IN EUROPE, W. van Ginneken ed., International social security association, Geneva (1996).
[1752] Due to the lack of data it is not possible to determine the volume of these costs.

damages is and whether and how tortfeasors should be contributing to social insurance systems in order to bear part or if possible, all of its costs.[1753]

This inefficient situation is a consequence of the structure of European product regulation that, to say the least, is quite patchy. It is often suggested that society can choose between tort (for deterrence) and insurance (for compensation) or on the other hand a system of regulation (for deterrence)[1754] and social insurance (for compensation).[1755] However, Europe has chosen neither one model nor the other. European product regulation has adopted a product liability directive, based on the belief of the higher capacity of product manufacturers to bear and spread accident costs,[1756] and a broad ex ante product safety regulatory body to ensure a certain level of safety of the products marketed in the European market. Thus, the model seems to rely on ex ante product safety regulation for deterrence and on ex post liability -- strict product liability -- for compensation. But the practical implementation of the model does not seem to function as the theoretical model would predict given that the role of social insurance seems to have a great impact on victims' compensation and on parties' incentives.

The composition and nature of the European product regulation is mixed between private remedies and public programs and results in an ineffective regime. Despite such inefficiency it may be accepted and determined that this is a good system. However, until there is data and an analysis of the cost of this decision it does not seem that such conclusion can be reached. In light of the social insurance crisis currently being

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[1753] SOCIAL SECURITY IN EUROPE: DEVELOPMENT OR DISMANTELMENT?, Niels Ploug and Jon Kvist, Kluwer Sovac, Series on Social Security, 29 (1996).

[1754] See Steven Shavell, Liability for harm versus regulation of safety, 13 Journal of Legal Studies 2, 374 (1984) and Steven Shavell, A model of the optimal use of liability and safety regulation, Rand Journal of Economics, 15(2), 271-280 (1984).

[1755] Göran Skogh, Public insurance and accident prevention, The international review of law and economics, vol 2, 67-80 (1982) and Göran Skogh, The combination of private and public regulation of safety, in ESSAYS IN LAW AND ECONOMICS. CORPORATIONS, ACCIDENT PREVENTION AND COMPENSATION FOR LOSSES, 87-101 M Fuare/R. van den Bergh (Eds.) (1987).

[1756] Sheila L. Birnbaum, Legislative reform or retreat? A response to the product liability crisis, 14 Forum 251, 253 (1978-1979). See also Richard W. Wright, The principles of product liability, 26 Rev. Litig. 1067, 1096 (2007) questioning the use of tort law as a risk spreading mechanism.

experienced in Europe, it seems that some kind of reform is necessary to alleviate the public system of these additional costs.

Product-related accident costs, despite not being quantifiable, might not solve the current problems of social insurance programs in Europe. But even if such costs were not relevant, from a policy perspective, the distortion on the allocation of costs has major effects for the incentives of the parties' involved and for the system as a whole: first, economically, even if they are not the major problem of the social insurance system, the public system bears costs that should be placed on the private parties who cause harm so that these parties are not implicitly receiving a public subsidy through social insurance. Second, there is a moral hazard problem caused by victims' reliance on no-fault benefits from social insurance systems that even if not full, provide benefits regardless of the level of care the victim adopted.[1757] Third, there is a dislocation of accident costs whenever the social insurance system ends up bearing them in cases where neither the victim not the social insurance agency pursues the products claim.[1758] Such dislocation causes a major distortion in the torfeasor's incentives for care and thus on deterrence given that tortfeasors do not internalize the cost of the damages they cause.[1759] As a result, tortfeasors have suboptimal incentives for care and are under-deterred.[1760]

[1757] Ulrich Magnus, THE IMPACT OF SOCIAL SECURITY LAW ON TORT LAW, vol. 3 (Tort and Insurance Law), 230, Springer ed. (2003).

[1758] This situation contrasts with the U.S. practice where private insurers pay much of the costs for which European governments assume responsibility. See Anita Bernstein, L'harmonie Dissonante: Strict Products Liability Attempted In The European Community, 31 Va. J. Int'l L. 673, 688-690 (1991).

[1759] This effect is surely present. However, the magnitude of this effect is difficult to quantify given that there is no data available to determine the amount of resources that the different social insurance systems in Europe devote to injured victims of product-related accidents.

[1760] The implementation of strict liability under the Directive has had little impact on the costs born by industry. Alfred E. Mottur, The European Product Liability Directive: A Comparison With U.S. Law, An Analysis of Its Impact On Trade, And A Recommendation For Reform So As To Accomplish Harmonization and Consumer Protection, 25 Law & Pol'y Int'l Bus. 983, 1007 (1994). See also Willem H. van Boom/ Michael G. Faure, Concluding Remarks to the book Shifts in Compensation between Private and Public Systems, 219-235, in TORT AND INSURANCE LAW IN SHIFTS IN COMPENSATION BETWEEN PRIVATE AND PUBLIC SYSTEMS, Willem H. van Boom/ Michael G. Faure (eds.) (Tort and Insurance Law), vol. 22, (2007) noting that the under-deterrence is justified in light that it provides easier and quicker compensation to injured victims.

The shift from private to public funding is generally defended on victim's protection grounds.[1761] But the effects and performance of the interaction between product liability and social insurance in Europe is not just a matter of efficiency but also a matter on the effectiveness of the law -- in this case, tort law -- and on the viability of social insurance systems in Europe.

This is not the place to discuss whether compensation under tort, under private or under social insurance is preferred. The goal of this chapter is not determining whether compensation should be mostly provided through social insurance[1762] and tort law should have a secondary role[1763] or whether accident deterrence should be the priority when talking about accidents and hence liability under tort should be the major compensation source and the role of private or public insurance should be secondary.

The issue is whether, in light of the inefficiencies arising from the current product liability regulatory structure and context, there is room for improvement and for reaching a more efficient and less disruptive structure. This is of special importance when considering that the welfare systems and more specifically, social insurance systems of the different European member states enjoy significant support among citizens,[1764] who generally endorse their principles and operations and accept their requirements and

[1761] Willem H. van Boom/ Michael G. Faure, Concluding Remarks to the book Shifts in Compensation between Private and Public Systems, TORT AND INSURANCE LAW IN SHIFTS IN COMPENSATION BETWEEN PRIVATE AND PUBLIC SYSTEMS, Willem H. van Boom/ Michael G. Faure (eds.), Tort and Insurance Law, vol. 22, 219-235 (2007).

[1762] See Tom Baker, Containing the Promise of Insurance: Adverse Selection and Risk Classification, University of Connecticut School of Law Working Paper Series 3, 15 (2001). This article is available at http://lsr.nellco.org/uconn/ucwps/papers/3 noting that the insurance literature often assumes that private insurance is better than public insurance without much inquiry on whether it is true.

[1763] W. Kip Viscusi, Toward a diminished role of tort liability: social insurance, government regulation, and contemporary risks to health and safety, 6 Yale J. on Reg. 65, 67 (1989).

[1764] See Jules Stuyck, European Consumer Law After The Treaty Of Amsterdam: Consumer Policy In Or Beyond The Internal Market?, Common Market Law Review 37: 367-400, 370, 375 (2000) noting that the role of the European states in protecting consumers in their market transactions is more paternalistic than the role of the U.S. In this sense, European member states and regulations take greater care of consumer interests in providing information rights, education and instruments of organization in order to safeguard their interests.

outcomes.[1765] If, as it seems today, viability and sustainability is an issue and challenge, the interaction between social insurance and product liability in Europe should be revisited. Placing the costs of product-related accidents on the party who should bear them or instead, having social insurance systems bearing the costs of such accidents through contributions of potential tortfeasors subject to the product liability directive would be a first step to rationalize the social insurance system that today is in serious struggle.[1766]

[1765] Jochen Clasen, WHAT FUTURE FOR SOCIAL SECURITY? DEBATES AND REFORMS IN NATIONAL AND CROSS-NATIONAL PERSPECTIVE, 33, Policy Press (2002).
[1766] Geraint G. Howells & Mark Mildred, Is European Products Liability More Protective Than The Restatement (Third) Of Torts: Products Liability?, 65 Tenn. L. Rev. 985, 1029 (1998).

