Chapter 3

Agricultural Biotechnology, Politics, Ethics, and Policy

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The aim of this chapter is to address the policy, regulatory, and ethical issues surrounding agricultural biotechnology. The chapter provides background on the shaping of policy and on regulatory frameworks within the European Union and the United States, among others, as well as outlining the global framework in which all countries have to operate. In addition it summarizes the United Nations–led initiative to assist developing countries to implement biosafety frameworks devised by a specific country for that country. The chapter also highlights the ongoing debate in the areas of environmental protection, public perception and acceptance, and intellectual property rights.

The most important reason for addressing the policies of the European Union and the United States on genetically modified organisms rather than the policies of other nations is that they are very different in concept—although in practice, once the regulatory system has been triggered their formal treatment of such organisms is very much the same.

The introduction of a new technology such as agricultural biotechnology may depend on the perceived balance between the benefits of the technology and the potential risks to the environment and human health. This chapter aims to put forward the arguments and issues related to the potential benefits of agricultural biotechnology against a background of perceived risks, but it does not seek to provide the answers.

Policy

Different uses of modern biotechnology to produce transgenic organisms elicit varying reactions in most countries. The use of genetic modification to provide medicines is not as controversial as the genetic modification of crops for human consumption. Often the genetic modification of animals (especially reproductive cloning) is considered less acceptable than the modification of plants. Modification of the germ line in humans, for example, is often considered immoral or contrary to *ordre public.*[1] This is made explicit in Article 6 of Directive 98/44/EC of the European Union (European Union 1998a).

Many opinion polls indicate that the public discriminates markedly between uses of biotechnology. Using such technology in medicine and horticulture/floriculture is often found to be acceptable, whereas the genetic modification of crops for food use and the modification of animals and humans are less acceptable. Hallman et al. (2002, p. 26) report: "While most Americans say they would be in favour of at least some genetically modified food products, and nearly two-thirds believe that genetically modified foods will benefit many people, more than half (56 percent) say that the issue of genetic modification causes them great concern."

History

It may be useful to provide some historical background on the many issues that arise in response to the use of modern biotechnology. Policy on the safe use of biotechnology sets precedents. It is often the case that safety legislation is introduced because an accident has occurred and systems need to be put into place to ensure that such an accident does not recur. The possible risks of modern biotechnology were recognized at the very beginning of its use, and steps were taken to ensure that it was used safely.

The potential uses of genetic modification[2] were obvious from the moment that researchers first identified the techniques that enabled the transfer of genes from one organism to another unrelated organism. A committee (the Ashby Committee) established by the government of the United Kingdom reported in 1975 that genetic manipulation techniques would provide "substantial though unpredictable benefits" and that "application of the techniques might enable agricultural scientists to extend the climatic range of crops and to equip plants to secure their nitrogen supply from the air" (United Kingdom, Working Party, 1975). A meeting of scientists using the new recombinant DNA technology at Asilomar, California, in February 1975 produced a set of guidelines for the use of biotechnology. The formal goals of the meeting included identifying the "possible risks involved for the investigator and/or others" and "the measures that can be employed to test for and min-

imize the biohazards so that the work can go on" (Wright 1994, p. 145). In the view of the Ashby Committee, the benefits of the new technology far outweighed the risks if suitable precautions were put in place (United Kingdom, Working Party, 1975; emphasis added).

Although in many countries the public has been fearful of the introduction of the products of this technology, governing bodies have not been as reticent, and have recognized both the benefits that may arise from its use and the risks that it theoretically poses. On May 13, 1993, the Parliamentary Assembly of the Council of Europe passed Recommendation 1213 on developments in biotechnology, for which it indicated there were many wonderful prospects, but for which there were also many concerns (Council of Europe, Parliamentary Assembly 1993).[3] The Council of Europe includes many countries of central and eastern Europe as well as those of the affluent European Union.[4] The resolution noted that the gene pool has been widened far beyond the limits of sexual compatibility to encompass the possibility of transferring genes from almost any organism to others. Among the many uses of biotechnology it identified were increasing agricultural outputs (or reducing inputs), replacing chemical herbicides and insecticides or more efficient targeting of these products, increasing the use of plants in industry, reducing the response of crop plants to stress, and even cloning meat animals "for particular markets or to form embryo banks to maintain genetic diversity." The resolution noted that significant drawbacks might result from the application of the new biotechnology. The possibility of new diseases was raised, as were the potential environmental effects of transgenic organism.[5] Many of the benefits have been effected, although many people do not realize that many vaccines, pharmaceuticals, and food additives (such as chymosin and ascorbic acid) are the products of modern biotechnology.[6]

The Cartagena Protocol on Biosafety (Secretariat of the Convention on Biological Diversity 2000) was agreed to by the members of the Conference of the Parties to the Convention on Biological Diversity (CBD) in 2000 in Montreal.[7] This came after years of negotiation and argument, with the misgivings of many parties, but in an atmosphere that had changed from that which had prevailed at the time the negotiations had started in 1995 at the second meeting of the parties to the CBD in Jakarta. Article 19(3) of the Convention on Biological Diversity (Secretariat of the Convention on Biological Diversity 1992) had required parties to consider the possibility of adding to the convention a protocol that addressed the use (and primarily transboundary movement) of living modified organisms that might have an adverse impact on biological diversity.[8] Eight years later Europeans were no longer accepting modern biotechnology; products had disappeared from the shops, and there was a gloom and distrust in many countries not observed

elsewhere. Few if any products derived using modern biotechnology are now available in Europe (Royal Society of the United Kingdom 2002, para. 2). In North America, farmers adopted transgenic organisms with little opposition, and products derived from them have been in shops for more than five years.

The developing countries wanted far more to be included in the protocol than they were able to get, including many more safeguards. The producer countries fought hard to ensure that, insofar as it was possible, few if any controls would be applied, particularly to commodity goods. The size of the commodity market alone, they argued, made it difficult to contemplate a regime that required what amounted to "visas" at country entry points.

The Cartagena Protocol required 50 ratifications to come into force. In accordance with its Article 36, the protocol was opened for signature at the UN office in Nairobi during the fifth ordinary meeting of the Conference of the Parties to the Convention on Biological Diversity in Nairobi, Kenya, May 15–26, 2000. It remained open for signature at the UN headquarters in New York from June 5, 2000, to June 4, 2001. By that date the protocol had received 103 signatures. The Cartagena Protocol entered into force on September 11, 2003, some 90 days after receipt of the 50th instrument of ratification. African countries that have ratified the protocol are Algeria, Botswana, Burkina Faso, Cameroon, Djibouti, Egypt, Ethiopia, Gambia, Ghana, Kenya, Lesotho, Liberia, Madagascar, Mali, Mauritius, Mozambique, Namibia, Niger, Nigeria, Rwanda, Senegal, Seychelles, South Africa, Togo, Tunisia, Uganda, the United Republic of Tanzania, and Zambia. Zimbabwe signed the protocol in 2001 but has not yet ratified it. Most of these countries do not yet have the legal systems in place to implement the requirements of the protocol.

The need for specific legislation in regard to the use of genetically modified organisms was never presumed even though it was recognized that regulation was needed from the earliest days of the use of this technology. The United Kingdom had regulated the genetic "manipulation" of microorganisms starting in 1978, and by 1983 it had a full set of legally binding regulations in place. The United States, on the other hand, had specified guidelines (the National Institutes of Health [NIH] guidelines) that identified the manner in which such organisms should be used by those funded by the NIH.

In 1986 the U.S. government published its Coordinated Framework for the Regulation of Biotechnology (U.S. Office of Science and Technology Policy 1986), which described the "comprehensive federal regulatory policy for ensuring the safety of biotechnology research and products." The document set forth some of the assumptions on which it was based, as follows: "Existing statutes provide a basic network of agency jurisdiction over both research and products; this network forms

the basis of this coordinated framework and helps assure reasonable safeguards for the public. This framework is expected to evolve in accord with the experiences of the industry and the agencies." The laws that already existed in the United States regulated the uses of specific products, such as foods or pesticides. It had been thought that genetically modified organisms posed no new risks that could not be covered using the existing system. But according to the document, "This approach [that offered by the framework] provides the opportunity for similar products to be treated similarly by particular regulatory agencies" (pp. 23302–23350).

The framework describes the rationale for its development:

> The underlying policy question was whether the regulatory framework that pertained to products developed by traditional genetic manipulation techniques was adequate for products obtained with the new techniques. A similar question arose regarding the sufficiency of the review process for research conducted for agricultural and environmental applications. . . . Upon examination of the existing laws available for the regulation of products developed by traditional genetic manipulation techniques, the working group concluded that, for the most part, these laws as currently implemented would address regulatory needs adequately. For certain microbial products, however, additional regulatory requirements, available under existing statutory authority, needed to be established." (U.S. Office of Science and Technology Policy 1986, p. 23302)

The U.S. government decided to identify the various tasks needed to regulate biotechnologies and clearly indicate the agency and even the law that would be used to ensure that these technologies were used safely. Other countries did not (at the time) have a range of environmental, food, drug, and safety legislation in place that permitted effective use of existing legislation. In the United States it was decided that jurisdiction over the many different biotechnology products would be determined by their use rather than by the manner of their production, just as was the case for traditional products (see Table 3.1).

