
Liability Prevention and Biotechnology: A Brief History of Successful Industrial Stewardship

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Agricultural biotechnology’s “waves” of grain are not amber, but red, white and green. “Green” applications were the first to arrive: the commercial food- and feed-production side of agricultural biotechnology. “Red” refers to plant-made pharmaceutical applications, whereas “white” refers to industrial applications.

Agricultural biotechnology’s “waves” of grain are not amber, but red, white and green. “Green” applications were the first to arrive: the commercial food- and feed-production side of agricultural biotechnology. “Red” refers to plant-made pharmaceutical applications, whereas “white” refers to industrial applications of biotechnology (including biofuels, bioremediation and chemical substitutes (*e.g.*, enzymes that can replace chlorine bleach). Each sector has the potential to provide significant benefits to society, if the risks—including adverse economic impacts—can be managed to the satisfaction of key stakeholders, from farm to fork.

This article sums up the regulatory and liability hurdles that stand in the way of launching new products in each of these categories, beginning with lessons learned from green products. A brief review of successes and failures and existing risk-management methods may help overcome legal barriers to entry. Also discussed are novel barriers to entry posed by risks that may not be compensable, including economic losses incurred by other growers.

These liability risks and the market barriers they create are elusive and hard for American innovators to understand fully and manage effectively. Fortunately, industry-stewardship processes have evolved to anticipate and prevent novel liability risks, including the elusive economic-loss risks. Such stewardship standards also avoid regulatory recalls and help to support a sustained pipeline of productive innovation (Abramson and Carrato, 2001). The largest of the biotech-seed companies have a wealth of experience in identity-preserved production. This allows them to draw upon historical data and experience as they strive to develop stewardship systems that meet modern standards and market expectations for genetic purity.

THE PRODUCT PIPELINE AND REGULATORY ROADMAP

The agricultural biotechnology industry can be visualized as a large oak tree, the trunk of which is made up of the top four crops: soy, corn, canola and cotton. Each of these four intertwined trunks has its own history of successes and failures, and each has helped to establish biotech crops as essential to modern agricultural production. The environmental benefits of these genetically modified (GM) crops—from soil conservation to reduction in insecticide inputs—are now well documented.

Unfortunately, the tree lost entire limbs after the industry invested significant research funds (over \$100 million in some cases) getting product lines ready for commercial launch. While some biotech crops have done remarkably well, there are many more innovative products of agricultural biotechnology that advanced to the verge of commercial launch, only to be shelved pending overseas regulatory approval or resolution of consumer concerns. These other crops lie scattered around the base of the oak like branches blown down by a storm. These product lines, like *Bt* potato, could have brought significant benefits to growers, consumers and the environment. To date, however, plans to revive the GM potato, tomato, wheat, beet, flax, barley, lettuce and other abandoned biotech crops are up in the air.

The challenge facing the agricultural biotechnology industry is to learn from past mistakes and to adjust to realities. While trees will grow in the paths of hurricanes, tropical species evolved roots and trunks that bend better than those of oaks. For agricultural biotechnology to succeed, innovators need to foresee the predictable market forces that may prevent product launch, and design business strategies that meet consumer demand without triggering the barriers erected by regulators or other consumers.

Green Biotech: Steadily Growing Despite “ZAP” Attacks and Traceability

Green-biotech products were first out of the door, paving the way for red and white products. The greenest of the green-biotech crops are the Roundup Ready™ and *Bt* families. The vast majority of soybean growers in the United States and Argentina have embraced Roundup Ready™ soybeans, in what is surely one of the fastest adoptions of new agricultural technology in history. Herbicide-tolerant canola has become the dominant option in Canadian and US fields. *Bt* corn and cotton show similar track records of success, reducing pesticide use and demonstrating their food safety despite the skepticism of activists.

These successful launches of multiple varieties of biotech corn, soy, cotton and canola are the fortunate ones, however. Many other equally useful and innovative crops have been

sidelined due to consumer and food-company queasiness over potential loss of market share. Any food company worth its salt will honor even a seemingly small percentage of concerned and vocal (*i.e.*, “squeaky wheel”) customers, for perfectly valid business reasons. A business may not be able to justify losing a 5% share of a branded product’s market just to use a lower-cost input that benefits the environment (through reduced insecticide use or soil-conservation benefits). While this corporate marketing decision denies the majority of consumers the choice to support environmentally beneficial, lower-cost biotech crops, such is the stark reality of the modern mass-produced marketplace.