Table 7.2 - European Social Insurance Systems

The information of this chart has been mostly obtained from two different sources:

- Social Security Administration (SSA) and the International Social Security Association (ISSA), Social security programs throughout the World: Europe, 2010 (2010). Available at http://www.ssa.gov/policy/docs/progdesc/ssptw/2010-2011/europe/index.html
- Bernard A. Koch and Helmut Koziol (eds.), COMPENSATION FOR PERSONAL INJURY IN A COMPARATIVE PERSPECTIVE, (Tort and Insurance Law, vol. 4), European Centre of Tort and Insurance Law, Springer-Verlag, Wien (2003).

STATE	GENERAL SOCIAL INSURANCE SYSTEM			MEDICAL CARE		
	Regulatory Framework	**Coverage**	**Source of Funds**	**Coverage**	**Source of Funds**	**Medical Benefits**
AUSTRIA	**Current social insurance applicable laws:** law of 1955 (employees) and law of 1978 (self-employed).	Wage earners and salaried employees (separate systems with essentially identical provisions) earning at least €366.33 a month, and apprentices. Special systems for miners, notaries, public employees, and self-employed persons in trade, industry, and agriculture.	**Insured person:** 10.25% of earnings. **Employer:** 12.55% of payroll. **Government:** A subsidy and the cost of the care benefit and income-tested allowance. Maximum earnings for contribution and benefit purposes are €4.795 a month.	Employed persons earning €366.33 or more a month, apprentices, and pensioners. Special systems for public and railway employees and self-employed in agriculture and trade.	**Insured person:** Wage earners, 3.95% of wages; salaried employees, 3.82% of covered salary; pensioners, 5.10% of the pension. **Employer:** Wage earners, 3.70% of payroll; salaried employees, 3.83%. **Government:** 70% of cash maternity benefits. Maximum earnings for contribution and benefit calculation purposes are €4.110 a month.	Employer pays 100% of earnings for up to 12 weeks (plus additional 4 weeks at 50%) depending on length of service. After right to full benefit from employer is exhausted, sickness funds pay 50% (60% after 6 weeks) of assessment base (25% to those receiving 50% of earnings from employer) plus family supplements for 26 to 52 weeks depending on length of contributions. Maximum is 75% of covered earnings.
	RIGHT OF RECOURSE IN AUSTRIA					
	Where the injured person does have a tort claim against a tortfeasor, this claims passes by way of legal cession to the social insurance agency insofar and to the extent that the agency is bound to satisfy the claim by granting benefits to the victim. This cession presupposes that the tort claim and the social insurance benefits have the same purpose. Where tort liability of certain persons is mainly excluded, the social insurance agency has a statutory claim of its own against the liable person but only in case of this person's intentional or grossly negligent conduct. The employer has to continue payment of full wages even if the employee is unable to work because of an injury caused by another person. The employer has also then a right of recourse against the tortfeasor for those paid wages.					

STATE	GENERAL SOCIAL INSURANCE SYSTEM			MEDICAL CARE		
	Regulatory Framework	**Coverage**	**Source of Funds**	**Coverage**	**Source of Funds**	**Medical Benefits**
BELGIUM	**Current social insurance laws:** 1967, 1994 and 2001 (guaranteed income)	Employed persons (special provision for miners and seamen). Special systems for self-employed persons and civil servants.	**Insured person:** 7.5% of earnings. Pensioners contribute 0.5% to 2% of pensions or pre-pensions. **Employer:** 8.86% of payroll (100% of gross earnings for white-collar workers and 108% of the insured's gross earnings for blue-collar workers). **Government:** Annual subsidies.	Employed persons who are members of a mutual benefit society or an auxiliary sickness and disability fund. Pensioners and other social insurance beneficiaries are also covered for medical benefits. Special systems operate for self-employed persons (basic protection only) and seamen. Voluntary affiliation is possible.	**Insured person:** Medical benefits, 3.55% of earnings. Cash benefits and disability pensions, 1.15% of earnings. Pensioner, 3.55% of old-age and survivor pension (low-income pensioners are exempt from contribution). **Employer:** Medical benefits, 3.8% of reference earnings (100% gross earnings for white collar workers and 108% of gross earnings for blue-collar workers). **Government:** Subsidy for the management of the social insurance system. Proceeds from a surcharge on automobile insurance and on hospitalization insurance premiums, and a tax on the profit made on certain prescribed medicines and other taxes.	**Cash sickness benefit:** 60% of average lifetime earnings (the basis salary taken into account for the calculation of sickness and disability benefits has a ceiling of €118.36 per day). After the 31st day of incapacity the entitlement is 55%; 60% if there are dependents or if the insured is the sole breadwinner. In general, benefits are not payable if the employer provides a guaranteed salary.
	RIGHT OF RECOURSE IN BELGIUM[1767]					
	Recourse action is a quasi-subrogation action given that it is limited to the amount of compensatory payments that have been effectively paid by the public health insurance, at least in as far as this effective compensation does not exceed the damages paid by the tortfeasor (regulated in art 136 §2 Act 14 July 1994). Social insurance compensation for industrial accidents and for health care measures differs in so far as the latter is only available in addition to compensation in tort while the first excludes tort compensation in many situations. With reference to a recourse claim both social insurance agencies are entitled to reimbursement of the benefits rendered to the injured person as far as those benefits compensate for bodily impairment.					

[1767] See D. Simoens, Beginselen van Belgisch Privaatrecht: Buitencontractuele aansprakelijheid – Schade en schadeloosstelling, 329-411 (1999).

STATE	GENERAL SOCIAL INSURANCE SYSTEM			MEDICAL CARE		
	Regulatory Framework	**Coverage**	**Source of Funds**	**Coverage**	**Source of Funds**	**Medical Benefits**
DENMARK	**Current laws:** 2005 (partial early retirement pension), 2006 (ATP pension), 2007 (social pensions), and 2007 (anticipatory pensions). **Type of program:** Universal and social insurance systems.	**Universal basic and universal supplement pensions:** Citizens residing in Denmark and non-citizens meeting the minimum residency requirements or covered by reciprocal agreements. **Labor-market supplementary pension (ATP):** Employees aged 16 to 65 (including recipients of disability (voluntary for disability pensions granted before 2003) cash sickness, maternity, unemployment, and social assistance benefits. Voluntary coverage for persons previously insured for at least 3 years who begin non-salaried or self-employed work and for recipients of disability pensions (mandatory for disability pensions granted as of 2003), or early retirement benefits. Exclusions: Employees working less than 9 hours a week.	**Insured person** Universal basic and universal supplement pensions: None. ATP: Up to the maximum of 1080kroner a year for a full-time worker. Recipients of unemployment benefits, sickness and maternity benefits, and certain vocational training benefits pay double contributions. **Employer** Universal basic and universal supplement pensions: None. ATP: Up to a maximum of 2,160 kroner (for a full-time worker per employee per year) **Government** Universal basic and universal supplement pensions: Total cost ATP: Up to a maximum of 2,160 kroner (for a full-time worker) per year for recipients of social assistance benefits. Contributions are paid in doubled amounts for recipients of unemployment benefits, sickness and maternity benefits, and certain vocational training benefits.	**Medical benefits:** All residents. **Cash sickness and cash maternity benefits:** Employees and self-employed persons.	**Insured person:** None. **Employer:** The total cost of cash benefits for the first 2 weeks if the same employer has employed the employee for 8 weeks before the incapacity began. No contribution is made for medical benefits. **Government:** Local government meets the total cost of cash benefits from the third week (beginning on day 1 if ineligible for the 2-week benefit from employer) and is reimbursed fully by central government up to the end of the fourth week. After the cost is split equally between local and central governments.	**Sickness benefit:** Up to 3,760 kroner a week, based on the hourly wage; for employees, benefit is payable from the first day of illness; for the self-employed, benefit is payable from the third week of illness (may insure voluntarily for the first 2 weeks). Benefits under the national cash benefit program are payable weekly for 52 weeks within any 18-month period. Benefit may be extended under specified circumstances.