Regulatory Systems

Guidelines or regulations were quickly introduced in some countries, particularly to protect those who might come into contact with the modified organisms. In the United Kingdom the first regulations were introduced in 1978; in the United States the NIH guidelines were implemented soon after the 1975 meeting at Asilomar and applied to work funded through grants received from the NIH. Initially the "regulations" applied primarily to work in laboratories, because that was the

Table 3.1 Agencies responsible for approval of commercial biotechnology products under the U.S. Coordinated Framework for the Regulation of Biotechnology

Products	Agencies
Foods and food additives	Food and Drug Administration (FDA)
Human drugs, medical devices, and biologics	FDA
Animal drugs	FDA
Animal biologics	Animal and Plant Health Inspection Service (APHIS)
Other contained uses	Environmental Protection Agency (EPA)
Plants and animals	APHIS, Food Safety and Inspection Service (FSIS), FDA
Pesticide microorganisms released into the environment	EPA, APHIS
Other microorganisms, intergeneric combinations	EPA, APHIS
Intrageneric combinations: pathogenic source organisms	
1. Agricultural use	APHIS
2. Nonagricultural use	EPA, APHIS
Intrageneric combinations: no pathogenic source organisms	EPA
Nonengineered pathogens	
1. Agricultural use	APHIS
2. Nonagricultural use	EPA, APHIS
Nonengineered pathogens	EPA

Source: U.S. Office of Science and Technology Policy 1986, p. 23304.

only place in which the work could progress. They were aimed at the protection of those individuals who had access to the laboratories and attempted to ensure that the work was contained and that workers were protected from the hazards posed by the modified organisms. It was only in the late 1980s that the introduction of modified organisms into the environment became really feasible. At first it was expected that these releases would mainly be of microorganisms, but as methods capable of modifying plants became available and efficient it was clear that most environmental releases would be of plants. Very few modified microorganisms have been released. Many countries have decided to implement different systems of regulation for organisms intended for use in containment and those released into the environment. Organisms are considered to be used in containment when they are used in industrial plants and in processes for manufacturing in which the organisms themselves are not intended to be marketed or exposed to the "open" environment.

Most countries in the southern African region are considering the frameworks necessary for a regulatory system to ensure the safe use of modern biotechnology or have already enacted legislation. South Africa initially regulated transgenic organisms[9] through a voluntary system, but since 1997 has had legislation in place to ensure that in South Africa modified organisms are used safely (South Africa 1997). So far it is the only country in the region that has permitted the commercial use of any transgenic plants. According to an article in the *Financial Gazette,*

"Zimbabwe was the second country after South Africa to come up with biosafety regulations; was the first to come up with an institutional framework and is one of the few countries to have graduate training in biotechnology" (Nyathi 2002). Namibia was part of a pilot project funded by the United Nations Environment Program (UNEP) and the Global Environment Facility (GEF) that permitted 18 countries to start the process of regulating biotechnology, and it is now one of 12 countries financed by the GEF to implement the biosafety frameworks that have been devised for the country. Kenya, Uganda, and Zambia were also among the countries that participated in the pilot project, and Kenya and Uganda are among the 12 now implementing their frameworks with significant funding from the GEF. Botswana, Lesotho, Mozambique, Rwanda, Zimbabwe, and other countries in the region are currently being funded through a project implemented as a follow-up to the pilot project, which assists countries to design frameworks to ensure the safety of biotechnology.[10]

Countries have chosen to use a variety of triggers for the regulation of biotechnology. In Europe it is using modern biotechnology as defined in the directives (European Union 1998b and 2001)[11] that triggers the regulatory process. In the United States, because previously existing law is used the trigger tends to be the use of organisms that are pests—plant pests, for example—in the manufacture of the new organism if the Department of Agriculture is to be involved. Canada has chosen to use a concept of novelty to trigger the regulatory process. Many analyses have suggested that once the process is started, the risk assessment and management processes are very similar in the various countries.

Environmental Policy in Relation to Genetically Modified Organisms

All the countries that are participating in GEF-funded projects have signed the Cartagena Protocol (Secretariat of the Convention on Biological Diversity 2000), which specifically requires regulation in relation to the transboundary transfer of living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, also taking into account risks to human health.[12] Those participating in the "implementation" projects have also ratified or acceded to the protocol or have agreed to do so. They are also all party to the Convention on Biological Diversity (Secretariat of the Convention on Biological Diversity 1992), whose Article 8(g) requires that they institute national frameworks in order to "establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the

conservation and sustainable use of biological diversity, taking also into account the risks to human health." The provisions of the Cartagena Protocol extend only to those organisms resulting from modern biotechnology that might cause potential adverse effects to the conservation and sustainable use of biodiversity. Human health has "then" to be taken into account. However, when designing a regulatory system for biosafety, it is legitimate to ensure safety of the environment and human health in general, with the needs for the protocol forming a subset within the regulatory system. It seems likely that any attempt to link the protection of human health to legislation that primarily addresses biodiversity would not be acceptable to most legislatures.

Countries have understood that in this instance biosafety means primarily protection of the environment, and that the release of living modified organisms needs be regulated in order to protect the environment.[13] Safety concerns are not, however, limited to the impact of these organisms on the environment, and regulatory systems that attempt to ensure human and animal health are often different from those set in place for environmental protection. The European Novel Food Regulation agreed to in 1997 (European Union 1997)[14] provided extensive risk assessment and management for the use of genetically modified organisms or products derived from them in foods. This has now been replaced by Regulation 1829/2003 (European Union 2003a), which applies to food or feed produced using genetic modification. It provides "the basis for ensuring a high level of protection of human life and health, animal health and welfare, environment and consumer interests in relation to genetically modified food and feed, whilst ensuring the effective functioning of the internal market." It sets out the EU procedures for authorization and supervision of genetically modified products and contains provisions for the labeling of genetically modified food and feed (Article 1). Regulation 1830/2003 (European Union 2003b) addresses the traceability and labeling of genetically modified organisms and the traceability of food and feed products that have been derived from such organisms. These two regulations significantly extend the requirements that were put in place under the previous regulation. In particular, products derived from genetically modified organisms but in which the modification is not detectable (neither the DNA nor any protein produced due to the action of the inserted gene is present) must be labeled to indicate their derivation.

Precaution

Scientific data can be collected at many sites around the world that can provide an insight into the manner in which a product of biotechnology may interact with its environment when released into a particular environment. When data are not

available or when a country believes that its environment is different from that in which the organism was tested, field testing may be required before the organism is released or placed on the market. Where data are "knowable," further experimentation will provide information that may address concerns as to the likely behavior of the organism in a particular environment. However, because of the inherent variability of biological systems, such information may fall into the "not knowable" category; that is, no amount of information collected may be able to provide more than increased precision in determining the variability of the organism's behavior. Further experimentation will not provide any assurance that the organism will (or will not) affect the environment in an unacceptable manner. This "precautionary principle" or approach is invoked in order to address the absence of data. It is usually taken to refer to Principle 15 of Agenda 21 (UNCED 1992), agreed to in Rio de Janeiro in 1992: "In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."

Many cases of serious environmental degradation have made governments change their perception of environmental protection. These cases have also affected the public's perception of the environment. Outbreaks of disease in animals and humans due to perceived lack of care or to environmental pollution have had a significant effect on an appreciation of both known and potential risks to the environment and to human health and on public acceptance that these potential problems need to be addressed. According to the Organization for Economic Cooperation and Development (OECD 2002, p. 7): "The use of precaution cannot be limited to approving an action or process, or prohibiting it, but implies managing various levels of risk and uncertainty, and taking the appropriate measures at each level." A risk may vary significantly depending on the level of activity or the likelihood that an organism may persist and establish itself in the environment. The organism's interrelationship with other actions or processes or with other organisms with which genetic material may be exchanged may also require caution in analyzing the potential risk.

Annex III of the Cartagena Protocol (Secretariat of the Convention on Biological Diversity, 2000) identifies the principles for scientific risk assessment that member countries need to address when considering living modified organisms that might have adverse effects on biological diversity, also taking into account the impact on human health. It provides, inter alia, that "lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk."

This precautionary principle (or approach) has attracted many and various interpretations; for many it means that if the science is unknown and there is a risk of environmental damage, one should not proceed. Caution dictates that it implies that when there is doubt over the safety of an action, that action should not be taken until evidence is available that the steps to be taken will not have disastrous consequences for the environment. The concern in relation to transgenic organisms is due to the possibility that once an organism is in the environment it will be virtually impossible to recall and, because of its property of replication, it will not decay over time; indeed its numbers may increase disastrously. Others interpret this as an injunction to proceed with caution, considering each release into the environment on a case-by-case basis and probably also proceeding step-by-step, with small field trials preceding larger ones and the results analyzed before proceeding to commercial unfettered release (if ever). According to the Commission of the European Communities (2000, p. 1), recourse to the precautionary approach "presupposes that potentially dangerous effects deriving from a phenomenon, product or process have been identified, and that scientific evaluation does not allow the risk to be determined with sufficient certainty." A Canadian discussion document reflects the following view: "Decision making about risks in the context of a precautionary approach is further complicated by the inherent dynamics of science. Even though scientific information may be inconclusive, decisions will still have to be made to meet society's expectations that risks be addressed and living standards maintained" (Government of Canada 2001a). Scientists may be concerned that the 'principle' is used to stifle research, innovation, and competition. The Commission of the European Communities further states:

> Where action is deemed necessary, measures based on the precautionary principle should be, *inter alia:*
>
> - *proportional* to the chosen level of protection,
> - *nondiscriminatory* in their application,
> - *consistent* with similar measures already taken,
> - *based on an examination of the potential benefits and costs* of action or lack of action (including, where appropriate and feasible, an economic cost/benefit analysis),
> - *subject to review,* in the light of new scientific data, and
> - *capable of assigning responsibility for producing the scientific evidence* necessary for a more comprehensive risk assessment. (2000, p. 4, para. 6; emphasis in original)

The World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary (SPS) Measures (WTO 1994b) reflects precaution in Article 5.7, which allows members to adopt SPS measures where relevant scientific evidence is insufficient. If members are to use precaution, they should meet four specific conditions:[15]

- The measure must be provisional, although no time limit is set.
- It must be adopted on the basis of "available pertinent information."
- An attempt must be made "to obtain the additional information necessary for a more objective assessment of risk."
- The measure must be reviewed within a reasonable period of time.