This attention to detail led the biotech industry to build its own system for preventing the development of insect resistance, and to present it to the Environmental Protection Agency (EPA), which then imposed conditions on the growers of *Bt* crops to ensure compliance. For identity preservation, the same conscientious companies can adapt segregation practices, developed in seed production, to produce containment measures that are tailored to various types of agricultural biotechnology. These practices may be adjusted to ensure compliance with various levels of “tolerance” of adventitious presence of undesirable genotypes.

The European Union has only recently lifted a 7-year moratorium on regulatory approval of GM crops, under threat of World Trade Organization action by the United States, Canada and Argentina, who have lost billions in exports of grain (corn and soy) since 1998 due to the European Union’s anti-biotech policy. This barrier to marketing of new biotech crops has been lifted only in part, for some varieties of biotech crops.

To date, the first big success in biotech crops—Roundup Ready™ soybean—has proven its worth and gained access in major food and feed markets, but not environmental release. Major markets remain closed to many other biotech genetic events, and troubling moves toward traceability-based testing and associated recalls of unapproved biotech genetic events could make these barriers to entry pervasive and persistent. For example, the export barriers to entry forced soybean growers and processors (represented by the American Soybean Association, United Soybean Board and National Oilseeds Processors Association, “ASA-USB-NOPA”) to develop a policy (the “eleven-point plan”) that dictates a closed-loop identity-preservation (CLIP) standard for varieties lacking regulatory approval in major export markets. As a result, upcoming *Bt* varieties of soybean (produced under license from Monsanto) can be marketed in the United States only if there is a system that meets CLIP’s eleven points.

As a result, *Bt* soybean will have to be submitted to major markets for approval (or be grown in a CLIP system) as long as “zero tolerance,” and testing to enforce it, are maintained in the European Union. The United States and its grain-exporting allies have yet to achieve a globally recognized tolerance for adventitious presence of GM products in a world where a zero adventitious presence (ZAP) regulatory import standard (enforced via genetic testing and mandatory disclosure laws) is increasingly prevalent. These policies are spreading to other nations that are key trading partners of the United States, with even more extreme standards emerging. For example, China has adopted “zero tolerance” for GM-food labels, which is even more strict than the European Union’s standard of 0.9%.

Through a multilateral environmental agreement that became law on September 11, 2003, the Cartagena Protocol on Biosafety is promoting its “precautionary approach” to regulatory approval of biotech crops as a global standard. Paired with this delay-ridden approval process, the European Union has a ZAP standard for a variety that lacks approval. This is not unusual standing alone; the United States also has zero tolerance for unapproved varieties of biotech crops, but does not mandate disclosure or conduct extensive genetic testing (and rule-making is underway to allow some tolerance for adventitious presence where the variety in the pipeline is ultimately intended for food use).

In contrast to the United States, the European Union has attempted to address tolerances in seed purity, only to find opposition to any number other than zero (*i.e.*, less than the limit of testing). The European Union will use testing centers to track each GM event, forcing destruction of food based on traces of any unwanted DNA (*e.g.*, this is currently occurring with one shipment to Ireland that contains Syngenta’s Bt10 corn, which carries a gene for antibiotic resistance that is unapproved for importation by European Union nations).

This testing process and “traceability” for GM events could become a global standard if the parties to the Biosafety Protocol impose, at its next meeting in Brazil (March 13–17, 2006), an international requirement that commodity shipments list all biotech genetic events that they “may contain” (using unique identifiers for each event). This law would spread traceability and labeling for GM content bound for food/feed (known as FFTL in industry email loops) to the parties to that protocol (120 and rising). If these nations are even more concerned about biotech crops than the European Union, they are free to impose even stricter standards than the European Union.