STATE	GENERAL SOCIAL INSURANCE SYSTEM			MEDICAL CARE		
	Regulatory Framework	**Coverage**	**Source of Funds**	**Coverage**	**Source of Funds**	**Medical Benefits**
FINLAND	**Current laws:** 1961 (earnings-related pensions); 1969 (survivor pensions); 1986 (partial pension and early pension); 2007 (universal pensions), implemented in 2008; and 2007 (disability benefit), implemented in 2008. **Type of program:** Universal and social insurance systems	**Universal pension (income-tested):** All persons residing in Finland for at least 3 years after age 16; persons whose disabilities began while living in Finland and before reaching age 19, regardless of the length of residence in Finland. **Earnings-related pension:** All employees aged 18 to 68, persons caring for a child younger than age 3, and students who received a degree for study periods up to 5 years. Special systems for maritime workers, public-sector employees, and farmers.	**Insured person** Universal pension: none. Earnings-related pension: Employees, 4.5% of earnings for employees younger than 53; 5.7%of gross monthly earnings for employees 53 or older. Minimum monthly earnings to calculate contributions are €51.57. There is no maximum limit on the earnings used to calculate contributions. **Employer** Universal pension: None. Earnings-related pension: The average monthly contribution is 17.1%. The minimum monthly earnings used to calculate contributions are €51.57. There is no maximum limit on the earnings used to calculated contributions. **Government** Universal pension: Total cost of universal pensions, housing allowances, disability allowances, pensioner care allowances, survivor pensions, and war veterans' benefits. Earnings-related pension: The total cost of the earnings-related pension for self-employed persons whose earnings are less than the minimum annual earnings used to calculate contributions. The minimum annual earnings used to calculate contributions for self-employed persons are €6,775.60.	**Medical benefits:** All residents. **Cash benefits:** All residents.	**Insured person:** 1.47% of earnings. Pensioners contribute 1.64% of earnings. **Employer:** 2.23% of payroll. **Government:** Remaining cost. Subsidies as required.	**Sickness benefit:** 70% of daily earnings, if annual earnings are €32,892; 40% of daily earnings for annual earnings between €32.893 to €50.606 and 25% of daily earnings for annual earnings of €50,607 or more. **Sickness allowance (means-tested):** The allowance is paid after 55 days of incapacity provided that annual earnings are less than €1,264. The daily benefit is €22.04.

STATE	GENERAL SOCIAL INSURANCE SYSTEM			MEDICAL CARE		
	Regulatory Framework	**Coverage**	**Source of Funds**	**Coverage**	**Source of Funds**	**Medical Benefits**
FRANCE	**Current laws:** 1945 (nonagricultural employees); 1975 (disabled persons); 1996 (social security organization); 2001 (dependency benefits); 2003 (pension reform); 2006 (retirement reform); and 2009 (combination of disability benefit and gainful activity). **Type of program:** Social insurance system and social assistance system.	**Social insurance:** Employed persons in commerce and industry; housewives under certain conditions. Voluntary coverage for nonworking heads of household (old-age pension only), non-covered persons who previously had mandatory coverage for at least 6 months, non-employed persons caring for a family member with a disability, and French citizens working abroad. Special systems for agricultural, mining, railroad, public utility, and public-sector employees; seamen; nonagricultural self-employed persons; and agricultural self-employed persons. **Social assistance:** All elderly and dependent persons residing in France.	**Insured person:** 6.55% of covered earnings for old-age benefits (up to a maximum) plus 0.1% of total earnings for survivor allowance. **Employer:** 8.3% of insurable earnings plus 1.6% of total payroll. **Government:** Variable subsidies.	**Coverage** Employed persons. Pensioners and some groups of non-employed persons. Special systems for agricultural, clergy, mining, railroad, public utility, and public employees; seamen; non-agricultural self-employed; and agricultural self-employed (medical benefits are provided under the general system for some groups). Voluntary coverage is possible including for French citizens working abroad. .	**Insured person:** 0.75% of total earnings; old-age pensioners (low-income pensioners are exempt), 1.4% of old-age pension and 2.4% of private pension; unemployed, 1.7% of the pre-retirement allowance or 2% of the guaranteed minimum income plus 1% of unemployment benefits and training allowances. Flat-rate contributions for students, young persons, and others not covered otherwise. **Employer:** 12.80% of total payroll. **Government:** Proceeds from a 12% surcharge on automobile insurance premiums plus proceeds from an earmarked tax on the costs of pharmaceutical advertising, alcohol, and tobacco. Proceeds from a contribution levied on all individual income finance sickness insurance and family benefits. Government also provides funds for new hospital construction and part of the cost for certain health and social services. Government contributions also finance disability and survivor benefits	**Sickness benefit:** The benefit is 50% of the insured's average daily wage in the 3 months before the incapacity began and is paid for the first 30 days of sick leave; thereafter, 66.7% if the insured has at least three dependent children. The benefit is paid after a 3-day waiting period for up to 360 days in a 3-year period. For a chronic or prolonged illness, the total payment period is 3 years. The maximum monthly earnings used to calculate benefits are € 2,885. The minimum daily benefit is € 8.64 (€ 11.51 if the insured has dependent children). The maximum daily benefit is € 48.08 (€ 65.94 if the insured has dependent children). Benefits are adjusted according to changes in wages once benefits have been paid for more than 3 months.
	RIGHT OF RECOURSE IN FRANCE[1768]					
	Social insurance agencies have a statutory claim of their own against the wrongdoer who is liable in tort towards the victim to whom social insurance benefits are awarded. The only precondition for this subrogated right is that the benefits must be obtained as a result of the incident tortiously caused by the tortfeasor. The agency's recourse claim is independent of whether the victim would sue the tortfeasor. Reimbursement of future benefits can also be claimed.					

[1768] See Law of 1985 expanded the provisions of law of December 27, 1973 (current articles L 376-1 and 454-1 of the Social Security Code).