The use of precaution requires that a number of major considerations be taken into account. The Canadian discussion document provides a starting point for defining policy in relation to precaution:

1. "The decision-making process for managing risks always requires sound and rigorous judgment" where "[J]udgment means determining what is a *sufficiently* sound or credible scientific basis, what *follow-up* activities may be warranted, and *who* should produce a credible scientific basis."

2. "To reduce significant scientific uncertainty and improve decision making, the precautionary approach usually includes follow-up activities such as research and scientific monitoring." However, it has to be noted that in many instances the collection of data may increase the precision of determination of variation, rather than provide data which permits the reduction of uncertainty. Monitoring can only provide assurance that expected events occur, and events predicted not to occur are not observed. Unexpected, unpredictable, indirect and delayed effects on the environment are by their nature difficult if not impossible to monitor." (Government of Canada 2001b, p. 4)

The arguments around the precaution principle are serious, for they have directly affected the policy decisions of many countries. In Europe the use of precaution in relation to transgenic organisms is taken to require case-by-case and step-by-step approaches to risk. This way of interpreting precaution is built into

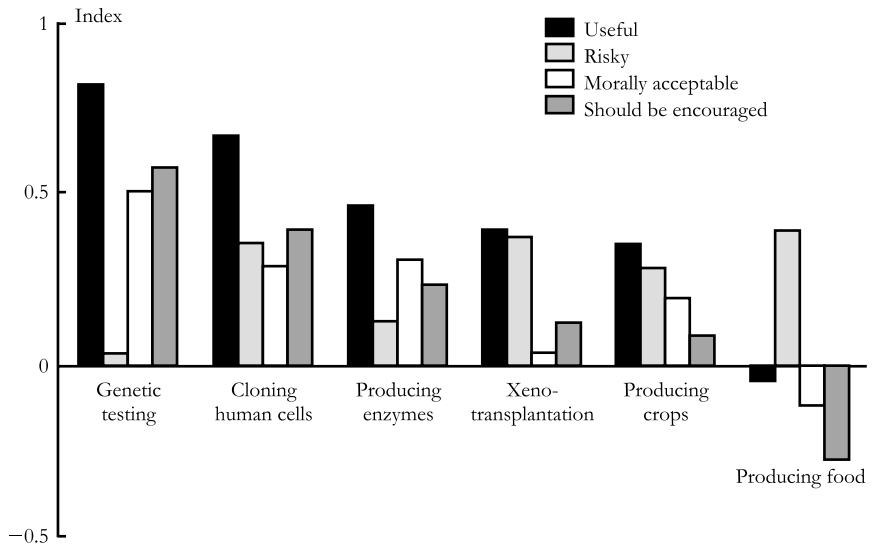
the Cartagena Protocol, which also requires a case-by-case process in assessing risk (Secretariat of the Convention on Biological Diversity 2000, Annex III.6).

Public Opinion

The controversy over the use of modern biotechnology has centered primarily on commercial release into the environment rather than on use in laboratories for research, contained use in industry, use in the production of pharmaceuticals and veterinary products, or even use in field trials. Protesters have, however, chosen to attack and destroy fields in which organisms are being tested. The industrial use of genetically modified organisms that may be the major use of modern biotechnology now and in the future. The Eurobarometer surveys show that considerable discrimination among the public (at least in Europe) in relation to the various uses of modern biotechnology (Eurobarometer 2000): "Europeans continue to distinguish between different types of applications, particularly medical in contrast to agri-food applications" (Gaskell, Allum, and Stares et al. 2003). Support for genetically modified crops and foods declined and opposition increased over the period between 1996 and 1999; from 1999 to 2002 there was almost no change in levels of support or opposition. European attitudes toward six applications of biotechnology (Gaskell, Allum, and Stares et al. 2003) indicate the discrimination that has been observed. The results displayed in Figure 3.1 indicate how discriminating the public is. For example, genetically modified food is considered risky, morally unacceptable, and not to be encouraged, yet genetically modified crops (much to the surprise of the researchers) are considered useful but risky, but their use is seen as morally acceptable and a slight majority favors their use! In a survey of Canadians it was found that "a total of 47.7% of Canadians consider the presence of GMOs [genetically modified organisms] in foods to be dangerous for human health while 20.7% feel they are not dangerous" (31.6 percent did not express an opinion) (Leger Marketing 2001).

The European public debate resulted in rejection of modern biotechnology, which in 1998 had the effect of influencing the main distribution companies to remove these products from European shelves. In the United States, there appeared to be little rejection, which the U.S. government attributed to the openness of the American system: "In 1994 approximately 7,000 acres were planted under 593 USDA [U.S. Department of Agriculture] field-test authorizations, compared to 57,000 acres under 1,117 authorizations in 2001. The first biotechnology-derived crops were commercialized in 1996 and, in 2001, approximately 88 million acres were planted in the United States and 130 million acres were planted world-wide" (U.S. Office of Science and Technology Policy 2002, pp. 50578–50580). Argentina,

Figure 3.1 European attitudes toward six applications of biotechnology, 2002



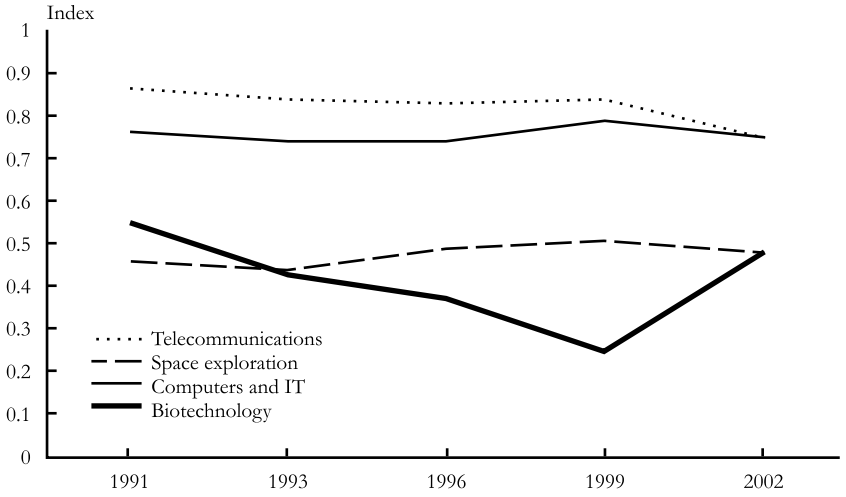
Source: From Gaskell, Allum, and Stares et al. 2003, p. 13.

Note: The response alternatives for these questions were on a four-point scale (definitely agree, tend to agree, tend to disagree, and definitely disagree) and were recoded by the authors as –1.5 to +1.5 (on the *y*-axis here) in order to show the midpoint of zero in the figure.

Canada, and Mexico are the only other countries that have made significant use of modern agricultural biotechnology, although many other countries, including Australia and South Africa, are starting to increase their use of living modified organisms in agriculture. China has approved a small number of transgenic varieties of cotton and expects to proceed to the commercial production of modified rice in the next two years. The latest Eurobarometer survey of European attitudes toward technology (Gaskell, Allum, and Stares et al. 2003) indicated that Europeans had recovered their faith in technology, including biotechnology, but the results, shown in Figure 3.2, may simply indicate that the de facto moratorium on the commercialization of plants manufactured using genetic modification techniques has taken the subject out of the public consciousness.

In the United States, according to Hallman and associates, the "American public's position on the acceptability of genetic modification of food is decidedly . . . undecided." Some 58 percent of Americans either strongly approve or somewhat approve of creating hybrid plants using genetic modification, while 37 percent disapprove (Hallman et al. 2002, p. 20).

Figure 3.2 European optimism about technologies, 1991–2002



Source: Gaskell, Allum, and Stares et al. 2003.

Many developing countries are fearful of the impact of agricultural biotechnology. Zambia and Zimbabwe, for example, have been wary of permitting food aid that includes transgenic maize to come into the country, even though many of their people are starving. This reluctance relates to concerns about the safety of the food when it forms a very high percentage of intake and also relates to the possible disappearance of major markets if crops are "contaminated" with transgenic material. Zimbabwe has accepted transgenic maize when it has been milled.