The power of ZAP standards for unapproved biotech crops should not be underestimated, since it empowers activists armed with genetic tests to force recalls of US shipments when they reach port. This is the least business-friendly arrangement imaginable, and it appears tailor-made for activists to rig to their tastes, testing only those corporate shippers whose policies displease them. This testing for GM events is now occurring with shipments of corn seed and feed to the European Union and Japan. Two seed shipments to Japan were found to contain Syngenta’s unapproved variety Bt10. The shipment to Ireland may require disposal of over 4,000 tonnes of corn-gluten feed.

In sum, the European Union is not alone in its quest to label GM food and trace biotech crops globally, and the regulatory environment worldwide could be taking a distinct turn toward anti-biotech policies among US trading partners. The best example of this troubling trend may be China, which has its own thriving biotech research industry with hundreds of crops in the pipeline (and millions of GM poplar trees lining its rain-ravaged hillsides). China has bowed to the European Union and imposed a GM-food labeling standard. To complement this standard, China has legalized only commercial production of biotech cotton (non-food) despite pressing food-security needs (and despite reports of growers using pirated GM rice and corn in violation of its laws). These global trends are increasingly raising barriers to importation of GM crops, leaving some markets (like wheat and rice) without the benefits that come from biotech innovation.

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“Red” Plant-Made Pharmaceuticals

Red biotechnology—plant-made pharmaceuticals (PMPs)—is necessary, according to pharmaceutical industry analysts, to meet increasing demands for protein-based large-molecule drugs that can be produced only in living organisms. Shortages of certain new large-molecule drugs, which are generally produced in cell cultures, have led biotech companies to explore new production methods. Corn and rice are particularly suitable for production of proteins for pharmaceutical applications, given the relative ease of storing, transporting and refining the protein.

The cost of maintaining compliance with “zero-tolerance contamination requirements” has led some observers to wonder whether “the economic payoffs from growing pharmaceutical plants outweigh the costs associated with the risk of food contamination.” (Elbehri, 2004). To weigh those costs in advance of creating a new PMP, the researcher needs to obtain data on identity-preservation costs, third-party oversight of the process, insurance coverage and other known expenses necessary to manage risk.

In general, the costs of insurance and third-party oversight for the production process will be hard to define. To the extent that these costs are part of a successful risk-management strategy, however, estimates should be incorporated into long-range planning. The comparative costs for different regions (with varying risks) should be factored into analysis of the feasibility of marketing and probable return on investment.

White Biotechnology—Industrial Biotech Comes of Age

White biotechnology is defined as the industrial use of GM crops or microorganisms (*e.g.* bacteria, fungi) to create enzymes, proteins and other industrial compounds and materials. Industrial biotechnology is creating compounds that can replace of hazardous chemicals, providing “greening” companies with new options for reducing hazardous waste. In one remarkable instance of industry reaping corporate value and environmental benefit from biodiversity, Diversa of San Diego has taken a gene from a thermophilic bacterium that encodes an enzyme allowing paper-manufacturing companies to avoid using tons of toxic chlorine bleach (Hessler, 2005).

When a plant is used as the source, rather than a microorganism, a “plant made industrial product” (PMIP) results. If the PMIP crop *per se* has significant export or consumer markets, the PMIP may encounter opposition at commercial launch. Concern has been expressed that PMIPS pose the same threat as PMPs, but do not have the same level of regulatory oversight. The PMIP has been cast as a neglected stepsister on issues like pollen drift, creating what appears to be a liability “bullseye.” This gap in understanding of pollen containment by regulators represents a threat to the food supply, since PMIPS that

are not approved for use in food and could be declared an “adulterants” by the FDA, or trigger export losses upon detection by European-Union or other overseas officials. These liability risks were pointed out to USDA by the American Soybean Association and the regulatory gaps were closed.

Identity preservation of the crop used to produce a PMIP is necessary to deliver a pure product, and is equally essential to prevent the undesirable release of a PMIP in a manner that could lead to cataclysmic economic impacts.

Nuisance Claims by Neighboring Growers

Post-StarLink™ case law could allow neighboring growers to recover their economic losses from the source company, if they prove actual commingling of GM variety unapproved in the European Union [see, *In re StarLink Corn Products Liability Litigation, Marvin Kramer v. Aventis CropScience USA Holding Inc.* (2002), 212 F. Supp. 2d 828 (U.S. District Court, N.D. Illinois)].