STATE	GENERAL SOCIAL INSURANCE SYSTEM			MEDICAL CARE		
	Regulatory Framework	**Coverage**	**Source of Funds**	**Coverage**	**Source of Funds**	**Medical Benefits**
GERMANY	**Current law:** 2002. **Type of program:** Social insurance system. Note: Following the unification of the Federal Republic of Germany (FRG) and the German Democratic Republic (GDR) on October 3, 1990, the social insurance system of the FRG remained in force and the system of the GDR continued to apply on an interim basis within the former GDR territory. The FRG and GDR systems were merged effective January 1, 1992, at which time Part VI of the Social Act came into force throughout the entire federal territory. In the summary that follows, particular provisions that were in place on January 1, 2002, in the new federal states are preceded by the designation "E".	Employed persons (including apprentices), certain self-employed persons, persons caring for a child under age 3, recipients of social benefits (such as unemployment benefits), conscripts or persons doing community service instead of military service, and voluntary care workers. Special systems for certain self-employed persons, miners, public employees (supplementary insurance), and farmers. Voluntary affiliation for all others aged 16 or older who are currently exempt from compulsory insurance, including German citizens residing abroad and resident foreigners.	**Insured person:** 9.55% of earnings; none if earnings are below €400 a month; reduced contribution is paid if monthly earnings are from €401 to €800. The maximum annual earnings used to calculate contributions are €66,000 (E–€55,800) if covered by the German Pension Insurance; €81,600 (E–€68,400) if covered by the German Pension Insurance for Miners-Railwaymen-Seamen. **Employer:** 9.95% of payroll. **Government:** Pays the cost of noninsurance-related benefits.	All wage and salary earners earning up to €49,950 a year; including the insured's spouse or civil partner and children up to age 18, pensioners, students, and persons with disabilities under certain conditions; apprentices and beneficiaries of unemployment benefits. Special systems for miners, artists, public employees, and self-employed farmers. Voluntary insurance in particular for persons whose compulsory insurance ends, subject to certain conditions. Long-term care for all persons covered by the statutory sickness insurance scheme and some special groups subject to certain conditions. Persons with private sickness insurance must buy equivalent private coverage for long-term care.	**Insured person**: On average, 7.9% of covered earnings, according to fund; no contribution if earning less than €400 a month. Pensioners contribute on average 7.9% of pension. **Employer:** On average, 7% of payroll, according to fund, and 13% for employees earning less than €400 a month. Government: Subsidy for maternity benefits; pensioned farmers' health benefits and noninsurance-related benefits. Maximum earnings for benefit and contribution purposes are €45,000 a year.	**Sickness benefit:** The employer pays 100% of the insured's earnings for up to 6 weeks; thereafter, Sickness funds pay 70% of gross earnings (up to a maximum of 90% of net earnings) for up to 78 weeks in 3 years for the same illness. r.
	RIGHT OF RECOURSE IN GERMANY					
	The tort claim of an injured person against a tortfeasor passes through cession to the social insurance agency to the extent that the latter compensates the damage. The					

STATE	GENERAL SOCIAL INSURANCE SYSTEM			MEDICAL CARE		
	Regulatory Framework	**Coverage**	**Source of Funds**	**Coverage**	**Source of Funds**	**Medical Benefits**
	claim of the German social insurance agency is established by §110-111 SGV (law on social insurance). The reimbursement is calculated not according to the damages caused to the victim but through standardized amounts depending on the victim's salary. If tortuous liability is limited in amount the recourse right ranks below the victim's own claim against the tortfeasor which must be satisfied first. In the field of work accidents where tort liability of employers, co-employees and further persons is mostly excluded, the recourse action of the social insurance agency against those persons is also restricted to cases where these persons acted with intent or gross negligence. Employers are also obliged to continue payment of full wages for 6 weeks when their employees are injured and unable to work. La recourse action lies against the tortfeasor and social insurance has a similar right of recourse when an employer fails to continue payment and the agency has stepped instead.					
GREECE	**Current laws:** 2004 (social security), 2008 (social security reform). **Type of program:** Social insurance system.	Employees in industry, commerce and related occupations, and certain urban self-employed workers. Exclusions: Employed and self-employed persons covered by approved occupational and public-sector funds providing equivalent benefits. Voluntary coverage is possible, subject to conditions. Special systems for agricultural workers, public-sector employees, doctors and dentists, architects, notaries, commercial motor vehicle operators, shipping agents, tradesmen, and craftsmen.	**Insured person:** 6.67% of earnings; 8.87% if in arduous or unhealthy employment. **Employer:** 13.33% of payroll; 14.73% if in arduous or unhealthy employment. **Government:** 10% of annual payroll as an employer and a guaranteed annual state.	Employees in industry, commerce and related occupations, and certain urban self-employed workers are covered. Pensioners are also covered for medical benefits. Exclusions: Employed and self-employed persons covered by approved occupational and public sector funds providing equivalent benefits. Special systems for agricultural workers, public-sector employees, doctors and dentists, architects, notaries, commercial motor vehicle operators, shipping agents, trades- men, and craftsmen.	**Insured person:** 0.4% of covered monthly earnings (cash benefits) and 2.15% of covered monthly earnings (medical benefits). Pensioners contribute 4% of the monthly pension. **Employer:** 0.8% of covered monthly payroll (cash benefits) and 4.3% of covered monthly payroll (medical benefits). There are no minimum earnings used to calculate contributions. **Government:** Guaranteed annual state subsidy.	**Cash sickness benefit:** The insured must have at least 120 days of contributions (100 if working in construction) in the calendar year before the incapacity began or 100 days of contributions in the last 15 months excluding the last quarter. The benefit is paid for 182 days to 720 days, according to the insured's contribution period.
	RIGHT OF RECOURSE IN GREECE					
	The right of recourse of Greek social insurance agencies against the liable tortfeasor is for all the benefits the agency has granted to the victim of the tort. In cases concerning accidents at work the recourse action against the employer, co-employer ….etc. is restricted to situations where these persons acted with intent.					

STATE	GENERAL SOCIAL INSURANCE SYSTEM			MEDICAL CARE		
	Regulatory Framework	**Coverage**	**Source of Funds**	**Coverage**	**Source of Funds**	**Medical Benefits**
IRELAND	**Current law:** 2005 (social welfare). **Type of program:** Dual social insurance and social assistance (means-tested) system.	Employed persons aged 16 to 65 with €38 or more in weekly covered earnings. Self-employed persons (annual earnings €3,174 or over and covered for contributory old-age and survivor benefits). Excludes part-time employees earning less than €38 a week, public servants who were permanent and pensionable before April 6, 1995, and casual domestic workers.	**Insured person:** With weekly earnings of €352 or less, none; with weekly earnings over €352, none for the first €127 of covered weekly earnings and 4% of covered weekly earnings from €128 to €75,036 and 5% of earnings over €75,036. The insured's contributions also pay for sickness and maternity, medical, work injury, unemployment, and adop- tion benefits. If weekly earnings are greater than €500, the insured pays an additional 4% of weekly earnings for medical benefits; the contribution is waived if the insured has a means-tested medical card or receives specified benefits or allowances. **Self-employed person:** With an annual income of €26,000 or less, 3% of covered income; with an annual income over €26,000, 7% of covered income, of which the self-employed person pays 4% of covered income for medical benefits. **Employer:** For employees with	**Cash benefits:** Employees under age 66. Excludes part-time employees earning less than €38 per week, self-employed (covered for maternity only), public servants who were permanent and eligible for pension before April 6, 1995, and casual domestic workers. **Medical services:** All residents.	**Government:** Medical care, total cost for low-income residents; partial cost for remainder of population.	**Sickness benefit (disability benefit):** Up to €196 a week, depending on weekly income. Payable after a 3-day waiting period for up to 52 weeks, or longer if contribution weeks total 260 or more. Dependent supplement: Up to €130.1 a week for qualified adult; €29.80 a week for each dependent child) or €14.90 if the qualified adult supplement is not paid.