What is happening in Europe is significant, because it has a direct bearing on what can be done in developing countries. In the first instance, the concerns being expressed by Greenpeace, Friends of the Earth, Christian Aid, and even the British Medical Association[16] create a groundswell against the use of this new technology. Can it be right to introduce these "untested" technologies in developing countries when public "informed" opinion is so virulently opposed to their use in Europe? When even statutory bodies like the nature conservation organizations in Britain and France reject modern biotechnology because of its predicted negative effect on the environment, are developing countries to embrace them? The United Nations Environment Program's International Guidelines (UNEP 1995) and the Cartagena Protocol (Secretariat of the Convention on Biological Diversity 2000) require that the public be informed and educated about biosafety, but the virulent reaction against this technology in Europe directly affects its public image more easily than

does a reasoned argument for the safe use of the technology. In Britain, during the first nine months of 1999 there were a continual series of press reports "implying that eating GM food would lead to all sorts of serious diseases" (United Kingdom, House of Commons 1999, para. 29).

The attention paid by the media to foods produced using modern biotechnology has been sustained over a long period and has been almost totally hostile. The coverage has stressed the technology rather than the products. The rejection of genetically modified foods by many European supermarkets and food producers has had an impact on the production and growing of genetically modified crops that have to be exported to one of the largest food markets in the world.[17] The possibility of growing rice modified so that it produces vitamin A is a wonderful prospect for nutrition in the many countries that depend on rice as a primary food. However, the produce cannot be exported as well, producers will be reluctant to grow it! Concern over the impact of genetically modified crops on the environment has been the primary concern, but fears about the long-term safety of eating modified foods and about the speed of entering the unknown have sent powerful messages to the public (Burton 1999). An article in a Christian Aid paper asks, "Are GM crops the next in a long line of inappropriate products to be dumped on poor countries?" It continues: "GM crops are irrelevant to ending hunger; the new technology puts too much power over food into too few hands; and too little is done to help small farmers grow food in sustainable and organic ways. . . . It is tempting to see biotechnology in agriculture as a clean neutral science, simply transferring progress from the laboratory to the field, improving the lot of everyone. This is illusory. All technologies are embedded in specific economic and social systems and have different costs and benefits" (Burton 1999).

This response to the new technology in Western Europe cannot easily be dismissed through assertions by scientists that there is negligible risk or that permits to market transgenic foods and crops (in particular) should be based solely on risk assessments that are science-based. If all the scientific information were available and a consensus among scientists could be achieved that the impact of such foods on the environment is minimal, it would be possible to argue for a totally science-based risk assessment process. An Irish consultation paper (Republic of Ireland, Department of the Environment and Local Government, 1999) expresses some of the problems: the concerns about potential environmental and human health effects arise due to an absence of familiarity with the regulatory systems; the technology is complex and developing rapidly; "there is little experience on the interaction of GMOs with their surrounding environment"; the information being provided to the public is probably inadequate, particularly in relation to labeling to allow choice; the use of antibiotic resistance marker genes is thought to be inimical

to their use in human and veterinary medicine; and the use of herbicide-tolerant crops might increase the use and build-up of herbicides in the environment.

In 2000 the Council of Europe Parliamentary Assembly once again looked at the use of modern biotechnology (and, in particular, the patenting of genes and gene fragments) and resolved: "Public opinion should be more strongly involved in political decision-making as regards scientific and technological choices and scientists should be encouraged to engage more in public debate" (Council of Europe, Parliamentary Assembly 2000).

Policy on involving the public has evolved in many different ways. Article 23 of the Cartagena Protocol (Secretariat of the Convention on Biological Diversity 2000) requires that countries engage their publics in decisionmaking both at the policy level and when considering individual applications for use of modern biotechnology:

1. The Parties shall:
   (a) Promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of living modified organisms in relation to the conservation and sustainable use of biological diversity, taking also into account risks to human health. In doing so, the Parties shall cooperate, as appropriate, with other States and international bodies;
   (b) Endeavour to ensure that public awareness and education encompass access to information on living modified organisms identified in accordance with this Protocol that may be imported.
2. The Parties shall, in accordance with their respective laws and regulations, consult the public in the decision-making process regarding living modified organisms and shall make the results of such decisions available to the public, while respecting confidential information in accordance with Article 21.

Even for countries with a history of involving their publics in the decisionmaking process this is not easy; for those not used to direct public involvement it may be much more difficult.

Science-Based Decisions

Many have argued that decisions on the use of living modified organisms must be based on science; policy may be defined when designing the system that is applied to individual applications, but the applications should be considered only in the light of this policy.

Decisions are usually made by governments based on advice received from a number of sources. The risk assessment procedure, at the very least, should be science-based. This is made very clear in the Cartagena Protocol (Secretariat of the Convention on Biological Diversity 2000). Article 15 states: "Risk assessments undertaken pursuant to this Protocol shall be carried out in a scientifically sound manner." A report by the Royal Society of Canada (2002, para. 3) asserts that "scientific assessments must inform policy decisions but cannot pre-empt them, and that public opinion must be taken into account throughout." The report writers continue: "We believe that the public debate about GM food must take account of wider issues than the science alone. We also wish to stress the importance of informing debate with sound science." Article 23 of the Cartagena Protocol (Secretariat of the Convention on Biological Diversity 2000) requires public involvement in the decisionmaking process, and Article 26 allows for specific socioeconomic issues to be taken into account in the process: "The Parties, in reaching a decision on import under this Protocol or under its domestic measures implementing the Protocol, may take into account, consistent with their international obligations, socioeconomic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities."

Unlike Canada, the European Union, and the United States, the vast majority of developing countries may not have expertise directly employed by the government in the vast array of disciplines needed to perform a complete risk assessment of transgenic organisms. The data needed to assess likely environmental degradation or impact may not be available in many countries. In such countries a different approach may be needed, whereby an applicant requesting a permit for the use of a transgenic organism must perform a detailed risk assessment—possibly even performing field tests in an appropriate environment—and submit the resulting data for audit to the government, rather than the government performing the risk assessment. Most scientists may feel more confident in auditing a detailed assessment than attempting the assessment themselves. Applicants could also be expected to design their own risk management, consultation, and monitoring procedures, with input from government-appointed assessors when appropriate. There is an obvious danger inherent in this approach, however, for the government's lack of trust in those applying to release organisms to provide all the necessary information may mitigate against the acceptance of the risk assessment. Can applicants be trusted to provide all the necessary information? If a decision is made to use an audit rather than a direct risk assessment by the government, it is important that the scientists involved in the audit be able to ask for further information and be able to identify gaps in the approach taken by the applicant.

Risk assessment of genetically modified organisms is largely based on the concept of familiarity, or of "substantial equivalence," which assumes that all the characteristics of the modified organism are those of the host organism except for the specific characteristics introduced. It is actually difficult to identify other ways of approaching the problem of identifying risk. But the Royal Society of Canada (2001) and the Royal Society of the United Kingdom (2001) have both indicated dissatisfaction with "substantial equivalence." Can the approach be justified when stress tolerance, modification of metabolism, or production of pharmacologically active compounds really begins?

Crop varieties developed through conventional plant-breeding techniques not involving modern biotechnologies are not generally tested for their safety. Rather they have to meet plant variety registration requirements that identify whether they are distinct from those currently on the market, uniform, and stable. These traditional methods use (primarily) crossing selection and back-crossing processes to select a desired characteristic and remove inadvertently introduced extra characteristics that initially accompany the introduced trait. These mechanisms introduce new and numerous gene combinations. If toxins or allergens are known to occur in these crops (e.g., glucosinolates in canola, glycol-alkaloid accumulation in potatoes), the new variety is normally tested to ensure that the level of toxin or allergen is no greater than the range that is normally observed for that substance. Interactions of traits introduced by traditional methods with other characteristics of the plant are normally ignored until they can be proven to make the variety unusable. According to the Royal Society of Canada (2001; emphasis in original): "The implicit assumption behind this methodology is that, even where a breeding-derived novel trait is involved, *new combinations of existing genes operating within highly selected germplasm are not expected to generate harmful outcomes.*"

The concept of substantial equivalence was introduced for use with transgenic crops. It was first described in a report of the OECD (1993) that suggested: "If a new food or food component is found to be substantially equivalent to an existing food or food component, it can be treated in the same manner with respect to safety." The World Health Organization published a report (WHO 1995) in which the concept of substantial equivalence as a decision threshold was promoted as the basis for safety assessment decisions concerning GMOs (Royal Society of Canada 2001, p. 179).

The Royal Society of the United Kingdom (2002) has said that substantial equivalence can be considered in three ways:

- The GM foodstuff might be regarded as substantially equivalent to its conventional counterpart both toxicologically and nutritionally. . . .

When a product has been shown to be substantially equivalent, no further safety assessment is required.

- It might be substantially equivalent apart from certain defined differences. Sometimes the GM food product includes the components deliberately introduced by genetic modification. In this case the GM food product might be regarded as "substantially equivalent to its conventional counterpart except for a small number of clearly defined differences." Assessment is then limited to examining the implications of the difference(s), perhaps by testing the novel components of the GM plant in isolation.
- The GM product might be regarded as not substantially equivalent to its conventional counterpart, or there might not be a suitable reference available for comparison. The product will then need a highly detailed safety assessment taking all the properties of the modified foodstuff and determining by direct measurement where necessary the impact on human health and the environment.

