FAO ETHICS SERIES

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Genetically modified organisms, consumers, food safety and the environment

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS
Rome, 2001

Editing, design, graphics and desktop publishing:
Editorial Group
FAO Information Division

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ISBN 92-5-104560-7

Foreword

Powerful tools provided by science and technology in recent years have had a profound impact on the food and agriculture sector worldwide. Innovative production and processing methods have revolutionized many traditional systems, and the world's capacity to generate food products for its growing population has evolved at an unprecedented rate.

These developments have naturally been accompanied by radical changes in economic forces and social organization as well as in management of the earth's productive resources. Our very relationship with nature has been overturned by technological advances that enable us not only to determine genetic improvements through selective breeding but to modify living organisms and create novel genetic combinations in the quest for stronger and more productive plants, animals and fish. Understandably, such developments invariably give rise to controversy, and arguments for and against their implementation tend to be intense and emotionally charged.

For several years now, genetic engineering has generated plants with an innate resistance to pests and tolerance to herbicides. It has enabled the production of fast-growing and cold-resistant fish, for example, and cheaper, more effective vaccines against livestock diseases as well as livestock feeds that increase the animals' ability to absorb nutrients; and its application in forestry has been studied with a view to increasing useful traits in plantation trees such as poplars. Genetically modified crops that allow reductions in insecticides could have a positive effect in terms of environmental impact and farmers' production costs, although there has been insufficient time for *ex post* analyses to be feasible.

Acknowledging the potential, and so far assumed, contributions of genetically modified products to world food production is not to ignore their possible risks with regard to food safety and unpredictable environmental hazards – the most commonly cited being the feared transfer of toxins or allergens and unintended negative effects on non-target species. Nor is it to minimize the possibility of undesirable consequences that these products may have in the long term, such as diminished biodiversity through the loss of traditional crops. Furthermore, genetically modified organisms (GMOs), like all the new technologies, are instruments that can be used for good and for bad in the same way that they can be either democratically managed to the benefit of the most needy or skewed to the advantage of specific groups that hold the vital political, economic and technological power. In the case of GMOs, it must be noted, the main beneficiaries to date have been the private sector technology developers and large-scale agricultural producers, mostly to be found in developed countries. To ensure that benefits are shared more fairly with developing countries and resource-poor farmers, the current system of intellectual property rights and similar barriers to the ready transfer of modern biotechnologies needs to be modified. Above all, research must be directed towards these countries and disadvantaged farmers, and ways must be found to guarantee that increased production benefits accrue to the poor and food-insecure.

The development of GMOs raises perhaps the broadest and most controversial array of ethical issues concerning food and agriculture today. As scientific progress presents us with evermore powerful tools and seemingly boundless opportunities, we must exercise caution and ensure thorough ethical consideration of how these should be used. Countries producing genetically modified products must have a clear and responsive regulatory policy and authoritative body to ensure that scientific risk analysis is carried out and that all possible safety measures are taken through testing before the release of biotechnology products, and afterwards through close monitoring. More important, the human rights to adequate food and democratic participation in debate and eventual decisions concerning the new technologies must be respected, as must the right to informed choice.

The FAO Ethics Series is one of a number of recent initiatives undertaken by the Organization in order to raise public awareness and further the general understanding of ethical issues in food and agriculture. The present publication – the second in the series – has been written with a view to sharing the current knowledge of genetically modified organisms in relation to consumers, the safety of their food and consequent protection of their health, and environmental conservation. A distinction is made between GMOs that have been released on a commercial scale, most of which can therefore be considered to have entered the agrifood supply chain, and those that are now under development.

The scientific and policy bases for examining issues and passing judgement on genetically engineered products are necessarily evolving as rapidly as the pace of evolution in biotechnology. Regarding the safety of genetically modified foods and the implications for consumers' health, FAO continues to stress the importance of accurate risk management and effective risk communication, while optimistically pointing out the real prospects of solving major nutrition problems and even preventing food safety problems with specifically developed GMOs.

Modern biotechnologies are a possible but optional means of selective breeding, and further study is required to assess their associated risks and benefits. Furthermore, the credibility of claims made as a result of this process can only be ascertained if necessary economic, environmental and ethical safeguards are in place. Ultimately, if basic ethical considerations are heeded and the human rights mentioned above are realized, the international debate and subsequent decisions on GMOs will be influenced by consumers worldwide. As this publication states, by exercising their choice of whether or not to purchase a product, consumers have a hand in determining its success or failure on the market. If they reject a product, producers are bound to react accordingly.