STATE	GENERAL SOCIAL INSURANCE SYSTEM			MEDICAL CARE		
	Regulatory Framework	**Coverage**	**Source of Funds**	**Coverage**	**Source of Funds**	**Medical Benefits**
			weekly earnings of €356 or less, 8.5% of gross wages; for employees with weekly earn- ings greater than €356, 10.75% of gross wages. There are no maximum earnings used to calculate the employer's contributions. **Government:** Any deficit in the social insurance fund and the total cost of means-tested allowances.			
ITALY	**Current laws:** 2009. **Type of program:** National defined contribution (NDC) and social insurance system.	Employed persons (including domestic employees). Special systems for public-sector workers and the self-employed.	**Insured person:** 9.19% of gross earnings. **Employer:** 23.81% of payroll. (A lower contribution rate is paid by some employers, including employers in certain economically depressed areas.) **Government:** Full cost of income-tested allowances and any overall deficit. The minimum daily earnings used to calculate workers' contributions in industry are €43.79 or the minimum daily wage, whichever is greater.	**Sickness benefit:** Employed persons and contract workers. **Medical benefits:** All residents.	**Insured person:** None. **Employer:** 2.68% of gross earnings for industrial blue-collar workers; 0.46% of gross earnings for industrial white-collar workers; 2.68% of gross earnings for employees in commerce and the service sector. Variable contributions are made for some categories of contract workers. **Government:** The total cost of maternity benefits for certain categories of workers, including home based, agricultural, and household workers.	50% of the insured's average daily earnings is paid for the first 20 days of incapacity; thereafter, 66.6%. The benefit is paid after a 3-day waiting period for up to 180 days a year; may be extended in special cases. For contract workers, the daily benefit is paid for up to 180 days of hospitalization, and the benefit varies according to the number of contributions made in the 12 months before hospitalization. The daily benefit may be paid under certain exceptions for sicknesses not requiring hospitalization, for up to 61 days a year.
	RIGHT OF RECOURSE IN ITALY					
	In cases where the liable subject is neither identified nor identifiable and hence a tort claim is not available, social insurance replaces completely tort law in compensating the injured victim.					

STATE	GENERAL SOCIAL INSURANCE SYSTEM			MEDICAL CARE		
	Regulatory Framework	**Coverage**	**Source of Funds**	**Coverage**	**Source of Funds**	**Medical Benefits**
	In other cases, when social insurance compensates an injured victim, social insurance agencies have a right of recourse against the liable tortfeasor under very restricted circumstances, while in others it is excluded. In some cases such as crime victims of victims of terrorism the social insurance agency might seek reimbursement from the tortfeasor. In the field of accidents in the work-place the social insurance recourse is restricted to cases where the employer or co-employer has been sentenced and held liable by a criminal court.					
LUXEMBURG	**Current law:** 1987 (unified pension insurance), 1989 (pension scheme), 1998 (special schemes), and 2000 (pension scheme). **Type of program:** Social insurance system.	All economically active persons in the private and public sectors including self-employed persons. General system for the private sector. Special systems for railway and public employees who entered employment before January 1, 1999.	**Insured person:** 8% of earnings. **Employer:** 8% of covered payroll. **Government:** 8% of covered earnings. The minimum amount for contribution and benefit calculation purposes is 100% of the social minimum wage (€1,682.76 per month); the maximum amount is five times the social minimum wage.	All private- and public-sector employees and social insurance beneficiaries. Self-employed persons, artists, and farmers are covered for medical and attendance benefits. Voluntary coverage for those without compulsory coverage. Special systems for self-employed persons, artists, and farmers (cash benefits).	**Insured person:** *Cash benefits:* 0.25% of covered earnings. *Medical benefits:* 2.7% of covered earnings. **Employer:** *Cash benefits:* 0.25% of covered payroll. *Medical benefits:* 2.7% of covered payroll. **Government:** *Cash benefits:* A subsidy of 29.5% of contributions covering cash benefits and the total cost of maternity allowances. *Medical benefits:* A subsidy of 37% of contributions covering health care benefits.	**Cash sickness benefit:** 100% of earnings, payable from the first day of incapacity for up to 52 weeks in a 104 week period (employer generally pays the first 13 weeks of benefits).
THE NETHERLANDS	**Current laws:** 1957 (old-age pension), 1959 (survivor pension), 1966 (disability pension for employed persons), 1998 (disability pension for self-employed workers), and 1998 (disability assistance for handicapped young persons) and 2006 (disability pension for employed persons). **Type of program:** Social insurance system.	**Old-age and survivor pensions:** All residents. **Disability pension:** Employed workers, persons receiving benefits since before 2006, persons disabled since childhood and students residing in the Netherlands.	**Insured person:** 17.90% of income for the old-age pension, 1.1% for the survivor pension. The maximum annual earnings used to calculate contributions are €32,738. **Employer:** 5.7% of payroll, plus a variable rate contribution for persons receiving disability benefits since before 2006. **Government:** A subsidy	**Medical benefits:** All persons residing in the Netherlands and persons who reside outside the Netherlands but conduct their professional activities in the Netherlands. **Cash benefits:** Coverage is mostly through private providers. (Under the Civil Code, employers must pay 70% of wages during	**Insured person:** Flat-rate contribution set by the sickness fund, earnings up to €33,189; 12.15% of annual earnings up to €32,738 for exceptional medical expenses insurance. **Employer:** 7.05% of covered payroll for medical benefits. The maximum annual earnings used to calculate contributions are €33,189 **Government:** Annually	**Sickness benefit:** 70% of earnings up to the daily maximum earnings up to €186.65 a day, and is paid for up to 104 weeks; may be extended for an additional 52 weeks.

STATE	GENERAL SOCIAL INSURANCE SYSTEM			MEDICAL CARE		
	Regulatory Framework	Coverage	Source of Funds	Coverage	Source of Funds	Medical Benefits
			to increase all benefits up to the applicable social minimum; the cost of pensions for persons disabled since childhood and students.	sick leave periods for up to 104 weeks.) Social insurance covers workers who have no employer or no longer have an employer (and, in a few special circum-stances, wage earners and salaried employees), including employees who have lost their jobs in the first 2 years of incapacity, incapacitated unemployed persons, temporary workers on sick leave without a permanent contract, the voluntarily insured, apprentices, organ donors, vocationally rehabilitated persons, and women incapacitated due to pregnancy or childbirth. (Entrepreneurs and directors with a major shareholding in a company are excluded.)	determined contribution toward the financing of medical benefits.	
	RIGHT OF RECOURSE IN THE NETHERLANDS					
	Most social insurance agencies have a right of recourse against the tortfeasor. Has adopted the traditional recourse solution regulated in (art 52aZw Sickness benefits act; art 6:107a BW Civil code and art 83b ZfW Public Health insurance act). Even though this right of recourse is not a subrogation right by itself, it takes the form and has the same effects than a subrogation right given that social insurance agencies might exercise it under the same conditions that would apply to a tort claim in tort pursued by the injured victim herself. If the injured party was contributorily negligent the recourse claim is reduced in proportion to the contribution of the injured party to the accident or his subsequent					