Many countries are deciding that using the term *substantial equivalence* is misleading. It suggests that if substantial equivalence is demonstrated, no further assessment need be done. A report by the Food and Agriculture Organization (FAO) and the World Health Organization (WHO) (2000) says that there was a "mistaken perception that the determination of substantial equivalence was the end point of a safety assessment rather than the starting point." In 2002 the Royal Society of the United Kingdom recommended: "Safety assessments should continue to consider potential effects of the transformation process. The phenotypic characteristics to be compared between foods derived from GM plants and their conventional counterparts should be defined. It may not be necessary or feasible to subject all GM foods to the full range of evaluations but those conditions that have to be satisfied should be defined" (Royal Society of the United Kingdom 2002, p. 10).

Intellectual Property Rights and Ethics

Many arguments have been made for and against the use of intellectual property rights in relation to modern biotechnology. According to a resolution of the Parliamentary Assembly of the Council of Europe: "The patent system, as a system for the protection of intellectual property, is an integral part of the market economy and therefore can be a driving force for innovation in many technological questions" (Council of Europe, Parliamentary Assembly, 1999). The same resolution notes that "living organisms are able to reproduce themselves even if they are patented, and in view of this special quality of living organisms the scope of a patent is

difficult to define, which makes it nearly impossible to find a balance between private and public interests." The resolution also notes that there are ethical concerns related to the use of patents on living systems:

> 9. The Assembly considers that monopolies granted by patent authorities may undermine the value of regional and worldwide genetic resources and of traditional knowledge in those countries that provide access to these resources.
> 10. It considers that the aim of sharing the benefits from the utilisation of genetic resources within this broader view does not necessarily require patent-holding but requires a balanced system for protecting both intellectual property and the "common heritage of mankind."
> 11. It also considers that the many outstanding questions regarding the patentability and the scope of protection of patents on living organisms in the agro-food sector must be solved swiftly taking into account all interests concerned, not least those of farmers and developing countries. (Council of Europe, Parliamentary Assembly, 1999)

Over the last few decades the global trading importance of biotechnology has been recognized. As a result, concerted and concentrated efforts have been made to protect the results of research and development involving genetic material. The result of this has been the extension of intellectual property protection to most forms of biological material. The trade importance of biological information has been underlined by the adoption of the Agreement on the Trade Related Aspects of Intellectual Property Rights (TRIPS) within the World Trade Organization (WTO 1994c). This agreement requires states party to the agreement to provide protection for all types of inventions irrespective of the field of technology. The aim of the agreement is to ensure that all member states provide effective and appropriate intellectual property protection and protect intellectual property rights by the appropriate enforcement mechanisms. The agreement sets down the minimum standards of protection.[18] Article 27(2) of the TRIPS agreement permits countries to exclude from patentability those inventions whose commercial exploitation may be contrary to *ordre public* or morality. Countries may exclude from patentability "diagnostic, therapeutic and surgical methods for the treatment of humans or animals." More important, Article 27(2) allows members to exclude from patentability innovations produced in order to protect animal or plant life or health or to avoid serious damage to the environment, and Article 27(3) provides for exclusion from patentability of "plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-

biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof" (WTO 1994c).

What constitutes sui generis protection for new plant varieties is not defined; hence countries are free to adopt a system that ensures intellectual property protection for plants. One option is for countries to implement UPOV (the International Union for the Protection of New Varieties of Plants), which was established by the International Convention for the Protection of New Varieties of Plants,[19] but Simon Walker believes that "this form of protection has been criticized for focusing too much on the rights of plant breeders, and too little on the rights of those using the seeds—farmers" (Walker 2001).

Although member states are obliged to provide protection systems, those "inventing" new products do not need to obtain that protection. The rights apply only in the country in which the inventors have chosen to invoke protection. In most African countries many of the biotechnology inventions have not been protected through patent rights and can legally be used as if in the public domain. It is only when products developed using patent protected materials or methods are exported into countries where protection is offered that the rights of the inventor must be respected.

There is an underlying assumption that the introduction of an intellectual property system will result in a dramatic increase in the innovative capacity of the private sector while allowing the public sector to become more self-financing. This may be true to an extent in countries with a substantial research capacity, but it is unlikely to be the case in developing countries, where the research and development sector is not as strong. A "Northern" intellectual property system may provide an incentive, but there may be limited local capacity to exploit it. Even when technologies are developed, firms in developing countries can seldom bear the costs of acquisition and maintenance of rights, much less those of enforcement (especially in those countries where substantial earnings may be realizable). The costs of establishing an infrastructure to support an intellectual property rights regime may be substantial, and mechanisms for the enforcement of such rights are costly both to government and to private stakeholders.

If a country has made a policy commitment to implement a rights system, perhaps the best way to proceed would be to look at the systems in Europe and the United States and adapt them to local and cultural needs. The required patent system would need to balance the costs and benefits against local needs and requirements. Those responsible for the implementation of such a system should examine whether there might be a need to

- raise the standard of the granting criteria of novelty, inventiveness, and industrial application to ensure that the reward of the patent is consummate with the benefit to society;

- widen the range of subject matter that can be excluded from patentability;

- provide an effective compulsory licensing system;

- include an exclusion of patentability on the grounds of "morality" similar to that found in Article 53(a) of the European Patent Convention; and

- consider the suitability of other forms of protection to encourage local innovation, such as utility models.

There is real concern about the use of intellectual property law in developing countries, particularly in relation to health care, but also in relation to what is emotively called biopiracy or bioprospecting. In May 2000 the revocation by the European Patent Office of a patent on a neem[20] product was undoubtedly a victory for India and developing countries. However, individual legal action is no substitute for a legally enforceable integrated approach to bioprospecting.

Pharmaceutical companies worldwide are interested in finding new and alternative therapies and have widened their search to include traditional medicines and practices largely based on medicinal plants endemic to developing countries. Many traditionally used herbal medicines may have real therapeutic properties. If a company takes traditional knowledge as the starting point for a search for new pharmaceuticals and extracts the active product, it is entitled to a patent on the extracted product even though it cannot replace the traditional product itself. Developing countries are thus faced with the acute dilemma of having their valuable indigenous wealth taken away and exploited commercially by the resource- and technology-rich transnational pharmaceutical companies.

Bioprospecting is not found just in the area of pharmaceuticals. In northwest Mexico, yellow beans have been cultivated for centuries as they are the staple diet of many Mexicans. In 1994 John Proctor, the owner of a small-seed company, POD-NERS, LLC, bought a bag of commercial bean seeds in Mexico and took them back to the United States. Proctor planted the yellow beans in Colorado and allowed them to self-pollinate. When yellow beans were selected over several generations, a segregating population resulted in which the color of the beans is uniform, stable, and changes little by season. In 1996 Proctor applied for a U.S. patent

that was granted in 1999.[21] With the patent granted, Proctor has an exclusive monopoly on yellow beans and can exclude the importation, sale, offer for sale, make, use for any purpose, including drying edible or propagation of any yellow bean exhibiting the yellow shade of the Enola beans.

Customs officials at the U.S.-Mexico border are now inspecting beans, searching for any patent-infringing beans being imported into the United States. Because of this bean alone and the threat of patent infringement, some export sales of yellow Mexican beans have dropped over 90 percent. This has also had an affect on the market for other nonyellow beans, as often the beans are not separated and yellow patent-infringing beans are mixed with nonyellow beans. As agriculture is the primary source of employment and livelihood for the people of northwest Mexico, this patent has had a serious effect on farmers in that area. Although farmers can still grow and sell the beans in Mexico, they can no longer export them to markets in the United States without paying royalties to the patent holder.

The International Center for Tropical Agriculture is legally challenging the patent, arguing that the patent claims are invalid because they fail to meet the requirements related to novelty and nonobviousness and disregard available prior art. The opposition proceedings have been slowed by the filing of new claims by POD-NERS, and no decision has been made as yet.

One extremely important lesson can be learned from what many people feel is an example of bioprospecting at its worst. In the United States,[22] according to 35 USC 102(a) an invention cannot be "known or used in this country, or patented or described in a *print publication* in this or a foreign country"(emphasis added). Therefore, mere use in Mexico without printed publication is insufficient to show a lack of novelty. Hence the need to document genetic resources, as we will discuss later.

Membership in the WTO requires that countries have in place an effective intellectual property regime. However, the simple implementation of the TRIPS agreement in national law is insufficient to protect a country's genetic resources, as Article 27(3b) is inadequate to meet their protection requirements. What is required is the enactment of legislation that incorporates the framework of current agreements and negotiations—TRIPS, along with the requirements of the Convention on Biological Diversity and the International Treaty for the Protection of Plant Genetic Resources.

In November 2001, at the WTO ministerial conference in Doha concerns of this sort resulted in a statement and an agreement to find a solution to some of these pressing problems before the end of 2002. No agreement has yet been reached. The Doha statement (WTO 2001a) recognized

- the gravity of the public health problems afflicting many developing and least developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics. . . .
- the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems. . . .
- that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health.

The final item continues: "Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all."

The ministers also recognized that compulsory licensing to produce drugs was not an option for many of the developing countries, and that other solutions would have to be found for many of these countries. Hence developing countries should consider the manner in which they implement the various agreements in order to protect their people and their resources, paying heed to the following:

1. Developing countries should enact appropriate biodiversity protection legislation including benefit sharing consistent with Article 8j[23] of the Convention on Biological Diversity (Secretariat of the Convention on Biological Diversity 2000) and access to genetic resources (covered in Article 15).

