The European Situation

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My opinions on biotech and of what is happening in Europe are from a general industrial perspective rather than from Nestlé's perspective in particular. To avoid any misunderstanding, the Nestlé corporate position on biotechnology is very clear: we believe that we need to develop and use it, and we will support it wherever and whenever we can. Only a few days ago, our CEO in Switzerland said that not developing biotechnology would be a greater risk than developing it. That is an unmistakable position, but we have to realize that we operate in the real world, and sometimes there are things that you want to do but cannot.

I gave a presentation on this subject here in the United States about a year and a half ago, and, in response, people saw me as a doomsayer, out of touch with reality. It is rather unfortunate, but the situation today is no more rosy than I pictured it then; if anything, it is probably worse than I predicted it would be. Take, for example, the shift in European soybean imports from the United States to Brazil. We believe that a major motive was that Brazil positioned itself as a "non-GM" country. Four million tons that previously came from United States now come from Brazil. Apparently, no one was hurt by that move, because global trade increased enormously with China. What could not be sold to Europe is being sold to China. Ironically, the Chinese use that genetically modified soy to grow chickens that are exported to Europe.

Not developing biotechnology would be a greater risk than developing it

LABELING

About twenty countries in the world now either have labeling regulations or are considering them. They are all different. The following is a short, perhaps imprecise, summary. One country has enacted a complete ban: Sri Lanka banned all GM ingredients as of May 1, 2001. We have been in discussion with Saudi Arabia for some time, because they are considering a ban. Their very restrictive labeling legislation will come into effect in November, 2001. Obviously, this is a significant barrier to trade. If you have centralized production and want to export to those countries, you face problems similar to those of about 20 or 25 years ago with additives and other ingredients.

PERSPECTIVE

I will spend a little time on how we got to this point, just a few remarks. We have seen food scares and mounting public distrust. Opinion polls on biotechnology in Europe, showed an across-the-board decrease of 10% in public acceptance between 1996 and 2000. This was not limited to agriculture and food, it included pharmaceuticals. More striking was that it focused on moral or ethical aspects of acceptability. Opinions being formed at the moment are not very positive. Uncertainty was at the root of the problem. When GM products came to the market in Europe, we were faced with contradictory statements or even silence both from regulators and from industry. This contributed substantially to the lack of confidence now prevalent.

European culture, food culture, and agriculture have been mentioned at this meeting. It would not be so bad if we Europeans were more modest. European food culture is extremely important, but, on the other side of coin, are the food scandals and scares of the past ten years, such as BSE and foot and mouth disease.

A little modesty would also help with European agriculture. I have the impression, when talking to Europeans — it does not matter which member state you are in — that farming is seen as part of the fabric of daily life. I commute seven minutes from my home to work and pass many farms, with sheep, horses, cows, grapes, corn, wheat, and potatoes. There is a feeling that European agriculture is purer and much closer to nature compared to industrial agriculture in the United States. Yet, if you look at data that are available on various web-sites, you will find that use of chemicals in Europe is much higher than it is in America. When I use this argument in Europe, they are not pleased to hear it. But, it is a fact. Therefore, more modesty would be beneficial.

POSITIVE DEVELOPMENTS

So far, it has been all gloom and doom. Let us consider positive developments, because there definitely have been some. It looks as if the ban on thinking and speaking about biotech has been broken! For years politicians did not dare

speak out on this subject, or they were very secretive. People who were supportive dared to say so only in closed meetings far away from publicity. That has changed. The European Parliament recently published a report on the future of biotechnology in Europe. There is a strong emphasis on pharmaceutical biotechnology and applications in the medical sector, but attention is given also to applications in the agri-food sector with a strong encouragement to look at it, to work on it, and to take what is applicable in a European situation. The same is true of an opinion drafted by Mikko Pesälä, a Finnish member of the European Parliament, which focuses on agriculture applications and is positive regarding environmental benefits in the short term and food-quality advantages in the longer term.

In the European Commission there is great deal of activity. Several commissioners are involved in getting biotechnology going again; one group is headed by the Commission President, Romano Prodi himself. Sound regulation that will authorize the possibility to grow genetically modified crops has finally been adopted. Currently under discussion is the framework for research, which is focusing on genomics and genetics.

The European Council, which consists of representatives of the European member states, convened in Stockholm and made very clear statements on the advantages of biotechnology, focusing mainly on pharmaceuticals, but including agricultural and food applications.

These are all positive elements; however, quite a few “buts” remain. The moratorium continues. Six member states have indicated that they will stop the moratorium only when traceability labeling and liability are regulated. The new proposals from the commission may or may not satisfy demands from those six member states, from activist organizations, from consumers, and from the biotech industry. There is fear that this collection of new proposals may overshoot the target because it is focusing completely on GMOs and includes fundamental change in certain policies.

