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TECHNOLOGICAL CHANGE IN THE EUROPEAN UNION: KEY ISSUES INCLUDING COMMONALITY OF STANDARDS, INTEGRATION AS PROMOTING CHANGE, AND IMPACT OF CHANGE ON A UNIFIED ECONOMIC GROUPING

Richard Wainwright*

I am a lawyer speaking after a very fascinating series of presentations by economists, and I am the lone European — still a European — I have not yet migrated, compared with a lot of North Americans.

I hope you will make allowances for all of that. As you have probably gathered, I am a government official. I work for the European Commission. I have been there for nearly twenty-five years. I am one of the old school of workers who stays more than two and a half years at a job. But, before that, I worked for a British oil company, The British Petroleum Company, and I have also worked in British government. I worked in a private capacity as a barrister in England. I have seen a little bit of the rest of the world.

I should also say that, though I am here as an employee of the European Commission, I have to give the usual "health warning," which we are required to do on these occasions. I am speaking in a personal capacity, and I am not giving the official line of the European Union, European Communities, the European Commission, or whichever other institution you would like to call it.

What I have decided to do is to speak to you about a particular issue which has caused a great many problems and stimulated much debate. In fact, it is even causing a great deal of problems and debate within the European Union. This is the debate about genetic engineering and the questions of the effects or non-effects of genetic engineering on foodstuffs.

I appreciate this is, in a sense, a single-issue topic, but it does give rise to a lot of general questions about the way Europe operates as a regulator. It also gives rise to a certain number of interesting questions about the internal distinctions within Europe, and also the differences, as far as they exist, between Europe and North America, which is a direct economic concern to a

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number of big food processing companies in the United States and North America.

But I should emphasize that this is just an example, this story I am going to tell. And in the time that is left to us, I would be very happy to talk to you, answer questions, or discuss with you any other more burning topics in relation to Europe. For example, in the same type of area, we could discuss hormones in beef, or, perhaps more generally, the resignation of the European Commission, my bosses, if you prefer, what effect it has, if any at all, on the ongoing work in Europe; or, indeed, things much more worldly, like the war in Kosovo.

Let us get back to genetic engineering. First, what is it? The definition given by the Organization for Economic Cooperation and Development (OECD), in a report they made in 1992, is as follows: "a technology including the component DNA technology which is used to isolate genes from an organism, manipulate them in the laboratory and inject them again into another organism." This gives rise to an organism sometimes called a genetically modified organism. It is a technology which unquestionably has an enormous potential to improve crop yields and production by, for example, creating useful characteristics for plants and animals, such as making them resistant to insects and giving them an enhanced flavor or a longer shelf life.

In 1989, it was estimated again by the OECD that by the year 2000, the value of agriculture biotechnology, including genetic engineering, could be as much as 100 billion dollars at farm level. This figure does not sound very big in relation to the capitalization of Microsoft, but for farmers, it is quite a lot of money.

This discussion revolves around three different levels of products. First, there are basic agriculture products, things like long-life tomatoes, sometimes called Flavr Sav'rs. Secondly, we have insect-resistant maize and soybeans, which are resistant to herbicides, and third, there are processed products that may contain genetically engineered characteristics, things like tomato puree, which comes from long-life tomatoes, or any processed foods which use genetically engineered foods, such as soybeans or corn.

Why are these products regulated? In fact, they are regulated not just in Europe, but in North America and other parts of the world. They are regulated because there is a perceived risk that there may be some injury or damage caused to other plants, for example, by increasing the insect resistance to herbicides. This could also be of harm to animals or humans, or by increasing resistance to certain antibiotics, it could interfere with medical treatment by antibiotics. There is a perceived need for government to regulate genetic en-

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1 Flavr Sav'r tomatoes, the first genetically altered food approved in the United States, are produced by Calgene, a U.S. company.
gineering, either at the reproduction stage, the trade of these products, or at the consumption level.

As far as the European Union is concerned, there is a one main rule which was adopted in 1990, which is called the directive on the so-called deliberate release into the environment of genetically modified organisms. This directive was adopted as a means of harmonizing internal markets. In other words, it was meant to counteract a perceived and actual threat that the different Member States of the European Union would go their own ways and have their own systems for authorizing the testing and marketing of genetically engineered products. This was adopted as an instrument for harmonizing the internal market, but it also had to take into account the underlying preoccupation with protecting human health and the environment. It was based on the concept of deliberate release—any intentional introduction into the environment without a provision for containment in order to limit its contact with the environment or the population, a non-research operation, for example. Certainly, the most obvious example of the most deliberate release would be the sale or marketing of a genetically engineered product.