StarLink™ was cited in a recent Canadian court decision denying a class action to organic growers who sought recovery of their economic losses from the marketing of GM canola varieties unapproved in the European Union [*Hoffman v. Monsanto*, 2005 SKQB 225 (2005)]. This action was filed against Monsanto and Bayer Crop Sciences (BCS) seeking to enjoin the marketing of Roundup Ready® wheat, and also adjudicate liability for price impacts to canola based on “contamination” of organic and non-GM canola that could not be exported by Canadian farmers to the European Union. The canola sold by Monsanto and BCS was fully approved in Canada and posed no known health or environmental risks. The *Hoffman* court denied plaintiffs the class action they sought, but hinted at recognition of claims for violations of environmental statutes (if canola is deemed a “pollutant”) (<http://204.83.249.88/judgments/2005/QB2005/2005SKQB225.pdf>).

The *Hoffman* court confirmed the basic idea that “pure economic loss” is not recoverable, holding that the facts did not present a situation allowing a claim for recovery of “pure economic loss” (with no “physical injury”), citing various policy reasons (2005 SKQB 225 at ¶ 80). The court also rejected the idea that defendants committed a “negligent undertaking” when they initiated identity preservation to preserve canola exports to Japan, then dropped that program when they received approval in Japan (even though the European market was still closed to any canola that was still commingled). While the plaintiffs still have a nuisance claim the court is willing to entertain, it remains to be seen how that action will play out (*i.e.*, the plaintiffs may run into the same barrier that the US District Court in Eastern Missouri imposed in *Monsanto v. Sample*, if they cannot prove a “physical injury” from actual commingling of the GM canola with their export-bound crops). With two causes of actions surviving, but no class certified, this decision (if not overturned on appeal) could lead to a flurry of individual filings if Saskatchewan’s certified organic farmers are willing to take Monsanto and BCS to court.

Secrecy of Field Trials

February 2005 saw another landmark court decision relating to identity preservation of biotech crops. District Court Judge David A. Ezra rendered his final decision ordering

disclosure of PMP and PMIP field trials [*Center for Food Safety v. Veneman*, No. 03-CV-621 (D. Haw, filed Nov. 12, 2003)]. This Hawaii federal court ordered representatives of the USDA to hand over to Earthjustice attorneys the precise locations of open-air field tests of PMP crops. This was the first time the federal government was forced to disclose the location of field tests of GM crops. Earthjustice, representing citizen groups Center for Food Safety, Friends of the Earth, Pesticide Action Network North America, and KAHEA (The Hawaiian-Environmental Alliance) filed the lawsuit to compel USDA to review the environmental and public-health impacts of such activities. In August, 2004, district court ordered the disclosure, rejecting the claims by the government and the Biotechnology Industry Organization (BIO) of potential “espionage,” “vandalism,” and “civil unrest.” The Court denied USDA and industry’s motion for a stay of disclosure, and the government handed the information to plaintiffs’ counsel.

The court has not yet ruled on the public-disclosure issue, however, and plaintiffs cannot reveal the information to the general public. The disclosure should allow plaintiffs to pursue their original objective of seeking environmental reviews that will determine “how close these experiments are to conventional food crops” and ecologically sensitive areas [see *Government Forced to Disclose Locations of Test Sites of Biopharmaceutical Crops (USA)*. <http://biotech.dnsalias.net/or/2005/02/3912.shtml>].

IDENTITY PRESERVATION 101: THE LEGAL TOOLS

Where a company marketing a PMIP or PMP will encounter concern about liability risks, including adverse economic impacts from unwanted commingling, it can use identity-preservation measures to reassure domestic food businesses, exporters, and overseas importers. The use of the approved identity-preservation system will ensure that the PMIP is not commingled with food or grain exports.