2. The TRIPS agreement requires not that countries institute a patent regime for plant material, but that they create a sui generis system for protection of the plant intellectual regime (Walker 2001). The replacement system could be designed to protect extant varieties that are in the public domain as well as new plant varieties and to provide for the needs of the country taking into account, for example, the communitarian approach to property that is often part of the culture of developing countries as well as the needs for innovation.

3. Developing countries may need to document and catalogue their biological assets not only to ensure protection but also to ensure future collaboration and exploitation. States have sovereign rights over their biodiversity and are responsible for conserving their biological diversity and for using their biological resources in a sustainable manner.[24] Article 3 of the Convention on Biological Diversity (Secretariat of the Convention on Biological Diversity 2000) reads: "States have, in accordance with the Charter of the United Nations and the

> principles of international law, the sovereign right to exploit their own resources pursuant to their own environmental policies, and the responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other States or of areas beyond the limits of national jurisdiction."

Many are concerned with the way in which intellectual property (IP) protection has been used in many countries. As Walker writes:

> The balance in many IP systems seems to be shifting too far in favour of technology producers. Negotiations over IPRs have been powerfully influenced by industry lobby groups and are being driven by concerns of trade liberalization and international investment between developed countries. The legitimate technological and developmental objectives of developing countries—generally technology users—are not being given due consideration. This shift in the ownership and control of information, and the resulting boon to private investors, has been called an "information land grab." (Walker 2001)[25]

Ethical Issues Raised by Modern Biotechnology

In May 1999 the Nuffield Council on Bioethics, an independent organization in the United Kingdom, published a major report titled "Genetically Modified Crops: The Ethical and Social Issues" (Nuffield Council on Bioethics 1999). The executive summary of the report states: "The application of genetic modification to crops has the potential to bring about significant benefits, such as improved nutrition, enhanced pest resistance, increased yields and new products such as vaccines. The moral imperative for making GM crops readily and economically available to developing countries who want them is compelling."

Many have argued that transgenic crops will assist in the task of providing enough food in the right places and at the right times to retain, as far as possible, the way of life of those who desperately need food. However, in order to do so, it is essential that the crops that are modified and the genes inserted be chosen with the needs of those who are hungry in mind. To suggest that the modified crops currently available are primarily anything other than products designed for industrialized farming is clearly wrong; however, the technology has been used where it was possible in the early stages of its development. The development of new uses that really do benefit those who are needy is imperative if this technology is to benefit the poor. In the words of the Council of Europe's Parliamentary Assembly (2000):

"It is increasingly important to include ethical considerations centred on humankind, society and the environment in deliberations regarding developments in biotechnologies, life sciences and technologies and their applications."

Natural and Unnatural Products

Many perceive the use of genetically modified organisms in the environment as equivalent to "playing God," as an unnatural act that should not be done. There is a deep-rooted belief in many societies that tinkering with nature, or the industrialization of nature, is unacceptable. This argument will be at least as strong in African societies as it is in Europe. Many hold the view that tampering with nature is inherently wrong, that we have "dominion" over nature,[26] which implies a responsibility to look after and protect nature rather than own it.

The idea that genetic modification "that could not happen naturally" is wrong is held by many people even though it is not often clearly enunciated. Many argue that this concept precludes any selective approach that results in improved crop plants, for by using such approaches we are playing God. Others argue that it is only that which could not have happened without human intervention that is unacceptable. Even if modification itself is seen as acceptable, there might be religious objections that would mean that the resulting organism would be unacceptable. For example, insertion into foods of genes derived from a pig could arguably be unacceptable to those whose religion precludes the use of products derived from this "unclean" animal.

Any discussion based on objections to playing God is generally not accessible to logical argument. Respect for such beliefs usually involves ensuring that there are mechanisms in place to permit believers to choose not to use such products. According to the Nuffield Council (1999, para. 6.7): "Proponents of the technology citing practical benefits may have an intrinsic value system that views science and progress as good things in themselves, and opponents may be analysing risks from a world-view that questions the rightness of technological progress."

The Principle of Justice

One of the most important issues that we need to recognize is that many different groups within a society have competing rights and fears. We need to attempt to balance these needs. "For example," writes the Nuffield Council (1999, para. 1.20), "if protecting the rights of consumers by providing adequate labeling was very expensive and was generally agreed to do nothing to prevent harm, most people would say that upholding the right to know would not be worth the loss of value

to producers, particularly if the producers were poor. Conversely, if informative but inexpensive labeling was desired by the majority of consumers, it would probably command wide public support." The principles at stake are not complex, but their implementation is. Securing a consensus is complicated by the fact that producers have an interest in exaggerating the difficulty of complying with new regulations, and pressure groups have an opposite interest in exaggerating the public demand for them. Questions about where the balance of burden and benefit is to be struck are the subject of everyday political debate.

This principle of justice poses many questions that need to be addressed. Is this new technology likely to increase the gap between the rich and the poor, both within countries (particularly in the developing countries) and between developed and developing countries? Are the products produced by the technology able to provide for those who really need them, the poor? Will the technology generate wealth for the society as a whole that can assist those who need it? If the technology is more efficient and will provide more food but at the expense of some who farm traditionally, is it acceptable?[27] According to the Nuffield Council (1999, para. 1.23), "GM crops are currently vulnerable to questions about their real usefulness and to questions about who benefits."

Economic and Social Benefits and Risks: The Principle of General Welfare

Of necessity biotechnology has to be applied for the benefit of human beings, society, and the environment. These beneficiaries are not necessarily the same, for the benefit to human beings may be at the short- or long-term expense of the environment. There is a presumption that the "acceptability" of the risk must include an improved quality of life, perhaps as we develop better (or more) food, better health, and an environment that is improved in a sustainable manner. Human usage of the environment in the 10,000 years of our exploitation of nature has been relatively benign. In the last 100 years, however, we have made rapid and possibly irretrievable changes to the environment, including the excessive use of fossil fuels relative to their replacement, excessive use of water, production of greenhouse gases, and even a huge increase in the human population. Humans are no longer in harmony with their environment, and we have to be aware of the effect on the environment. Whereas a primary goal of technology was once the pursuit of happiness (and the greatest good), we now have to pursue sustainability.

These concerns are human-centered. Many of those who live in southern Africa are suffering from severe malnutrition, and drought is wreaking havoc with and on the environment. If the application of modern biological techniques can

result in food products that can better survive drought and heat, and can also provide more food in the right places at the right times, there are clear benefits that can result from its use. It is axiomatic that food is essential for our survival. According to the FAO (2001, p. 3), "Both formal ethical systems and ethical practices in every society presume the necessity of providing those who are able-bodied with the means to obtain food and enabling those who are unable to feed themselves to receive food directly." And, in the words of the *Rome Declaration on World Food Security* (FAO 1996b):

> We consider it intolerable that more than 800 million people throughout the world, and particularly in developing countries, do not have enough food to meet their basic nutritional needs. This situation is unacceptable. Food supplies have increased substantially, but constraints on access to food and continuing inadequacy of household and national incomes to purchase food, instability of supply and demand, as well as natural and man-made disasters, prevent basic food needs from being fulfilled. The problems of hunger and food insecurity have global dimensions and are likely to persist, and even increase dramatically in some regions, unless urgent, determined and concerted action is taken, given the anticipated increase in the world's population and the stress on natural resources.

It is clear that we need to promote access to the genetic resources for food and agriculture for farmers, farming communities, and consumers.

Human health is important in this context. Health is improved when hunger is eliminated and the quality of food is improved. Healthy people are empowered in that they are able to participate in society and are better able to live meaningful lives. The FAO constitution identifies the need to raise levels of nutrition, secure improvements in the efficiency of production and distribution of all food and agricultural products, and better the conditions of those who live in rural areas.

For most consumers in developed countries the choice of whether to eat genetically modified foods is not an ethical issue. To eat genetically modified food would not be wicked, even if the individual was concerned as to its safety. However, if that food was proscribed by the society as (for example) not being *halal,* or kosher, not giving the people the ability to identify the food as proscribed would be unethical. When people are starving and a technology can help to provide them with more and nutritionally better food, but it is not made available, an ethical issue is at stake.

The industrialization of agriculture is an issue in many African countries, for it takes away the traditional structures of society and substitutes a more individualist system that may cause harm. This industrialization might arguably help in providing more and better food at the cost of disrupting traditional belief systems and

modifying the way of life of many in rural areas, which may result in a situation in which less food will be available where and when necessary.

The agreement setting up the WTO (WTO 1994a) tried to balance the many conflicting issues that this principle requires:

> Relations in the field of trade and economic endeavour should be conducted with a view to raising standards of living, ensuring full employment and a large and steadily growing volume of real income and effective demand, and expanding the production of and trade in goods and services, while allowing for the optimal use of the world's resources in accordance with the objective of sustainable development, seeking both to protect and preserve the environment and to enhance the means for doing so in a manner consistent with their respective needs and concerns at different levels of economic development.

The WTO and its disputes resolution system has placed the freedom to trade above environmental concerns, but there is recognition of the importance of environmental concerns.

