GENETICALLY MODIFIED ORGANISMS: A EUROPEAN SCIENTIST'S VIEW

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The "green revolution" following the Second World War modified the manner in which agriculture delivers food to people, particularly those persons in developed countries. The food that people in the United Kingdom currently take for granted was previously unavailable. Food on demand, at any time of the year, and the expectation of its purity and wholesomeness is a new phenomenon. During the last five years, people's expectations about food have changed significantly; whereas once people merely expected food to be available, they now demand large amounts and wide varieties of food. Organic foods, which are grown without the use of chemicals and which provided the impetus for the green revolution, are no longer merely fashionable goods consumed by the middle class. Now a large number of Europeans rely on the availability of organic foods.

Food now poses problems. For instance, eggs have been found to contain salmonella and cannot be used raw. The prevalence of bovine spongiform encephalopathy (BSE) in British beef cattle has frightened many consumers in Europe. Consequently, much of Europe has refused to accept British beef products even when governments and scientists have explained that there is no longer a valid cause for concern. Food poisoning, particularly that resulting from exposure to *Escherichia coli* O157, has made consumers wary of the foods available to them. Scientists are no longer trusted, for they are thought to have "deliberately" misled the public about the safety of food.¹

¹ See House of Commons Science and Technology Committee, First Report 1998-99, Scientific Advisory System: Genetically Modified Foods, para. 28 (citing

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In contrast to the green revolution, the biotechnological revolution promises much, particularly for those persons living in countries where the quantity and quality of food available in Europe and North America is not even a dream. This revolution, however, has not yet delivered. Currently, it is seen by many either to challenge the sustainable use of the Earth's resources, or to provide profits to large conglomerates with little return for those who need the fruits of the technology. Worse, the population of Europe perceives little benefit to the biotechnological revolution, and the media reaction to genetically engineered foods has been hysterical in the last year.² Yet, the impact of this "new green revolution" could be as important for those in less prosperous countries as the green revolution was for Europe and the United States.

The media and general populace believe that genetically modified organisms pose large and unnecessary risks of harm to human health and the environment. Scientists seem unable to understand the popular reaction since the risks of genetic engineering seem so much smaller than many of the other risks that modern society willingly takes. Other new technologies that pose risks, including the cellular phone, have been accepted without significant hesitation. Similarly, conventional plant-breeding techniques, including the induction of mutations, have led to thousands of new varieties of crop plants. These varieties have had the opportunity to spread their genes, but there are no reports of any problems, such as introgression into wild relatives.³

Biotechnology is obviously capable of providing much more than it currently provides. It can improve nutrition. It can be used to design far more balanced and palatable foods. It may enable the design of foods that will not spoil as quickly and are less susceptible to disease and losses through rodent and insect depredation. It may be used to design and make foods that are able to withstand the rigors of distribution in countries where sophisticated distribution systems are not present. It may even be

Letter from 19 Fellows of the Royal Society to the national press (Feb. 22, 1999)) (visited May 28, 2000) http://www.publications.parliament.uk/pa/cm199899/cmselect/cmsctech/286/28602.htm [hereinafter House of Commons Science and Technology Committee].

 $^{^2}$ Cf. id. at paras. 21-27 (considering the factors that have influenced public opinion on GMOs).

³ See Ian J. Senior & Philip J. Dale, Agri-biotechnology: What Products Can It Deliver?, 6 J. COM. BIOTECH. 97 (1999).

used to promote sustainability through the design of plants so that they grow in a manner less destructive to the environment. If a gene that qualifies a characteristic in any organism has been identified, then it will become possible to change the gene so that a similar characteristic is expressed in other organisms. As science becomes more adept, it will be possible to decide in which tissue a gene is expressed as well as the timing of this expression relative to the life cycle of a recipient organism.

The technology promises a great deal, but there is a lack of information about many of the genetically modified organisms. The changes introduced into genetically modified organisms may directly impact human health, although the risk assessment and testing requirements in most countries make immediate effects unlikely.⁴ The long-term or indirect effects on human health are almost impossible to identify because there is little knowledge about the consumption of unmodified foods. The chemistry of the modified organism may be altered by the modification process so that its impact on the environment, organisms, and other plant species that directly or indirectly depend on it is altered as well. If, for example, a food is modified to change its susceptibility to drought, it may impact the environment in which it is grown. It remains difficult to predict the impact and to compare its effect to other changes in agricultural practice. It is possible, however, that the impact will be no greater than that observed when farmers choose to grow new crops, or even new crop varieties, on their land.