Seed to Fate

What are the major changes? The framework goes further than “seed to plate”; it covers release into the environment including seed thresholds, traceability, labeling of food and feed, and monitoring and post-marketing of the final product. This is “seed to fate” rather than “seed to plate.” The food industry is concerned that the focus is on GMOs, as if they have become the scapegoat for everything wrong in our legislation, and in our European food culture and agriculture: thus, in bearing responsibility for all of these sins, biotechnology will be sacrificed. Singling out biotech will have a negative effect on the public. We do not have to look far to see that other problems are related to our agri-food chain.

What will change? First of all there is traceability, which is often confused with identity preservation. Traceability depends on the informatics, the

infrastructure of a country, and it already exists. Normally when you buy an ingredient, you know from whom you are buying and you know what you are buying. The producer of the ingredient knows from whom he is buying, and so on and so forth. There is a requirement in hygiene legislation and there will be a requirement in the new European food law for all of the players to preserve that information and to make it available. However, at this time, a gap exists and the gap is feed, and we think that that gap should be filled because many of our problems have originated from that sector.

So, traceability should be extended to the full chain for reasons of safety and quality. It is not information that is usually communicated—it is not information that is transported along the chain. There is no master dossier that goes with each ingredient to the end-producer. Some of the systems now in place are such that we can trace back to a certain time, say between 12:43 and 12:57, for a specific problem (of course not all parts of the chain are so precise).

Identity preservation is entirely different. To give you one example: yogurt made with apples or pears from Anjou is marketed in France. For a certain period of time, the yogurt is made using only those fruits. There you have a system with identity preservation, meaning that you go to the supplier, tell them what you want and get the information, which travels along the chain and is communicated to the consumer, and, eventually, that yogurt will be 10, 15, or 20% more expensive. In the discussions on-going in Brussels, this identity-preservation idea, where you limit your purchasing flexibility, where you increase costs, where you increase the amount of data and information to be managed, is seen as traceability and is explained as traceability. But I see it as being at odds with the concept of traceability.

The next aspect, labeling, has seen an important change. In the EU, as of mid-1999, we had to label all ingredients that were derived from raw materials with a GMO content of more than 1% based on DNA. Proteins also were mentioned, but no analytical methods are available. If you are below that 1% and have documentation to prove efforts to separate or segregate, labeling is not needed. If the ingredient is negative by PCR, you do not have to label. These are the three criteria for current European legislation. Along with other food producers, we at Nestlé introduced labeled products to the market that came heavily under fire and were removed from the shelves by the supermarkets. Genetically modified ingredients were slowly phased out, and, by and large, the European market no longer uses GM ingredients.

We saw a rapid decrease in consumer calls. In 1999, Nestlé France received more than 15,000 phone calls on GM: Are you using GMOs? What is it? Are they safe? Can you guarantee that it's not in there? *etc*. Labeling regulations brought clarity about what was happening, and we stopped receiving consumer calls on GM. In 2000, we had about 1,500 calls referring to GM, but they were all triggered by concern over BSE. From our perspective, calm had returned and consumers were reasonably happy with the situation.

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The Future

If I understand the proposals correctly—I saw the first draft only a week and half ago—then detectability, as a criterion, has disappeared. There is a move to process labeling, meaning that even if an ingredient is negative by PCR and you do not have documentation, you must label. It includes food ingredients, additives, and flavorings. As I see it, we are moving from practical labeling, based on facts, to ethical labeling. Practical labeling indicates when GM ingredients are present. If GM ingredients are not detectable, then the product is not labeled; however, realizing that the world is not an ideal place, a GM ingredient may be present—below a certain threshold—that you wish to avoid. With ethical labeling, the use of biotechnology anywhere in the process must be indicated on the label. This different proposition exists already, but only for some niche markets. Many people offer "organic" as an example of it, which is not entirely true since organic has a 5% tolerance. Ethical, or process, labeling is an entirely different approach from practical labeling, in my view.

We are concerned about the enforceability of this legislation. If there no longer is detectibility then reliance on a paper trail is necessary and we are afraid that, in practice, for highly processed products containing large numbers of ingredients, enforcement will be difficult.

It looks as if products that have already been authorized will have to be reauthorized within a period of four years after the law is enacted. I do not understand why. It may be that concerns remain about safety or that we want to adopt a ten-year limit also on those products.