Under the suggestion of the directive, notification has to be made by the company that wants to make the sale; and they have to get consent for their product, a little bit like you would if you wanted to put a pharmaceutical product on the market. You would have to notify the FDA for consent and conditions. Under the typical hybrid system, which was adopted under this directive, the notification initially has to be sent to the national authority, normally, the national authority where the company is established, which then has the responsibility of looking for any flaws and rejecting the application. If the authority thinks there are good grounds for accepting the application, it then moves on to a different plane.

The documentation is sent across to the European Commission, the other Member States are informed. There is a complicated system with time limits of confrontation and resolution if any conflicts arise. Ultimately, barring conflicts, it leads finally to a positive decision by the Commission to recommend the release of this particular product. In that case, the Commission will notify the original national authority which received the notification, telling them that the product may be placed on the market. Once this has been done, that product—and this is key from the point of view of the European Union—has a right and principle within the right to be put on the market anywhere within the European Union and to circulate freely within the European Union. There is, however, in the text of the directive a so-called safeguard clause that al-

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allows a provision that, even though a product has an authorization, can restrict or prohibit its use if it shows that there is still a risk to human health and/or the environment. There is, then, another procedure for consultation and eventual resolution.

How do these rules apply within the European Community? Under the directive, a number of positive directions have been taken by the Commission permitting the placing of genetically modified organisms on the market. But there are two particular cases which have given rise to a considerable amount of controversy which I would like to examine with you. They are of interest in North America, and they are also illustrative of the sorts of problems which still remain, particularly in Europe, when we are faced with new technologies, particularly new technologies in the field of food processing. There are still some rather difficult consumer resistances to be overcome.

The first case which I want to discuss involves a soybean engineered in the United States to be resistant to a particular herbicide. As far as Europe was concerned, the product went through all the proper hoops, and it was finally approved by the Commission on exhibition from the United Kingdom in April of 1996. In the reasoning of the decision, which was published for the public in the official journal, it was stated there was no reason to believe there could be any adverse effects from the soybeans on human health or the environment. There were no safety reasons to justify the segregation of this product from any other soybeans, and there were no safety reasons for any special labeling of this product.

This decision raised a storm of protests from a number of environmental groups within Europe, such as Greenpeace and Friends of the Earth, and also from some consumer groups. The consumer groups were particularly preoccupied with the decision that the product required no particular labeling either on the product itself nor on the final product into which this soybean would go.

The second very controversial product being authorized by the Commission was a maize plant, a corn plant, which was developed in Switzerland; it is now called Novatas, I think. It was designed to protect itself against a particular kind of pest. The document for this product was submitted to the European Commission by France, and the file itself proved even more controversial. The scientific evidence given to the European Commission was in favor of a positive decision, but that is not sufficient. The matter also has to be considered by the Regulatory Committee, which is a committee of representatives of the Member States who advise the Commission when they are making decisions such as this. This committee did not give a positive verdict. Under the system as it operates, the Commission has powers delegated to it by the Parliament and the Council. If they do not get a positive vote, the
matter has to go back to the Council for a final decision. The matter finally went back to the Commission, who looked at further scientific evidence, which still confirmed that there were no safety or health risks. Finally, in February of 1997, the Commission authorized putting this product on the market. It was communicated to the French authorities that the maize was authorized and could be used throughout the European Union.

Despite this, two Member States, Luxembourg and Austria, invoked the safeguard clause mentioned earlier, which allows them to prevent putting a product on the market in certain instances. The Commission then had to make a decision about that. The Consultative Committee, again, could not agree, and the matter again went back to the Commission. Currently, the matter is still in the air, at least as far as these safeguard clauses are concerned.

As just one further twist to this story, the French Consulate State also was seized by the environmental group Greenpeace sometime during last year, and it actually provisionally banned putting this product on the market in France and posed some interpretation questions to the European Court, which now has the case before it. That will probably take another year as well.

As far as the Novatas maize is concerned, they are in a difficult political regulatory situation, one of which is, of course, unsatisfactory for the producer of this product who invested, no doubt, many millions of dollars, if not more, in its development.