Many countries encourage people to adhere to the Precautionary Principle, which could be interpreted as "if you are not sure of the consequences, do not proceed." Consider, for example, that the application of the principle could have limited the development and implementation of water-borne sewage systems, because the impacts of the disposal of treated wastewater were unknown and potentially harmful. However, the Precautionary Principle should not be taken to mean that any risk, no matter how small, should preclude the use of a technology. In Europe, the principle has been interpreted as requiring any newly introduced genetically modified organism to be assessed

⁴ See House of Lords Select Committee on the European Communities, Second Report, 1998, *EC Regulation of Genetic Modification in Agriculture*, paras. 109-16 (last modified Jan. 21, 1999) http://www.publications.parliament. uk/pa/ld199899/ldselect/ldeucom/11/8121501.htm>.

on a case-by-case basis as to the risks it may pose to the environment and to human health and safety. European legislation requires only that the risk be assessed and managed:

The implementation of an approach based on the precautionary principle should start with a scientific evaluation, as complete as possible, and where possible, identifying at each stage the degree of scientific uncertainty.⁵

. . .

Although the precautionary principle is not explicitly mentioned in the Treaty except in the environmental field, its scope is far wider and covers those specific circumstances where scientific evidence is insufficient, inconclusive or uncertain and there are indications through preliminary objective scientific evaluation that there are reasonable grounds for concern that the potentially dangerous effects on the environment, human, animal or plant health may be inconsistent with the chosen level of protection.⁶

The release of genetically modified organisms into the environment falls within the scope of this legislation, because the ecological impact of many of the newly identified organisms cannot be fully assessed. The legislation in Europe requires that risk-analysis, appraisal, management, and eventually communication be considered. Because traditional plant-breeding methods are generally not regulated, the benefits and impacts of these techniques do not have to be considered under European legislation.⁷

Risk assessment uses scientific reasoning and information from many disciplines to make decisions. "Familiarity" with natural organisms is used to predict the behavior of modified organisms of a similar type. This approach (called "substantial equivalence" when applied to foods) may not be applicable when the modification is likely to have a significant impact on the survival of the new organisms in unusual environments. However,

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⁵ Communication from the Commission to the European Council on the Precautionary Principle, COM(2000)1 final at 4.

⁶ Id. at 10.

⁷ *Cf.* Council Directive 98/81 of 26 October 1998 Amending Council Directive 90/219 on the Contained Use of Genetically Modified Microorganisms, 1998 O.J. (L 330) 13-31 (governing, in part, the use of, release of, and risk assessments for GMOs); Council Directive 90/220 of 23 April 1990 on the Deliberate Release into the Environment of Genetically Modified Organisms, 1990 O.J. (L117), 15-27 (governing, in part, the deliberate release of GMOs and their entry into the market); Julian Kinderlerer, *The Regulatory Framework: An EU Perspective*, 6 J. COM. BIOTECH. 116 (1999).

there are many who argue that the process of risk assessment, and the decisions relating to the use of biotechnology, should be science-based.⁸ Henry I. Miller, former director of the Office of Biotechnology at the U.S. Food and Drug Administration, is concerned that:

a new OECD analysis will conclude that foods made with the techniques of new biotechnology are sufficiently new and untried that they need some sort of case-by-case government review—a view consistent with EU policy but at odds with official US policy and the long-standing and widely held consensus of the scientific community worldwide.⁹

This approach is also problematic because much of the basic data about the impact of unmodified crops and plants on the environment and the evidence needed to produce a complete quantitative risk assessment is unavailable. For example, the interactions between organisms and their impact on the ecosystem cannot easily be explained or predicted. Scientists see biotechnology as capable of redressing the balance between the rich and poor countries of the world. Scientists are often accused of arrogance as they try to explain that while there are risks, the risks are believed to be very small.¹⁰ There are those who simply say that genetically modified foods are unsafe or harmful to the environment.¹¹ Scientists have been wary to state the opposite, for they do not have the data to definitively decide on the safety of genetically modified foods. It may be possible for scientists to identify risks to human health or to the environment for particular modified foods, but to ascribe danger to all foods or products produced using the new biotechnology does not make scientific sense.