The other new element is post-market monitoring or surveillance. I have had a number of very confusing discussions on post-market surveillance. A few weeks ago, a group of eminent European scientists, food-safety experts, and molecular biologists, gathered in an EC research center in Italy. I was there as a representative of the food industry. Consumers were represented also. Discussion ensued on the safety of "one-gene" products currently on the market and those expected in the next five to ten years. Within a few hours

there was agreement that these do not constitute a serious safety issue. We have the tools, we have the people, and we have the equipment to come to consistent conclusions about safety. But when discussing more complicated products, the group felt that reviews of equipment and available tools would be needed, to verify safety. Some people said that there is a need to look for unknown long-term effects of ingredients and components that come from the consumption of GM raw materials in the long term. This confuses me. I can imagine that you would have post-market monitoring if you have a product that is said to have a certain effects, such as decreasing blood pressure or reducing cholesterol. If you want to monitor those effects, you can devise tools accordingly. A product might have a negative side effect that you would want to monitor in a certain sensitive group, although I have difficulty envisaging a company marketing such an item. If the idea behind post-market surveillance is that the product might not be safe, then, in my opinion, it should not be on the market. If you have post-market surveillance for safety reasons, you might also ask, why do we have food-safety authorities? I do not believe that any responsible company would bring a food product to market if it was to be monitored for general safety reasons. Certainly it would not be done in the United States, where liability is commonly an issue. I would be happy to discover that I misunderstand the intent here, because this development seems dangerous.

What will be the effect of this package? If all goes well, if questions are resolved about traceability, about labeling, and about liability, we may see approvals of GM crops. But if labeling will be extended to virtually every product, given the current situation, it will result in increased demands for non-GM foods. I believe the European market will follow the clean-label policy in the current climate. We will also see increased pressure on GM animal feed and derived animal products. The moment you have an ethical basis for labeling, it is very difficult to keep it contained to the original intent because there seldom exists a good argument not to extend it to other areas.

The situation regarding processing and use of components such as enzymes is also unclear. Currently they are not within the scope of the legislation, but we do not know how this will evolve. We see world-trade implications as major issues for the future that may involve the WTO. Importation of a composite product is going to be extremely difficult to monitor and control. Enforcement is going to be extremely difficult also. Availability of ingredients may become an issue. And finally, formulating legislation on the premise that GM is fundamentally dangerous engenders public concern. Therefore, I am afraid that safety will re-enter the general discussion.

Q: Having looked a lot at nutrition surveys, the thing I don't understand is how do people imagine you can do a post-market surveillance? How would you recognize a cause-and-effect relationship in the complexity of the human diet, considering the small amount of any one particular product that people eat?

A: Frankly, I haven't a clue. There is a system that involves physicians. It differs with each member states, but if there is a persistent pattern of problems, then at a certain point, after having passed a number of hurdles, it goes into the health system and, based on epidemiological studies, a link may be found. Certain cases are known over the past twenty years even, where this has happened. Based on clusters of symptoms, the system reacts. But it is largely passive, and I fail to see how it could be made active when the symptoms are unknown at the outset.

Q: About labeling: if it does go into effect as you suggest, wouldn't almost everything get the "GM" label and then the stigma would be lost?

A: It is true that if you do have massive labeling, it's over. If everybody would label there would no longer be a problem. First of all you could question the value of having massive labeling. Secondly, we saw with the labeling exercise we went through in the late 1990s, that despite all of the agreements, all sorts of people wiggled out. You get a very disturbed market and a situation that is very difficult to handle.

Q: Along those lines, what kind of label were people responding to? Was it a big label on the front of the package? Was there any law on how you had to display the fact that there was a GMO in there?

A: The labeling in Europe is quite clear. If you have a soy protein, then immediately following the soy protein name on the label it must be stated that it comes from genetically modified soya, or you can do it with an asterisk if there are other ingredients. The asterisk indicates that it contains GM soya. We should not forget one thing, however that the initial introduction provoked no reaction whatsoever from the public. Only after activists discovered long-term food safety in the supermarket as their battlefield, did problems arise.

Q: Will any food processor in Europe ever market a product containing GMOs, given these conditions?

A: That depends on the product. There are practical considerations why you would not use GM ingredients. You do not offer the consumer a choice of two similar products if the GM ingredient is not characteristic or critical; you look for the simple solution. Where you have an ingredient that is characteristic for the product, an ingredient to which the consumer attaches value, then you offer the choice. I am not saying that you will never see any GM product in Europe. We will go through a prolonged difficult period during which we will see avoidance efforts. But, the moment something appears that is attractive or the moment somebody comes to the conclusion that it will be better for the environment to use GM crops in Europe, and that idea is sold, there will be a turn-around.

Q: It seems rather amazing to many of us in the United States that a process label could be put in place—an ethical label could be put in place. How can you limit then what goes on to a label if people are concerned about pesticide use, if people are concerned about what ethnic group produced their food, *etc*.?

A: That's a question mark.