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are rapidly evolving to meet the demands of the market.*

Identity preservation of commodity grain crops to meet specialized customer needs has a long and successful history in seed production. The production of seeds generally operates on tolerances for unwanted input of various types, including genetic off-types. Historically, this posed no problem of commercial significance; corn out-crossed freely in commercial production. In today’s world, however, any corn that is bound for export must be “channelled” to particular elevators. One stray corn kernel that lacks regulatory approval in an overseas market can lead to destruction of an entire cargo, where the standard for commingling is “zero tolerance” and a trace of an unapproved variety is found (as occurred in 2005 when the Syngenta Bt10 variety was detected in four separate shipments of US-origin corn). As a result, the processes for identity preservation and seed-purity assurance are rapidly evolving to meet the demands of the market.

Industry Standards

Innovation in agricultural biotechnology begins with the novel steps that lead to an invention meriting a patent; however, the path to market requires sound agricultural management. Industry standards for identity preservation provide a biotech-seed company (“the Company”) with a standard of care to follow that meets both quality-control and liability-prevention needs. To protect the Company’s investment in innovation, the developer of a new application using agricultural biotechnology, such as a PMP or PMIP, should adapt existing standards to create detailed methods for stewardship in the production process. Stewardship methods for the agricultural management of biotech crops vary with the crop and the location of the production process.

The simplest route to maintaining identity preservation is to anticipate the demands of customers and regulatory agencies, develop an industry standard and stick to it. Industry organizations, led by BIO, developed the Confinement Analysis and Critical Control Point (CACCP) concept for molecular farming applications including ProdiGene’s corn-produced vaccine for piglets, and PMIPs (Phillips, 2004).

A sound model for identity preservation of PMPs and PMIPs was generated by the Canadian Food Inspection Agency (CFIA, 2004). After reviewing various methods for identity preservation, the CFIA recommended, in its January 2004 report, eleven elements of confinement systems for “molecular farming crops” (*i.e.* PMPs and PMIPs). This paper is patterned after the CACCP system developed by BIO, and it mandates supervision by a third party, preferably regulators. One item that is missing, in comparison to the ASA/USB/NOPA “eleven point plan” is the express assumption of liability for system failure attributable to the biotech-seed company.

Identity preservation methods have been developed in consultation with growers and grain handlers. The ASA/USB/NOPA CLIP process has been used since 1998 to protect US-export flows of soybeans to the European Union and other major markets, while allowing limited releases of new biotech soybeans. The ASA/USB/NOPA “eleven point plan” for the CLIP process requires the biotech-seed company to assume liability for system failure. This generally precludes the company from using contractual clauses that unfairly shift to growers all the risk of commingling. Properly and fairly operated, such systems for identity preservation will continue to provide grower and biotech-seed companies with protection from liability lawsuits.

Similarly, the National Corn Growers has developed the “Know Before You Grow” process for identity preservation of corn-gluten feed that is bound for export. While exports of whole corn to the European Union have been foreclosed since 1997 by the commingling of GM events that lacked regulatory approval, recent efforts to comply with the European Union’s new traceability directives (effective 4/18/04) have succeeded in keeping the \$400 million per year in corn-gluten feed flowing to the European Union from the United States.

Identity-preservation methodology has been developed through trial and error, as major life-sciences companies developed their stewardship programs in consultation with growers associations. The ASA/USB/NOPA CLIP process has been applied for the

production of DuPont's high oleic soybean, which is used in specialized biodegradable lubricant applications. This same eleven-point plan was previously presented in 1998 to AgrEvo USA, the corporate predecessor of Aventis Crop Sciences, Inc., which adopted it for a Liberty Link® soybean stewardship program (which soybean was not, however, marketed in the United States, in contrast to the high oleic cultivar).

Under the CLIP system, the first level of concern involves the terms of the contract for sale of the biotech seed. The contract with the grower of the specialty PMP or PMIP crop should have conditions similar to those for certified seed production or federally permitted field trials, including regular inspections and scientifically defensible minimum isolation distances from neighboring crops. The contract should also guarantee the grower a premium adequate to cover the costs of preventing commingling with other crops (field isolation and inspection requirements can be costly for the grower). Only contracted growers should be allowed to grow the specialty crop.

The second level concerns planning to coordinate the harvest process. Growers need training to ensure that combines and transport vehicles do not cause commingling and are cleaned out to industry standards. The Company needs to identify elevators where there is willingness to accept the identity-preserved production while keeping it completely separate from all other commodities. These elevators should be confined to particular regions, not widely scattered throughout the farm belt. Coordination of inspections between the elevator and the field inspectors will allow the midseason yield estimates to be matched to the actual delivery, to ensure that the entire crop is delivered and not diverted to other uses.