I would like to come back to the question of labeling because labeling of the foods produced from genetically engineered products has become probably the key issue which may or may not lead to a solution of the dilemma within which we find ourselves. I should say that, until recently, the Communities had no rules requiring labels on food produced from genetically modified organisms. I mention this fact because it was felt that there were no safety grounds, either human health or environmental safety grounds, within the sense of this directive. The directive itself covered the ingredient, the bean or the seed, and not the final processed product.

There has been a lot of political pressure over this issue from the European Parliament and from a number of non-governmental organizations. Because of this, a number of Member States are starting to go their own way. The Committee is requiring, despite the express rules of the directive, that there be such labeling. This is particularly important, getting back to the soybean, because more than half, it seems, of processed foods on the European market contain soybeans or derivatives of soybeans.

The Commission, which is an executive committee with some political function, could not resist this pressure. It did come up with a series of rules, first in September of 1997, and finally adopted a year later in September of
1998, which required that there should be a specific mention on the final product stating that it been raised from genetically modified soil or produced, as the case may be, with additives and some flavorings.

This exclusion was criticized by the environmentalists, who claimed that a number of products escaped the labeling requirements, such as oils, fats, and chocolates. The suppliers, of course, are very unhappy with the new regulations because it is well-known, or it seems to be well-known, that the European consumer tends to be reluctant, for a rather complicated series of psychological and historical reasons, to buy food if it states clearly on the label that it is made from anything that is genetically modified.

A number of firms have started to set aside special product lines for supply to the European market which would contain nothing but non-genetically modified corn, maize, or other products. But, again, there is a difficulty because the tests that certify this are, apparently, not very reliable, and there is a risk that the product could fall through the trap, even if the supplier takes a number of precautions to avoid this. Indeed, most retailers in European cities are aware of the hesitation by the consumer, and they make it very clear they will not buy these products if they are required to put this information on the label.

That is a little bit of a lesson, perhaps, not a very encouraging one, of the effects of technological change on Europe. It also indicates the reaction of European politicians and the consumer regulators to technological change. I do not want to suggest necessarily that this is the only case, nor do I want to suggest that it is typical, but I think it is something that you have to bear in mind, particularly when you are operating in a sector which is, apparently, for the European consumer, as sensitive as the food sector.

This genetic engineering saga is a classic example of a conflict between what is sometimes called the anger industry on the one hand, and the consumer or the environmentalist lobby on the other. It is a conflict which we see in other areas as well, particularly an area or issue which has been judged by the World Trade Organization. On the 13th of May, the European Union will have to take some action in order to comply with the provision of the World Trade Organization, that is the problem of hormones in beef, hormones which are added to cattle as growth promotors.4

Supporters of genetic engineering argue that there is a potential for job creation. There is even a possibility of increasing the quality of products for

the consumer. It is accepted that, because of the risks to health and the environment, the sector must be regulated. But they insist that these regulations must be based on a scientific assessment of the real risk and safety, not on vague fears. Because of the large investment, they need great certainty. On the other hand, environmentalists and consumer groups, in particular, argue that there are still dangers that are not properly understood. It cannot be overestimated what the effect was on the food industry in Europe by the so-called “BSE crises,” the crises that arose from meat which comes from animals contaminated with this BSE disease, bovine spongiform encephalopathy, more commonly known as “mad cow disease.” It was mostly a problem in the United Kingdom. Despite all the scientific protestations and arguments about being responsible for a particular nasty and fatal disease called Jacobs Disease, this saga of the early 1990s has had a very marked effect on both the regulatory and the consumer scene.

It is probably fair to say now that the general public does not trust the scientists anymore in Europe. They do not trust the scientists when they say something is safe and that there is no problem for the consumer or for the environment. Above all, what the consumers are saying is that they are entitled to know what they are eating; they are entitled to know whether the food they are eating is being produced from a genetic engineering process or not, and they should be able to chose whether to eat that food or not. In between these two camps, by the regulatory bodies and, particularly, both in the Commission and the Member States, they are very uncertain and very nervous. They do not like to entrust themselves entirely to the scientific community and the scientific assessment, but, of course, they do not really have any other solid basis upon which to act.

The only thing which seems very clear is that they have been moving toward compulsory labeling. This in itself is a relatively negative conclusion for the industry, because it will quite clearly have a significant effect on the growth of this industry at the retail level in Europe, and perhaps even more so, at the level of research and production. It seems quite clear that this is going to give another boost to what one might call the general issue of research and development, particularly in the areas of biochemistry and genetic engineering, which is going to mean that Europe is going to fall even further behind in this field than the United States and, perhaps, Canada, as well.

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