STATE	GENERAL SOCIAL INSURANCE SYSTEM			MEDICAL CARE		
	Regulatory Framework	**Coverage**	**Source of Funds**	**Coverage**	**Source of Funds**	**Medical Benefits**
	injuries. This right of recourse might not be exercised against employers and colleagues except when they intentionally or consciously injure victims or the injuries are caused by the tortfeasor's gross negligence. Family members are also excluded. The law is silent regarding priority but consensus and practice seem to agree that the victim's claim has priority over the agency's recourse right. The tort claim of the injured person in most cases passes on to the social insurance agency from which the victim obtains benefits for the tortuous damage. Employers and co-employees are not subjected to recourse actions unless they have caused damage to another employee either to recourse actions unless they have caused damage to another employee either with intent or consciously and with gross negligence. However, in 1992 legislation excluded most recourse actions where liability of the tortfeasor is only founded in strict liability the right of recourse presupposes negligence o the part of the tortfeasor.					
PORTUGAL	**Current laws:** 1980 (noncontributory scheme), 2007 (general scheme), 2007 (social security), and 2009 (disability). **Type of program:** Social insurance and social assistance program.	Social insurance: Employed persons and self-employed persons with gross annual income greater than 6 times the social benefit rate. Voluntary coverage for self-employed persons with gross annual income up to 6 times the value of the social benefit rate and for persons not covered by the contributory program. The social benefit rate is €419.22 a month. Special systems for miners, longshoremen, fishermen, merchant seamen, civil aviation workers, air traffic controllers, and dancers. (Special systems are being gradually unified with the general system.) **Social assistance:** Persons not covered under a contributory program.	**Insured person:** 11% of earnings. Of the total 34.75% of gross earnings contributed by the insured person and employer, 16.01% finances old-age benefits, 3.42% finances disability benefits, and 3.67% finances survivor benefits. The insured's contributions also finance sickness and maternity, occupational disease, unemployment, and family benefits. **Employer:** 23.75% of payroll. Of the total 34.75% of payroll contributed by the insured person and employer, 16.01% finances old-age benefits, 3.42% finances disability benefits, 3.67% finances survivor benefits. The employer's contributions also finance sickness and maternity, occupational	**Medical benefits:** All Portuguese citizens; foreign citizens residing in Portugal whose home country has a reciprocal agreement with Portugal. **Cash sickness benefits:** Employed persons. Voluntary coverage for self-employed persons and certain categories of persons not covered by any other contributory program.	**Insured person:** Of the total 34.75% of gross earnings contributed by the insured person and the employer under Old Age, disability, and survivors, 3.05% of gross earnings finances sickness benefits and 0.73% finances maternity benefits. **Employer:** Of the total 34.75% of payroll contributed by the insured person and the employer under Old Age, Disability, and Survivors, 3.05% finances sickness benefits and 0.73% finances maternity benefits. **Government:** The cost of cash benefits for social assistance recipients; subsidizes medical benefits.	**Sickness benefit:** 65% of the insured's average daily earnings are paid for the first 90 days and 70% from the 91st up to the 365th day; thereafter, 75%. For cases of tuberculosis, 80% of the insured's average daily earnings are paid if the insured has at least two dependents; 100% if there are three of more dependents. The benefit is paid after a 3-day waiting period (30 days for self-employed persons); the waiting period is waived in cases of hospitalization or tuberculosis or during the postpartum period. The benefit is paid for up to 1,095 days (365 days for self-employed persons); no limit for cases of tuberculosis. Average daily earnings are based on the insured's earnings in the 6 months prior to the last 2 months before the incapacity began.

STATE	GENERAL SOCIAL INSURANCE SYSTEM			MEDICAL CARE		
	Regulatory Framework	**Coverage**	**Source of Funds**	**Coverage**	**Source of Funds**	**Medical Benefits**
			disease, unemployment, and family benefits. **Government:** Subsidy for the social pension.			The minimum sickness benefit is either 30% of the social benefit rate or the average daily earnings used for cash sickness benefit calculation, whichever is less. The social benefit rate is €419.22 a month.
SPAIN	**Current law:** 1994. **Type of program:** Social insurance system.	Employees in industry and services (classified according to 11 occupational classes). Voluntary coverage is not possible. Special systems for agricultural workers and small farmers, domestic servants, self-employed, seamen, and coal miners.	**Insured person:** 4.7% of covered earnings. The insured's contributions also finance sickness, maternity, paternity, and work injury benefits. The minimum monthly earnings used to calculate contributions are €738.85; the minimum daily earnings used to calculate contributions are €24.27. The maximum monthly earnings used to calculate contributions are €3,198; the maximum daily earnings used to calculate contributions for certain occupational classes are €106.6. **Employer:** 23.6% of covered earnings. The employer's contributions also finance sickness, maternity, paternity, and work injury benefits. The minimum monthly earnings used to calculate contributions	Employed persons and certain self-employed persons. (Insured persons who leave covered employment may sign a special agreement to continue coverage.) Pensioners are covered for medical benefits. Voluntary coverage for temporary disability is possible for agricultural workers. Special systems for public-sector employees, armed forces personnel, certain self-employed persons, agricultural workers and small farmers, household workers, seamen, and coal miners.	**Insured person:** 4.7% of covered earnings. The insured's contributions also finance sickness, maternity, paternity, and work injury benefits. The minimum monthly earnings used to calculate contributions are €738.85; the minimum daily earnings used to calculate contributions are €24.27. The maximum monthly earnings used to calculate contributions are €3,198; the maximum daily earnings used to calculate contributions for certain occupational classes are €106.6. **Employer:** 23.6% of covered earnings. The employer's contributions also finance sickness, maternity, paternity, and work injury benefits. The minimum monthly earnings used to calculate contributions	**Sickness benefit:** The insured must have at least 180 days of contributions in the last 5 years. There is no minimum contribution period for non-work-related accidents.

STATE	GENERAL SOCIAL INSURANCE SYSTEM			MEDICAL CARE		
	Regulatory Framework	**Coverage**	**Source of Funds**	**Coverage**	**Source of Funds**	**Medical Benefits**
			are €738.85; the minimum daily earnings used to calculate contributions are €24.27. The maximum monthly earnings used to calculate contributions are €3,198; the maximum daily earnings used to calculate contributions for certain occupational classes are €106.6. **Government:** Annual subsidy.		are €738.85; the minimum daily earnings used to calculate contributions are €24.27. The maximum monthly earnings used to calculate contributions are €3,198; the maximum daily earnings used to calculate contributions for certain occupational classes are €106.6. **Government:** Annual subsidy.	
	RIGHT OF RECOURSE IN SPAIN					
	Based on article 127.3 of the Law 1/1994 on Social insurance, the Spanish social insurance agency which has borne the injured person's medical expenses can recover these costs from the tortfeasor who is liable for the injury under civil law. Other heads of damages cannot be recovered. Spanish court practice is divided on the question whether social insurance benefits should be taken into account for the computation of the amount of damages is liable for. Section 1st and 3rd of the Spanish Supreme Court apply the collateral source rule while Section 4th of the Spanish Supreme Court applies the collateral benefit offset.					
SWEDEN	**Current laws:** 1962, 1998 (implemented in 1999), 2000; and 2008. **Type of program:** Universal and social insurance system (old system) and universal, notional defined contribution (NDC), and mandatory individual accounts system (new system).	**Earnings-related pension (old system):** All employees and self-employed persons 43,300 kronor a year. There is a gradual transition from the old to the new system for persons born between 1938 and 1953. **Earnings-related pension (new system):** All employed and self-employed persons born in 1954 or later and earning more than 17,935 kronor a year. **Premium pension (new**	**Insured person:** 7% of assessable income; no contribution for the survivor pension. The maximum annual income used to calculate contributions is 412,377 kronor. In addition, insured persons covered by the new system pay administrative fees for the premium pension (an average of 0.5% of assets in 2009). **Employer:** 10.21% of payroll for old-age insurance plus	**Cash benefits:** Gainfully occupied persons earning 10.176 kronor a year or more. **Medical benefits:** All residents in Sweden.	**Insured person** Cash benefits: none Medical benefits: none. **Employer** Cash benefits: 8.645% of payroll plus 2.2% for parents' cash benefits (parental insurance). Medical care: None. **Government** Cash benefits: None. Medical care: Total cost met by regional councils.	**Sickness benefit: T**he insured's annual income from employment exceeds 10,176 kronor; or involuntarily unemployed and registered with the employment service.