Thirdly, the CLIP system requires that the Company contract with a third party to certify the process. There are seed-certifying agencies that have conducted such audits for decades [*e.g.*, the Association of Official Seed Certifying Agencies (<http://www.aosca.org>) and newer specialized operations such as Novecta (<http://www.novecta.com>) and the United States Department of Agriculture's Process Verified Program (<http://processverified.usda.gov>)].

Lastly, the CLIP system requires that the Company agrees to assume—and not attempt to disclaim or limit—the legal and financial liability that arises from negligence or other breaches. Under the ASA/USB/NOPA CLIP system, the focus is upon crops that may lead to lost trade with overseas soybean export markets. Commingling of an unapproved variety, in particular a PMIP or PMP variety that is not approved for any food or feed use at any tolerance, can lead to cataclysmic economic loss in major export crops.

These systems have not worked perfectly, as the StarLink™ corn recall and ProdiGene commingling incidents illustrate. In the StarLink™ episode, Aventis Crop Sciences had been warned of the potentially “cataclysmic” economic impacts that existing US precedent pointed toward (Censky, 1999). Despite this warning, Aventis sold StarLink™ corn with inadequate stewardship. Along the same lines, tiny ProdiGene's sprouting corn volunteers contaminated a soybean field, despite a USDA inspector's warning. This commingling incident ended at one elevator, but still required an interest-free loan from USDA to maintain a viable business.

Detecting Gaps in Regulation and Stewardship

The practice of identifying and managing risks adequately is not a perfect process, and troublesome gaps have emerged in regulation of particular aspects of biotechnology. One example in USDA regulation involves setback distances to preclude pollen drift from PMP plants. This glaring gap in regulatory oversight was apparent to anyone comparing the planting distances in the regulations, and it was quickly corrected through the timely intervention of the American Soybean Association. Had this gap not been corrected, the overview of a “bullseye” made a target for plaintiffs’ attorneys that exposed a failure to exercise “due care” in the segregation of crops.

This “biotech bullseye” episode provides a “near miss” in liability law, which helped to prevent serious commingling with PMPs. It also provides confirmation that the existing stewardship practices of the most responsible seed companies (Monsanto, DuPont, *etc.*) were more alert to the risks of out-crossing from PMP plants than were USDA regulators. The seed industry had already determined through testing that a 1-mile planting distance is required to maintain a very low tolerance for out-crossing in corn production. These seed companies foresaw the need for stewardship standards that track potential liability risks, including those that might elude a busy regulatory agency.

This does not mean that USDA is incompetent in terms of managing risk, but merely highlights the need to supplement regulatory review with industry oversight. It is a basic principle of product-liability law that even the most proactive regulatory authority can only set a “one size fits all” minimum, based on limited knowledge of the product, while the alert company is expected to know its product and foresee its hazards with more precision.

ISO 9000 and ISO 14000 are process standards that can be used to identify customer needs and product hazards, and to implement processes to prevent both product-related (under ISO 9000) and environmental liability (under ISO 14000). Biotech-seed companies may use these standards or a modified system that is not certified by an ISO registrar but still provides necessary oversight that regulation cannot impart.

The US Supreme Court recently affirmed the role of industry in post-market surveillance for product risks. In *Bates v. Dow* (2005), the Court put all pesticide manufacturers on notice of the power of tort law to keep them alert to new risks that emerge over time, which may elude the detection of regulators. This landmark decision expands the horizon of biotech-seed-company liability for certain EPA-registered crops, and creates a feedback loop, as described by Justice Stevens, requiring companies to adjust their practices to avoid the adverse event that triggered the state’s tort law.

Companies that do not quickly react to feedback can find their markets disappearing due to consumer opposition. In the PMP setting, this occurred in the ProdiGene case; failure to remove volunteer PMP corn from a soybean field led to a \$3 million loss of the elevator’s commingled contents. Subsequently, the biotech industry implemented additional safeguards and regulatory agencies reviewed inspection policies.