Scientists were the first to suggest that there be a moratorium on the use of the technology until regulatory structures were established to ensure its safe use.¹² There is no evidence that harm has resulted from the use of modern biotechnology,

⁸ See, e.g., Henry I. Miller, Nasty Taste From G-8 GM Food Policy, 17 NA-TURE BIOTECH. 730 (1999).

⁹ Id.

¹⁰ See House of Commons Science and Technology Committee, *supra* note 1, at paras. 27-31.

¹¹ See, e.g., Greenpeace International, *The Sound of Unsound Science: EPA Regulation of Bt Crops and Effects on Non-target Insects* (visited May 28, 2000) http://www.greenpeace.org/~geneng/reports/gmo/gmo021.htm>.

¹² See Susan Wright, Molecular Politics: Developing American and British Regulatory Policy for Genetic Engineering, 1972-1982

even though it has been used for twenty-five years and has periodically been subjected to scrutiny and risk evaluation. The European regulatory structure has been instituted proactively rather than retroactively (as is usual for safety legislation), since there have been no accidents that might normally have preceded legislation to ensure safety. This may have provided an instinctive basis for fear because, if it is regulated, many people will assume that the technology is dangerous, since experience indicates that safety systems have been utilized when other technologies have been demonstrated to be harmful.

The revolution in biology has provided a series of tools that may be applied to solve or create problems. Obsession with the technology used, rather than the products that arise from its use, puzzles and surprises scientists as well as the general population living and working in North America. Why blame technology for changes in our capacity to achieve new and different products?

In the United States and Canada, objections to the introduction of foods produced using biotechnology have been muted. Although the debate concerning transgenic plants in the United States has intensified as a result of the international climate, the country is only considering new regulations.¹³ However, relatively little public support exists in North America for campaigns against the introduction of foods produced through biotechnology, and modified foods currently are not required to be labeled. Indeed, the United States Department of Agriculture (USDA) and Food and Drug Administration (FDA) believe that labeling food as genetically modified would be misleading.¹⁴ Both agencies cite their regulatory system's openness as the main reason for the lack of protest.

This difference in the regulatory cultures of the United States and Canada as compared to Europe leads to different responses to the introduction of genetically modified foods in the respective countries. Europe appears to ask the question "why," whereas the United States asks the question "why not?" There is little land in Europe that remains untouched by agriculture—almost seventy-five percent of available land is in use. In the

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^{136-59 (1994) (}considering the initial response by scientists to recombinant DNA developments, 1972-76).

¹³ See generally Committee on Genetically Modified Pest-Protected Plants, National Research Council, Genetically Modified Pest-Protected Plants: Science and Regulation (forthcoming 2000).

¹⁴ See Food Gene Label Unneeded, L.A.TIMES, Feb. 1, 2000, at B6.

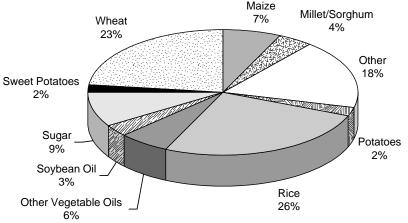
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United States, however, less than thirty percent of available land is used, and there is separation between agriculture and the natural environment.¹⁵ The size of farms in the United States means that "gene drift" is not likely to engender the same type of fearful reaction found in Europe where farms are small and the crops grown in one field may impact those in adjacent fields owned by other farmers.

The products that have been introduced into the market so far have had little direct impact on consumers themselves, but have had a direct impact on their perception of environmental harm. Almost all commercial products have been modified to produce herbicide tolerance or pest resistance, important on farms, but not to the consumer. These modified products are not essential in Europe and many, if not most, people in Europe are saying that they do not want such items. Perhaps the products sound scary to those not familiar with the technology, who appear to believe that products clearly must be poisonous if they act as herbicides and pesticides. The modified products are important commodity crops, such as wheat or rice grown in bulk, which have little impact on the environment and promote sustainability. Neither modified wheat nor rice, the main staple commodity crops, are available as commercial varieties. Soybean oil and maize, representing ten percent of the world's major agricultural production,¹⁶ are the most important of the modified commodity crops.

¹⁵ See House of Commons Environmental Audit Committee, Fifth Report 1999, *GMOs and the Environment, Coordination of Government Policy*, para. 17 (visited May 28, 2000) <http://www.publications.uk/pa/cm199899/cmselect/ cmenvaud/58/5802.htm>.