STATE	GENERAL SOCIAL INSURANCE SYSTEM			MEDICAL CARE		
	Regulatory Framework	**Coverage**	**Source of Funds**	**Coverage**	**Source of Funds**	**Medical Benefits**
		system): All employed and self-employed persons earning more than 17,935 kronor a year. **Guarantee pension:** All residents in Sweden.	1.7% of payroll for the survivor pension. Of the total contributions, 16% finances the earnings-related component and 2.5% finances the premium pension component. **Government:** The total cost of the guarantee pension (new system) and permanent disability benefits. The government pays earnings-related contributions for central government civil servants.			
	RIGHT OF RECOURSE IN SWEDEN					
	Since 1976, a recourse action from social insurance agencies against a liable tortfeasor is prohibited. This is the only European country where the social insurance agency has no recourse right with respect to the benefits granted to the victim of a liable tortfeasor. This solution if accompanied by a reduction of tort damages in the amount of such benefits. In 1999, a Parliamentary Committee set up by the government aimed at revisit this situation and consider the introduction of the recourse right. The work was presented in January 2002 but rejected the right of recourse based on solidarity and in considering that all socially should bear these damage costs. Further, the exclusion of recourse rights was justified on avoiding transaction costs. It seems to be a political question.					
UNITED KINGDOM	**Current laws:** 1992 (consolidated legislation), 1995 (pensions), 1999 (welfare reform and pensions), 2000 (child support, pensions and social security), 2002 (pension credit), 2004 (pensions), and 2007 (pensions). **Type of program:** Dual social insurance and social assistance system.	**Contributory benefits:** Employed persons aged 16 to 65 (men) or aged 16 to 60 (women) with weekly earnings of £97 to £844 (April 2010). Self-employed persons aged 16 to 65 (men) or aged 16 to 60 (women) with annual income of at least £5,075 are covered for all benefits except the state second pension,	**Insured person:** 11% of weekly earnings from £110 to £844 (April 2010); certain married women and widows contribute 4.85% of weekly earnings from £110 to £844 plus 1% of weekly earnings greater than £844. Voluntary contributors pay a flat-rate of £12.05	**Statutory sick pay:** Paid by the employer to employees with average weekly earnings of at least £97 (April 2010). **Employment and support allowance:** All employed and self-employed who are not eligible for statutory sick pay; unemployed and non-	**Insured person:** For employment and support allowance (incapacity benefit) and maternity allowance, see source of funds under Old Age, Disability, and Survivors. **Employer: f**or employment and support allowance (incapacity benefit) and maternity allowance, see source of	**Statutory sick pay:** £79.15 a week (April 2010) is paid for up to 28 weeks of incapacity after a 3-day waiting period. **Employment and support allowance:** £65.45 a week (April 2010) is paid after a 3-day waiting period for 13 weeks while capacity for work is assessed. After

STATE	GENERAL SOCIAL INSURANCE SYSTEM			MEDICAL CARE		
	Regulatory Framework	**Coverage**	**Source of Funds**	**Coverage**	**Source of Funds**	**Medical Benefits**
		work injury benefits, and contributory job seeker's allowance. Voluntary contributors are covered for the basic state retirement pension and survivor benefits only. **Employment and support allowance (incapacity benefit):** All employed and self-employed who are not eligible for statutory sick pay; unemployed and non-employed persons who satisfy contribution conditions. **Noncontributory benefits:** All persons residing in the United Kingdom.	a week. From the insured's contributions, 2.05% on earnings from £110 to £844 a week and 1% over £844 is allocated to the National Health Service for medical benefits. The insured's contributions also finance sickness and maternity benefits, work injury benefits, and unemployment benefits. **Employer:** 12.8% of each employee's earnings greater than £110 a week (April 2010). 1.9% of the employer's contribution is allocated to the National Health Service for medical benefits. The employer's contributions also finance sickness and maternity benefits, work injury benefits, and unemployment benefits. **Government:** The total cost of means-tested allowances and other noncontributory benefits. Also pays a treasury grant to contributory programs for any deficit.	employed persons who satisfy contri-bution conditions. **Statutory sick pay:** Paid by employer to employees with average earnings of £97 or more a week (April 2010). **Medical care:** All residents, irrespective of nationality, payment of contributions or income tax.	funds under Old Age, Disability, and Survivors. The total cost of statutory sick pay (in certain cases, part of the cost) and 8% of statutory maternity and paternity pay. **Government:** 92% of statutory maternity pay (100% in the case of some small employers); small portion of statutory sick pay; most of medical care (National Health Service). Total cost of means-tested allowances. **Medical care:** Funded mainly from general taxation.	the assessment, £65.45 a week plus £31.40 a week (if the disability has a severe effect on the ability to work) or £25.95 a week (if there is capacity for limited work) is paid (April 2010).
	RIGHT OF RECOURSE IN THE UNITED KINGDOM					
	The state social insurance agencies had no right of recourse until 1989. Since then, the Compensatory Recovery Unit was established with the purpose to claw back					

STATE	GENERAL SOCIAL INSURANCE SYSTEM			MEDICAL CARE		
	Regulatory Framework	Coverage	Source of Funds	Coverage	Source of Funds	Medical Benefits
	those benefits whenever a tortfeasor is liable for the damage of the person receiving insurance benefits. Nevertheless recourse actions of the Compensation Recovery Unit are an exception. This is achieved through a duty to inquire into the benefits which have been paid to the victim. This duty is placed on the "compensator" either the tortfeasor or an insurer who is in turn obliged to repay all benefits to the Unit and compensate the victim for the remaining loss. There are also limitations in the time and substance on the recoverable benefits. However, it is understood that the impact of this recourse is not only on the value of the tort claim but also on the speed and method tort claims are handled since it gives a string incentive to settle tort claims rapidly.					

CHAPTER 8

CONCLUSIONS

Using European product liability as its focus, this thesis reaches beyond liability in order to address the context of product liability regulation, its nature, its interaction with other regulatory mechanisms and the effects of its interaction with alternative compensation mechanisms.

The original question that sparked this thesis was why Europe's product liability directive has ended up having such different effects than the U.S. law on which it was modeled, section 402A of the Restatement Second of Torts. Many and different factors can help to explain how similar regulations may lead to different results depending on their contexts. In this thesis, we have considered a number of arguments for the different results achieved by the European product liability directive and the U.S. Restatement.

Chapter 2 extensively analyzed and discussed the European product liability directive. Being part of European product regulation, the product liability directive introduced a strict product liability regime for the first time in Europe. Framed in a context where the functioning of the European internal market was a priority, the authorities of the different member states represented a threat to the internal market because they had other priorities and were tempted to introduce regulations or protective measures in favor of their own companies and domestic markets. In light of the different interests of some member states and of European authorities, the European Commission viewed the harmonization of product liability as a need. The product liability directive was a way for the European Commission to respond to the goal of ensuring the functioning of the European internal common market while also harmonizing the rights of injured victims throughout the European member states.

The product liability directive aimed to facilitate the tort claims of people who had been injured by products. Yet, although the directive provided injured victims with a previously unavailable legal claim or, at least, a legal claim with a lower burden of proof than they previously faced, it does not appear to have been relied on to a large extent by these victims. Despite being entitled to seek redress through litigation based on a strict product liability claim, injured victims still face challenges that affect their incentives for doing so and often lead them to avoid litigation.

This thesis offers four major factors that may explain the reluctance of European product victims to seek redress through the court system: the rules of civil procedure in force in most European member states, the abstract wording and content of the product liability directive, which tends towards negligence standards even while holding out strict liability on its face, the effects of broad ex ante product safety regulations and the interaction of these regulations with product liability, and finally, the role of alternative compensation systems such as social insurance which plays such an important role in the model of economic and social welfare state of most European member states.