However, policy positions of major players in the chain of commerce shifted to a more anti-biotechnology position after StarLink™ (with help from the ProdiGene-PMP commingling event). The Grocery Manufacturers of America (GMA) began insisting on

abandoning any use of food crops for PMP production, whereas grower and grain associations merely insisted on the use of well tested closed-loop identity preservation. GMA's position was not irrational or poorly considered; its board is made up of CEOs whose judgment is well informed. This position reflected a loss of trust from a critical group of customers—the primary buyers of “green” biotechnology products had lost faith in the ability of the makers of “white” and “red” products to maintain necessary segregation in production. Winning back trust, once lost, is much more difficult than the effort required not to breach that trust in the first instance.

There are hazards from food that are heightened by anti-biotech regulations that deny consumers access to use of the best available technologies for controlling carcinogenic mycotoxins in their staple food supply.

WILL A LIABILITY BACKLASH FOLLOW THE EUROPEAN UNION'S PRECAUTIONARY APPROACH?

Two potential backlashes are created by the European Union's ZAP approach to GM crops. First and foremost, there are hazards from food that are heightened by anti-biotech regulations that deny consumers access to use of the best available technologies for controlling carcinogenic mycotoxins in their staple food supply. These toxins, which can be better controlled with use of *Bt* corn, are not a hazard of significance in the United States or the European Union (which have resources to detect it and avoid exposure). However, they pose a significant risk to the health of mothers and children in Africa, Central America and Mexico where less-varied diets lead to higher corn consumption in farming communities.

The European Union has implemented both GM labeling and ZAP regulatory approval by invoking the “precautionary principle,” an approach to regulatory approval that would consider the presence of antibiotic-resistance genes in corn-gluten feed cause for concern and, paradoxically, would mandate the destruction of said feed. This would apply even if the destroyed feed would be healthier than the alternative due to lower mycotoxin levels.

Although liability laws dictate the use of the best available technology to avoid feeding carcinogens to children and pregnant women, the regulatory environment instituted by the European Union to meet “collective preferences” operates to ban any trace of this best available technology—setting up a future where liability could apply even if the company in question were to assert as a defense in court, “The European Union made me do it.” The law in the European Union and the United States may provide a presumption of reasonable behavior based on regulatory requirements, but it can be overcome by a tort theory stating that there was a risk that required a warning or could be implemented at minimal cost (in the case of biotech crops, the cost of using them could be lower).

The anti-biotech activists who run the show in Germany have succeeded in creating their own innovative approach to liability, which helps to close the door to any grower who might attempt to use the “best available technology” for mycotoxin-insecticide reduction (the European Union has approved some varieties of *Bt* corn). German growers of biotech crops are discouraged by a GM liability law that forces them to avoid any commingling with other growers, who may have agreed to supply non-GM products.

The concept of protecting the non-GM grower’s contractual promise of “zero” is also emerging in the negotiations of the Biosafety Protocol’s liability regime, which is now underway with hopes of producing a text by September 11, 2007, for approval by the parties to the Biosafety Protocol. Activists have suggested innovations in liability law that would:

- reverse the burden of proof to the GM-crop grower or grain exporter,
- protect the economic loss of the non-GM grower (who may be harboring a reservoir of “biodiversity” in his choice of seed), and
- place the ultimate blame on the company that developed the biotech seed, since the GM event that “harmed” the non-GM grower can be traced.

The seed of anti-biotech liability law now sprouting in Germany could have a broad dispersal if the parties to the Biosafety Protocol do not come to their senses and reject such standards.

With member states free to impose their own liability regimes like this one, and balk at European Union-wide regulatory approval, the European Union’s misguided anti-biotech-innovation policy could take decades—or an entire century—to reverse, even if it is shown without dispute to have caused well documented harm to human health and the environment. To ensure that the costs of the European Union’s precautionary approach and ZAP testing are counted, foundations that care about neglected populations of people (*e.g.*, African refugees who are denied food aid based on traces of locally unapproved GM events) and neglected plants (*e.g.*, wild and indigenous soybean, rice and other crops) need to stand up to the challenge of tracking the harm that can be caused by misguided regulation.