¹⁶ See Food and Agriculture Organization of the United Nations, The State of the World's Plant Genetic Resources for Food and Agriculture 15 (1998).



Most important crops for food energy supply¹⁷

Biotechnology is not providing all of what is currently needed, but the technology provides systematic tools that allow us to deliberately design for sustainability. People may say that genetic modification is unacceptable as a tool and that the unsustainable agricultural practices currently operating should be replaced by agricultural practices that are more likely to sustain the environment. It is questionable, however, whether we will be able to produce the food we expect without genetic modification.

The climate of Europe is different from that of the United States and, consequently, many plants grown without difficulty on one side of the Atlantic have caused problems on the other side. The World Trade Organization (WTO) can issue an adverse environmental impact statement on a project, thereby prohibiting development in one geographical area even though a similar project causes no environmental problems elsewhere. An argument for further testing and monitoring of such crops should at least be considered. This argument, however, cannot easily be maintained where the food, already licensed in one country, is excluded from another. Adverse public opinion cannot be used before the WTO as an argument against growing maize and soybean products (e.g. oil, flour, lecithin, or even the commodity itself) where there is no intention to grow them. But if the food has been accepted as a safe food or feed through the Codex Ali*mentarius*, however biased that organisation is believed to be, an

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¹⁷ See id.

argument to stop its import will not easily be maintained. The one avenue open to us in Europe is to label these foods, but labeling will prove extremely difficult when a vast array of compound products contain a proportion of transgenic products.

There are many concerns in developing countries about the risks of genetically modified organisms and what can be done to limit those risks. Developing countries have observed the concerns in Europe and have wondered whether European and American companies are essentially dumping transgenic organisms on them because they cannot be grown or sold in Europe. The European fear of GMOs has spread to these countries. Consequently, it is important to question whether European concerns about risks, which are almost certainly insignificant, are hindering the development of biotechnology in countries where it is desperately needed.

The introduction of modern biotechnology products might result in changes in agricultural practice (including a change in the use of chemicals) or the loss of economic sustainability as new products enter the market. This may lead to further changes in social structures that might subsequently affect the types of foods grown, as well as food distribution needs. A monopoly control of chemicals used in agriculture and of seeds that allow plants to resist these chemicals could place a strain on the economy of developing countries and could also be used for exploitative purposes. Intensive agriculture may result in the use of a particular variety of plant (or animal) that may lead to the loss of other varieties. Use of a small number of varieties in a significant part of the total area planted could lead to crop susceptibility to pests and environmental hazards.

The Convention on Biological Diversity, signed in Rio de Janeiro in 1992, is an important signpost in the debate on transgenic foods. Genes found in organisms within a country's borders are considered the property of that country, rather than part of man's common heritage. The assertion of rights to "intellectual property" derived from discoveries in a particular country is especially important. As a result of these rights, a new crime, called "bio-piracy," has been created. This crime may take two forms, both of which need solutions. The first form—called "bioprospecting"—involves the deliberate discovery of novel plants or micro-organisms containing genes or chemicals that may be used in pharmaceutical or other industries and which were not

known previously. The second form involves the use of indigenous knowledge, known for many generations within a community, to derive useful chemicals. An example of this second form of bio-piracy is the attempt to patent basmati rice in the United States. To many in countries that place great value on their traditional knowledge, the only solution to the bio-piracy problem is to deny patents for products derived from plants traditionally known to have pharmacological properties. A need exists to compensate the owners for the knowledge and to ensure that the manner in which the owners have traditionally used the plants may still be employed with sufficient protection in new markets. There is also a clear need to use knowledge to the benefit of all people and if that requires the imposition of some negative right for twenty years, then an equitable way of achieving that end must be found.

Both politicians and scientists in the United States have taken very different views from those of European politicians and scientists regarding the manner in which GM foods should be regulated. The excitement about the application of modern genetics to agriculture and food, welcomed by scientists as a progression that produces better and higher-yielding food crops, is not shared by many in Europe, especially the general public. For those who have enough to eat, the avoidance of foods produced through modern technology is not a problem. However, if the application of molecular biology to food crops is stifled so near its birth, the impact on those not getting enough to eat may be severe. Already, there is evidence that the European reluctance to accept these foods is affecting the acceptability of such foods by developing countries.