Chapter 3 presented the major differences between the rules of civil procedure in force in the different member states and those in force in the United States. It argued that the European procedural rules have functioned as barriers to product liability claims for the victims of product-related accidents. Procedural rules often act to dissuade plaintiffs from pursuing tort claims generally. They are of special importance in product liability cases where victims often suffer damages of little value that are not worth pursuing in court when the litigation process is lengthy, costly and uncertain. The product liability directive's approach to facilitating product liability claims did not include adjustments of procedural rules to give injured victims easier access to courts. Even though access to courts is one of the concerns of the European Commission, the issue falls within the internal jurisdiction of the states and not within the jurisdiction of European authorities. This remains a pending issue given that the legislatures of the different member states

have not introduced any regulations that might help reduce the procedural barriers faced by the victims of product-related accidents in exercising their rights in court.

A second element that affects the victims' incentives to bring their product liability claims in Europe is the content of the product liability directive itself. Despite the European Commission's intent to introduce strict product liability in Europe, the product liability directive includes various provisions that function as escape valves from the strict liability regime and introduce negligence considerations that significantly undermine its strictness and effectiveness. Chapter 4 discussed these valves, highlighting the ways in which they are echo negligence standards. These negligence-based elements may be the result of the difficult negotiation process between the member states and European authorities when drafting the final text of the product liability directive. These negotiations resulted in a more diluted liability regime than the one initially intended by the European Commission in the text of the directive. The distance between the goals of the European Commission and the content of the regulatory instruments adopted is a common phenomenon in the European harmonization processes. Initial goals of the European Commission often are diluted during the negotiation process among the different member states. The difficult drafting process of the product liability directive, with a European Commission aiming at harmonizing product liability by making product manufacturers liable for the harm caused by defective products regardless of care and with member states fearing the consequences that such liability regime would have for their domestic industries, resulted in the introduction of a defectiveness test -- the consumer expectation test -- and of some optional provisions such as the development risk defense that introduce considerations of care and thus of negligence when establishing both defect and knowledge of product risks.

In addition to the procedural rules and the provisions included in the product liability directive, the regulatory context in which the directive is framed is of crucial importance. Chapters 5 and 6 looked beyond product liability and focused on the

regulatory context, with special attention to the existence, application and interaction with the broad ex ante safety regulation in force in Europe. Product regulation in Europe has been designed and adopted in a non-systematic way, which has caused the regime to be inconsistent at times. While product liability is part of the European common internal market regulation, ex ante safety regulation is part of the European consumer protection regulation that aims to ensure a high level of consumer protection across the European market. These two regulatory bodies, with different goals and different natures, directly impact product manufacturers' decisions about investing in care, and the effects of each regulatory body sometimes dilute the effects of the other.

Product manufacturers must comply with broad ex ante safety regulations before introducing products into the European market. European product safety regulation mixes mandatory as well as voluntary safety requirements that have direct effects on manufacturers' investments in care and on their potential exposure to subsequent liability under tort. Chapter 6 focused on the joint use of product safety and product liability laws in Europe. This chapter discussed the implications of the joint use of these regulations and of their interaction through the compliance defense. Today, the compliance defense included in the product liability directive is significantly restricted. Thus, product manufacturers are generally subject to ex ante safety regulations, which require a certain level of product safety, but also are subject to product liability in case they manufacture defective products that caused harm to a consumer or user. The current interaction between ex ante product safety and ex post product liability results in potential tortfeasors over-investing in care. This is because potential tortfeasors must meet the safety requirements established by ex ante product safety while at the same time being exposed to strict product liability and thus having to perform cost-benefit analyses to determine the optimal investment in care under that rule. Hence, the current interaction between product safety and product liability results in an inefficient outcome as compared to the outcome of each regulatory mechanism alone. Reconsidering the interaction and structure

of these two regulatory bodies as well as the scope of the compliance defense could enhance the performance of the overall system and could result in more efficient investments in care and hence in better accident deterrence.

An additional major goal of the product liability directive was to facilitate victim's compensation. As explained in chapters 2 and 6, the introduction of strict product liability was often presented as a way to lower plaintiffs' burdens of proof in product liability litigation, making it easier for them to obtain compensation. This argument relied on the assumption that victims would seek redress through tort for the harm suffered. But in light of the relatively low level of product liability litigation, it does not seem that victims of product-related accidents in Europe have turned to the court systems of the different member states in order to seek redress for the accidents they suffered.

As explained in Chapter 2, the product liability directive does not entitle to compensation for all types of injuries or all amounts of harm suffered by injured victims. Instead, it includes a mandatory minimum damage threshold and an optional damage cap. Further, compensation under tort is framed within different alternative compensation mechanisms available to victims of product-related accidents.

Chapter 7 addressed the compensation function of tort law and its interaction with alternative compensation sources and presented, from theoretical and economic perspectives, the main compensation mechanisms available, their role, their coordination -- or absence of coordination -- and the resulting efficiency of the system.

There are three major compensation mechanisms for victims of product-related accidents in Europe: the tort system -- through the product liability directive and its transposition laws -- private insurance, and public insurance. If these different compensation systems were simultaneously applied, victims could be over-compensated and tortfeasors would be over-deterred. Hence, the outcome would be significantly inefficient. In order to avoid such an inefficient situation, there are three main systems

available for coordinating the different alternative compensation mechanisms: a right of reimbursement by the collateral source, a collateral source rule, and a collateral benefit offset rule. Each of these mechanisms has advantages and disadvantages when analyzed from the perspective of compensating victims and creating efficient incentives for potential tortfeasors to invest in care. The most common coordination system in place in the different member states is a right of reimbursement, often in the form of a subrogation right, by the collateral source against the tortfeasor for benefits already paid to the injured victim.

Evidence from private insurance companies suggests that liability insurance premiums have not increased after the introduction of the product liability directive and its subsequent transposition laws. Thus, the compensation system that seems to bear most of the costs of victims of product-related accidents seems to be social insurance. As shown in Chapter 7, the existence and important role of European welfare systems suggests that the low level of product liability litigation in Europe is due to the role of collateral sources, such as public social insurance, in compensating victims of product accidents.

European product liability would create better incentives for deterrence to tortfeasors if social insurance agencies would seek reimbursement for the benefits paid to injured victims or if victims would have effective tools -- both procedural as well as substantive -- to facilitate their tort claims. But neither social insurance agencies nor victims seem to be pursuing such claims. Under the current structure the costs of product-related accidents become hidden costs born by social insurance systems.

This dislocation of costs has three major effects: First, the social insurance system bears costs that should be privately born by the tortfeasors responsible for causing them. Second, victims are under-compensated since social insurance benefits do not provide full compensation as tort would. Finally, product manufacturers are under-deterred since they do not internalize the costs of the accidents they cause. The current structure should

be revised in order to better compensate victims, create efficient incentives for tortfeasors and protect social insurance systems from a burden they should not bear. Social insurance agencies should use new technologies and keep records of injuries and benefits paid in order improve their abilities to exercise reimbursement rights.

Today, social insurance systems and the entire European welfare state are struggling in the face of budget cuts and increasing questions about their future viability. Revising and restructuring the allocation of costs of product-related accidents could help these systems conserve economic resources. Most importantly, this could also help improve the effectiveness and efficiency of the product liability system as a whole.

European product liability faces many challenges in ensuring victims' access to justice from procedural and substantive perspectives, achieving efficient interaction with other product regulations such as ex ante safety regulation, and placing the burden of the costs of product-related accidents on the parties who should bear them instead on the public insurance system. This arises as an important task when considering the current economic situation and the step back that the different welfare systems are undergoing today.

The product liability directive and its subsequent transposition laws were adopted and introduced over twenty years ago. It is time to reconsider the private or public nature of the regime, the incentives that it generates for the different parties involved and its overall performance. The current structure presents enough distortions to justify revisiting the overall model so that its goals can be achieved and its effectiveness maximized.

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