The WTO (2001b, p. 47) outlined some of the issues it would have to address: "If one country believes another country's trade damages the environment, what can it do under the terms of the WTO agreements? Can it restrict the other country's trade? If it can, under what circumstances? At the moment, there are no definitive legal interpretations, largely because the questions have not yet been tested in a legal dispute either inside or outside the WTO." When both countries are party to an international environmental agreement, their dispute may be able to be addressed through that agreement. If one of the countries is not a party to the agreement, it is not yet possible to decide what the implications might be. It will depend on the obligations placed on the member country by the treaty and by the specifications identified in the agreement in regard to relations between parties and nonparties. If neither country involved in the dispute is party to an environmental agreement (or if there is no agreement relating to that issue), WTO rules apply. They have been interpreted to mean that trade restrictions cannot be imposed on a product purely because of the way it has been produced and that any one country cannot impose its standards on another.

Sustainable Development

In 1987 the Brundtland Report of the World Commission for the Environment and Development, also known as *Our Common Future,* considered the need to ensure that economic development was achieved without the depletion of natural

resources. The report asserted that it is necessary to provide for the future without harming the environment. Published by an international group of politicians, civil servants, and experts on the environment and development, the report provided a key statement on sustainable development:

> It is in the hands of humanity to make development sustainable, that is to say, seek to meet the needs and aspirations of the present without compromising the ability of future generations to meet their own. The concept of sustainable development implies limits—not absolute limits, but limitations that the present state of technology or social organisation and the capacity of the biosphere to absorb the effects of human activities impose on the resources of the environment—but both technology and social organisation can be organised and improved so that they will open the way to a new era of economic growth. The Commission believes that poverty is no longer inevitable. Poverty is not only a malaise in itself. Sustainable development demands that the basic needs of all are satisfied and that the opportunity of fulfilling their expectations of a better life is extended to all. A world where poverty is endemic will always be susceptible to suffering an ecological or any other kind of catastrophe. (Bruntland 1987)

According to the online *Encyclopaedia of the Atmospheric Environment* (Buchdahl and Hare 2000), "The report highlighted three fundamental components to sustainable development: environmental protection, economic growth and social equity. The environment should be conserved and our resource base enhanced, by gradually changing the ways in which we develop and use technologies. Developing nations must be allowed to meet their basic needs of employment, food, energy, water and sanitation. If this is to be done in a sustainable manner, then there is a definite need for a sustainable level of population. Economic growth should be revived and developing nations should be allowed a growth of equal quality to the developed nations."

This is an important policy statement; it provides for an approach to our environment that must inform the manner in which crops are produced and land is used.

Autonomy, Dignity, Integrity, and Vulnerability

Human autonomy and dignity need to be respected. Article 2 of the United Nations Educational, Scientific, and Cultural Organization (UNESCO) Universal Declaration on the Human Genome and Human Rights (1997)[28] states:

(a) Everyone has a right to respect for their dignity and for their rights regardless of their genetic characteristics.
(b) That dignity makes it imperative not to reduce individuals to their genetic characteristics and to respect their uniqueness and diversity.

Article 6 reads: "No one shall be subjected to discrimination based on genetic characteristics that is intended to infringe or has the effect of infringing human rights, fundamental freedoms and human dignity." Governments are expected to treat the deeply held convictions of their citizens with respect: they have to pursue policies that can command a general consensus even where some views cannot be accepted because they are in direct contradiction with others (Nuffield Council on Bioethics 1999, sect. 1.09). Animals and the natural world are also entitled to respect for their integrity and vulnerability (Nielsen and Faber 2002, p. 12).

There are also concerns that the new technology will lead to exploitation of those living in the "developing" countries. For instance,

- monopoly control of chemicals used in agriculture and of seeds that allow plants to resist these chemicals might be exploitative and place a strain on the economies of developing countries, and

- major changes in social structures might sequentially affect the types of agriculture and needs for distribution of foods and food products.

Just Distribution of Benefits and Burdens

Ethical use of biotechnology requires just distribution. This is particularly important in the context of developing countries, for it has been argued that for obvious reasons most of the products derived from modern biotechnology are being introduced by private companies that have an obligation to maximize earnings for their shareholders, and that therefore the products are aimed at markets that can best pay for their use. If the technology simply increases the divide between rich and poor, can it be ethical? This question will have to be addressed through public and private funds that attempt to provide for those who cannot purchase the new products.

The most important means of providing aid to those living in countries that rely on subsistence agriculture is to ensure the provision of adequate food and clean water. Important benefits may accrue from the provision of technological expertise. It has been argued that the manner in which agricultural resources are distributed should be equitable. Many conflicting arguments have been offered about the equitable distribution of food and farmland between the rich and poor, both in

developed and developing countries. According to Gary Comstock (2000), the need to redistribute land to the people of Zimbabwe and to dispossess those who had taken the land during the colonial past was seen as part of an equitable redistribution within Zimbabwe. Comstock also addresses the role of the industrialization of agriculture:

> Most of the world's poor are small tenant farmers. In order to increase the standard of living of these farmers, the governments of many developing countries adopted in the 1970s the policy of "industrializing" agriculture; making their farmers over in the image of large successful farmers in more developed countries. During the green revolution of the 1960s and 70s, countries such as India, Costa Rica, and Nigeria increased the efficiency of farmers' yields by borrowing money from international lending agencies such as the World Bank. The funds were used to extend credit to farmers who in turn were taught to buy high yielding varieties of seeds (such as rice, wheat, and maize) and to use the necessary accompanying technologies: mechanical implements (tractors) and synthetic chemicals (herbicides and pesticides). Many farmers flourished and nations that once were importing grain became self-sufficient in certain crops.

A majority of the world's resource-poor farmers are women. Worldwide, women produce more than 50 percent of all the food that is grown. In many developing countries, this percentage is much higher. For instance, it is estimated that women produce 80 percent of the food grown in sub-Saharan Africa, 50 to 60 percent of that in Asia, 46 percent of that in the Caribbean, 31 percent of the food grown in north Africa and the Middle East, and about 30 percent of that in Latin America. The advent of modern crops may release those working in the fields from much of the tedium of subsistence agriculture, but may also lead to an increase in poverty and in migration into cities (FAO 1996a).

Openness

Decisions on whether biotechnology should be used in a particular context will have to be addressed through an open process in which respect is given to all viewpoints and the structure of the society to which the technology is made available is respected. The Cartagena Protocol (Secretariat of the Convention on Biological Diversity 2000) requires that the public be consulted. Consultation should extend from the design of the regulatory system through individual decisions concerning products. There is an expectation that parties to the Protocol will "promote and facilitate public awareness, education and participation concerning the safe trans-

fer, handling and use of living modified organisms in relation to the conservation and sustainable use of biological diversity, taking also into account risks to human health. In doing so, the Parties shall cooperate, as appropriate, with other States and international bodies." In addition, the parties are expected (insofar as their law permits) to "consult the public in the decision-making process regarding living modified organisms and . . . make the results of such decisions available to the public, while respecting confidential information in accordance with Article 21" (Article 23, sections 1a and 2).

Consumer Choice and Rights

Perhaps the simplest way of ensuring that all views are respected is to provide real choice to the consumer. Those who do not wish to eat meat derived from pigs, for example, should be respected in that foods should be labeled to provide them with choice. Some seek simply to avoid GM food; could this be a reason for labeling food or for ensuring that food is not provided that could offend these sensibilities? This issue is particularly important for those who cannot easily purchase food and are being provided with food aid. The inability to purchase food should not strip them of their rights. A balance should be struck between these consumer needs and the expectation of commercial firms that they will be able to operate in a predictable environment (Nuffield Council on Bioethics 1999, para. 1.16).

Exploitation

In terms of control of genetic resources or food resources, two quite different types of exploitation of a position of power may be distinguished:

- Blocking access to products or to technology. Some fear that this will happen on a significant scale if the IPR systems in place are abused. Although this is theoretically conceivable, it goes against the primary interest of owners of such rights, which is to make money out of their ownership by selling the product.

- Dumping unwanted products that have not been properly tested or that are not approved in the industrialized countries.

It is often stated that only 30 crops "feed the world." These are the crops that provide 95 percent of dietary energy (calories) or protein. Wheat, rice, and maize alone provide more than half of the global plant-derived energy intake. These are the crops that have received the most investment in terms of conservation and

improvement. A further six crops or commodities—sorghum, millet, potatoes, sweet potatoes, soybeans, and sugar (cane and beet)—bring the total to 75 percent of energy intake. This information is based on data on national food energy supplies aggregated at the global level. When food energy supplies are analyzed at the subregional level, however, a greater number of crops emerge as significant. For example, cassava supplies over half of plant-derived energy in Central Africa, although at a global level the figure is only 1.6 percent. Beans and plantain also emerge as very important staples in particular subregions. These major food crops, as well as others such as groundnuts, pigeon peas, lentils, cowpeas, and yams are the dietary staples of millions of the world's poorer people, though they receive relatively little research and development attention (FAO 1996a). Resource-poor farmers constitute over half the world's farmers and produce 15 to 20 percent of the world's food. These farmers have not benefited as much as others from modem high-yielding varieties. It is estimated that some 1,400 million people, approximately 100 million in Latin America, 300 million in Africa, and 1,000 million in Asia, are now dependent on resource-poor farming systems in marginal environments (FAO 1996a).

Bias against the Poor

One of the issues that has been mentioned on a number of occasions in this report is that the use of modern biotechnology could, if not used in a careful manner that respects the integrity and needs of all, be a force driving increasing inequity. According to the FAO document on ethical issues (FAO 2001, p. 12): "Most societies were once structured so that, even though many people were poor, most had access to sufficient food to ensure their survival. Social, economic and technological changes have since eroded the traditional 'safety nets,' and ties to the land have been weakened or severed, making it difficult or impossible for the poor to grow their own food." Widespread bias against the hungry and the poor is thus viewed as one of the most egregious problems raised by technological advance of any kind. Pressures to recoup the high costs of investment in biotechnology likely create the conditions for additional bias toward solving the problems of the rich.