While the US federal regulatory system is streamlined and efficiently operating to manage risks, there are emerging roles for states, counties and cities to react to authorities that seek to protect economic interests and social, cultural or indigenous concerns.

STATE LAW BARRIERS AND TOOLS FOR MARKETING BIOTECH CROPS

While the US federal regulatory system is streamlined and efficiently operating to manage risks, there are emerging roles for states, counties and cities to react to authorities that seek to protect economic interests and social, cultural or indigenous concerns. These local

authorities may be reacting to international opposition that limits markets from particular states. In response to California's rice industry, a bill was passed in 2000, Assembly Bill 2622, that licensed all rice for its economic impacts—specifically addressing the threat that biotech rice poses to export markets; Arkansas passed a similar law in March 11, 2005, that gives the Arkansas State Plant Board the power to regulate “commercial impact” of rice commingling—without specifically mentioning biotech rice (HB 2574, 3/11/05).

For example, Iowa has passed a law precluding any county from declaring itself GM free (a reaction, no doubt, to the three California counties that went “GM free” in 2004). Iowa grower Bill Horan just reported that production of a PMP will finally be allowed to occur in Iowa, at a military base over a mile from other corn production. The Iowa experiment now underway will provide more data on the cost-effectiveness of growing pharmaceutical corn in the nation's largest corn-producing state.

The story of Ventria's rice provides a narrative that touches upon the entire range of regulatory and liability issues facing new PMPs launched in the United States, and the key stakeholders in the commercial launch of a PMP. Ventria started out trying for state-level regulatory approval in California. While the California Rice Commission approved Ventria's application, leaving it up to the state Department of Agriculture to decide, the announcement that a public hearing would be held resulted in Ventria's choosing to relocate its operations to Missouri, giving up on California approval.

Missouri proved inhospitable to Ventria as well, as major food producers who use Missouri and Arkansas rice expressed concern about commingling. Press reports indicated that a counterseasonal South American site may be next in line, or a small plot in North Carolina.

If the agricultural biotechnology industry is going to meet customer expectations for segregation of the green, white and red, it may need to work with growers to create districts that establish identity preservation as a matter of civic law.

One little known legal aspect of the Ventria story is the unused Missouri “grower district” statute that was enacted in late 2004 (effective January 1, 2005) with Ventria in mind (but not used by Ventria) to line up growers in a dedicated region (a solution that might have reassured rice interests opposed to Ventria's plans). A future PMP- or PMIP-production system can avail itself of this tool, however. This concept of a grower district appears in a new Missouri statute that was passed in 2004, around the time frame when Ventria moved its operations from California to Missouri in early 2005. If the agricultural biotechnology industry is going to meet customer expectations for segregation of the green, white and red, it may need to work with growers to create districts that establish identity preservation as a matter of civic law.

Other novel agricultural technologies have arrived on the scene with similar segregation issues. Canola only recently became an edible food product by innovations adjusting rapeseed's nutritional profile. The canola industry uses a variety of production methods to maintain the necessary segregation, including grower districts in Idaho and Washington.

Another angle on PMP production that is under review is simply to go underground in the farm belt. This allows production to occur close to existing processing centers in the midwest (*e.g.* Sigma Aldrich in St. Louis, MO), while avoiding the controversy and exposure to eco-terrorism that can occur aboveground. Like any innovative step, however, this option will have to prove its economic worth before innovators will adopt it.

CONCLUSION

Despite past successes, and the knowledge gained from failures and near misses, the road to future commercial success in agricultural biotechnology remains as full of hidden economic hazards as the road to the Baghdad airport. The European Union and its like-minded trading partners will continue to hold their ZAP standards over the heads of grain exporters and will increasingly drive innovation in agricultural biotechnology into contained, closed-loop production systems. Like a game of three-dimensional chess, biotech crops will face three levels of regulatory oversight, starting with federal approvals, but with more requirements emerging at the state level (even in counties and/or cities), and overseas. For many biotech crops, international approvals that may be required prior to market launch in the United States (for soybean, rice, wheat and other primarily export-bound crops). As a result, US agricultural biotechnology operations will need to maintain perfect divisions between the green, white and red sectors—as neatly divided in the fields of America as the stripes in the Italian or Irish flags, which do not blur their colors together.

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