Animals

There may be intrinsic objections to the use of modern biotechnology when working with animals. It is recognized that particular kinds and degrees of harm should not be inflicted on any animal. When harm is permissible, it needs to be justified and must be outweighed by benefit either to animals in general or to human beings (United Kingdom Ministry of Agriculture, Fisheries and Food 1993). However, such harm must be minimized.

It has been argued that genetic modification of animals is unethical in that it involves humans' playing God. For some whose religious convictions forbid the eating of certain animals, care must be taken to permit them to avoid modified plants and animals into which such animal genes have been placed. Placing human genes in animals or plants may be offensive to some. The Netherlands' Advisory Committee on Ethics and Biotechnology in Animals (1990) has written:

> Traditionally, ethical and juridical systems in Western society are highly human orientated. Insofar as individual animals were valued, the value was derived from the importance of animals to man. . . . The sense of values with regard to animals is shifting. Especially the criticism of the use of animals as experimental animals and of livestock housing has resulted in the recognition that *animals have a value of their own, or an intrinsic value to man.* . . . Animals come to fall under the province of ethics, not in the sense that animals are thought to act morally, but in the sense of deserving moral care. (Emphasis in original)

According to the Royal Society of the United Kingdom (2001): "Application of genetic modification technology to animals can be used in medical research to create models of human disease. Such models help identify disease pathways and allow assessment of new therapies. Analysing gene function is an area in which the use of GM animals is likely to rise significantly, because by modifying a gene, its various roles in different functional systems of the body can be identified." The concept of stewardship is critical for animals, as we perceive them to have feelings but they are not able to fend for themselves.

The use of animals in biotechnology does pose risks. There may be new allergic reactions when humans come into contact with animals or eat them. There may be toxic effects on humans, animals, and other organisms. Changes in behavior may be important, and the bonds between animals within the same family group may be modified by the modification or an animal might have to be taken out of its social context in order to maintain its freedom from disease. It is possible that transgenic animals may be able to transmit to humans and other animals diseases that could not be transmitted before.

Conclusion

The policy choices made by countries that are members of the OECD have been different. The United States chose not to introduce new laws for the products of biotechnology, relying on its existing regulatory structure. The European Union has made the use of modern biotechnology a trigger for regulation, and Canada regulates all novel products. These choices and the resulting concern about the

safety of transgenic organisms in the environment have been confusing to those in the least developed countries. Reasons for decisions need to be clear. There is clearly a need to balance benefits to human health and the environment with risks. The risks are often unclear, speculative, and impossible to test. The benefits of the new crops have not yet been fully demonstrated. People need to feel safe and to be assured that their safety, their health, and their beliefs have been taken into account as far as possible before the introduction of new forms of food products. Although it is undoubtedly a useful exercise to observe the arguments and discussions other countries are having or have had when implementing agricultural biotechnology, in the end it is up to each country, whether developed or developing, to assess the benefits and risks to their own culture and environment when deciding the best way to move forward.

Notes

1. The applicable section of the directive reads as follows:

Article 6.2: The following inventions include those that are unpatentable where their exploitation would be contrary to *ordre public* or morality:

- processes for cloning human beings;
- processes for modifying the germ-line genetic identity of human beings;
- uses of human embryos for industrial or commercial purposes;
- processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

2. Variously and at various times called genetic modification, genetic manipulation, or genetic engineering.

3. The resolution reads as follows:

Biotechnology can be used to promote contrasting aims:

i. to raise agricultural outputs or reduce inputs;
ii. to make luxury products or basic necessities;
iii. to replace chemical herbicides and insecticides or target them more efficiently;
iv. to upgrade pedigree flocks and herds or expand indigenous stock in developed countries;
v. to upgrade plants for industrial use;
vi. to convert grain into biodegradable plastics or into methanol for fuel;
vii. to hasten maturity in livestock or prevent sexual maturation in locusts or in farmed salmon;
viii. to produce more nutritious and better flavoured foods or diagnose tests for bacterial contamination;
ix. to engineer crops for fertile temperature zones or for semi-arid regions;
x. to fight viral epizootic or build up populations of endangered species;

xi. to reduce production of "greenhouse gases" or utilise them in food production;
xii. to clone meat animals for particular markets or form embryo banks to maintain genetic diversity.

4. Some 44 countries in Europe are members of the Council of Europe.

5. As used in this chapter, "'Transgenic organism" is synonymous with "living modified organism" or "genetically modified organism."

6. For example, on chymosin see http://www.ncbe.reading.ac.uk/NCBE/GMFOOD/chymosin.html.

7. At the First Extraordinary Meeting of the Conference of the Parties to the Convention on Biological Diversity, Cartagena, Colombia, and Montreal, Canada, February 22–23, 1999, and January 24–28, 2000).

8. Article 19(3) reads as follows: "The Parties shall consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity."

9. In this overview document, "transgenic," "genetically modified," and even "living modified organisms" are used synonymously.

10. The UNEP/GEF Project on the Development of National Biosafety Frameworks; see http://www.unep.ch/biosafety and specifically http://www.unep.ch/biosafety/countries.htm.

11. Article 2(2) of European Union Directive 2001/18 (European Union 2001) provides the following definition: "Genetically modified organism (GMO) means an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination. . . . [G]enetic modification occurs at least through the use of the techniques listed in Annex I A, part 1." And Annex IA lists these techniques as follows:

(1) recombinant nucleic acid techniques involving the formation of new combinations of genetic material by the insertion of nucleic acid molecules produced by whatever means outside an organism, into any virus, bacterial plasmid or other vector system and their incorporation into a host organism in which they do not naturally occur but in which they are capable of continued propagation;
(2) techniques involving the direct introduction into an organism of heritable material prepared outside the organism including micro-injection, macro-injection and micro-encapsulation;
(3) cell fusion (including protoplast fusion) or hybridisation techniques where live cells with new combinations of heritable genetic material are formed through the fusion of two or more cells by means of methods that do not occur naturally.

12. Article 1 (Objective) of the Cartagena Protocol on Biosafety (http://www.biodiv.org/biosafety/protocol.asp#) states: "In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of this Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements."

13. Paragraph 29 of the *Advisory Opinion on the Legality of the Threat or Use of Nuclear Weapons* of the International Court of Justice (1996) reads: "The environment is not an abstraction but represents the living space, the quality of life and the very health of human beings, including generations unborn."

14. Regulation no. 258/97 of the European Parliament and of the Council of 27 (1997) concerning novel foods and novel food ingredients. Note that this regulation is about to be substantially modified to take into account the greater public awareness of GM technology since 1997.

15. Article 5.7 reads: "In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time."

16. For an example of Greenpeace concerns, go to http://archive.greenpeace.org/~geneng/ or http://ge.greenpeace.org/campaigns/intro?campaign%5fid=3942. For an example of Friends of the Earth concerns, go to http://www.foe.org/foodaid/. For an example of Christian Aid concerns, go to http://www.christian-aid.org.uk/indepth/0003bios/biosafet.htm. For an example of British Medical Association concerns, go to http://www.foeeurope.org/GMOs/bma.doc or http://www.saynotogmos.org/bma_statement.htm.

17. The following was reported in the July 1999 issue of *Natural Foods Merchandiser:* "The world's two largest food production companies have decided they no longer will accept genetically modified ingredients for products sold in Europe. Within hours of one another, both Unilever UK and Nestle UK announced a policy change in response to continued demonstrations by European consumers worried about potential consequences of GMO crops."

18. Article 27(1) of the agreement reads: "Patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced."

19. The convention was adopted in Paris in 1961 and was revised in 1972, 1978, and 1991. The objective of the convention is the protection of new varieties of plants by an intellectual property right.

20. The neem tree (*Azadirachta indica*) is a tropical evergreen related to mahogany. Native to east India and Burma, it grows in much of southeast Asia and west Africa. The people of India have long revered the neem tree. For centuries millions have used parts of the neem tree for medicinal purposes, for instance, as a general antiseptic against a variety of skin diseases including septic sores, boils, ulcers, and eczema. In particular, neem may be the harbinger of a new generation of "soft" pesticides that will allow people to protect crops in benign ways. The active ingredient isolated from neem, azadirachtin, appears to be responsible for 90 percent of the effect on most pests. It does not kill insects, at least not immediately. Instead it both repels them and disrupts their growth and reproduction.

21. U.S. Patent no. 5,894,079.

22. This provision does not exist in the European Patent Convention.

23. Article 8j says that a nation should, "subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embody-

ing traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices."

24. See the preamble to the Cartagena Protocol (Secretariat of the Convention on Biological Diversity 2000).

25. Walker's quote is from J. Boyle, "Sold Out," *New York Times,* March 31, 1996, http://www.wcl.american.edu/pub/faculty/boyle/sold_out.htm.

26. Genesis 1:26 reads: "Let man have dominion over the fish of the sea, and over the fowl of the air, and over every living thing that moves upon the earth."

27. For more on issues of GM food and justice, see Nuffield Council on Bioethics 1999, paras. 1.20–1.31.

28. See http://www.unesco.org/human_rights/hrbc.htm.

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