FAO's ethics programme is a priority area for interdisciplinary action across its technical and normative divisions. Together with the catalytic role that FAO fills as a neutral forum, it is my hope that the knowledge and experience we bring to bear on this vital subject will stimulate and lend direction to what is currently a wide-ranging and often contentious global debate on ethical issues. •

Jacques Diouf
FAO Director-General

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FAO/11735/A. ODOUL

Both classical plant breeding and modern biotechnologies depend on naturally occurring genes as raw materials. The maintenance of biodiversity is therefore a major global concern.

Introduction

People in most cultures have developed many biotechnologies, which they continue to use and adapt. Some biotechnologies, such as manipulating micro-organisms in fermentation to make bread, wine or fish paste, or applying rennin to make cheese, have been documented for millennia. A major subset of modern biotechnologies is genetic engineering, or the manipulation of an organism's genetic endowment by introducing or eliminating specific genes through modern molecular biology techniques. A genetically modified organism (GMO), otherwise referred to as a living modified organism (LMO) or transgenic organism, means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology.[1]

Classical plant breeding and modern biotechnologies both comprise sets of tools that depend on naturally occurring genes as raw materials. For this reason, the maintenance of biodiversity is a global concern. No country today can do without resources from elsewhere. From this interdependence arise the ethical questions surrounding the rights of the poor and the powerless to equitable benefit sharing, equitable access to genetic resources and technologies and a voice in the debate on these resources. These questions and related issues requiring follow-up action are important and are dealt with in other fora and papers.

The greatest agricultural genetic diversity is found in the tropical zones, yet the tools of modern biotechnology are largely owned by private sector concerns in the temperate zones. People and corporations use these tools to make products or commodities, including GMOs, for distribution. The tools used to produce GMOs hold the potential for more precise adaptation of genotypes to environmental conditions, nutritional and dietary needs and market preferences. But are GMOs increasing the amount of food available today, and do they make food more accessible and nutritious for the hungry? Or have they been limited so far to increasing profits on the farm and in corporate balance sheets? Ethical questions concerning the tools that researchers use to create GMOs could focus on how they might make a better contribution to food security, especially in food-deficit importing countries.

Some ethical questions concern the proprietary nature of most of the key

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[1] This definition of LMO is taken from the Cartagena Protocol on Biosafety, Article 3 (g). In Article 3 (i), "modern biotechnology" is defined as "the application of [techniques such as]:

a. *In vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or

b. Fusion of cells beyond the taxonomic family,

that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection".

enabling biotechnologies used today. In a recent report,[2] the National Academies of Sciences in Brazil, China, India, Mexico, the United Kingdom and the United States jointly called upon private corporations and research institutions to make arrangements to share genetic engineering technology with responsible scientists for alleviating hunger and enhancing food security in developing countries. That technology is now held under strict patents and licensing agreements.

A second set of ethical questions regarding modern biotechnology is related to the potential consequences of applying GMOs, or other new technologies, to intensify food production with a view to achieving greater food security. The experiences of the green revolution 40 years ago led some observers to conclude that richer farmers benefited earlier and disproportionately more than others from inputs-responsive varieties. While net benefits, consisting of more abundant, cheaper food, have been achieved through the operation of markets in many green revolution districts that have adequate infrastructure, less favoured locations still lag behind. Women represent a special concern, since they are greatly involved in the sustainable cultivation and the preparation of food crops for their families' consumption. They may be greatly affected (economically and socially) by the loss of traditional crops as well as by changes in land use patterns and any subsequent health problems to which their families may be subjected.

FAO/20005/I. SPAULL

Women – and their families' nutritional status – may be greatly affected by the loss of traditional food crops

The third and final set of ethical questions related to the potential application of GMOs for achieving food security has to do with unintended consequences. As GMOs enter the food and fibre supply chains, they will be increasingly released into ecosystems, including agro-ecosystems. Earlier experiences – involving overly narrow genetic bases of crops and animals, excessive doses of fertilizers and pesticides, and waste runoff from intensified farm animal production units – all suggest that environmental impacts start with the production functions of agricultural ecosystems before spreading to surrounding ecosystems. In addition to their effect on agricultural production, environmental impacts can disrupt other useful ecosystem services such as carbon sequestration and ecotoxicological remediation.

Before considering the global debate on GMOs, which is largely concerned with food safety and the environment, it is worth noting that questions arising from the potential application of modern biotechnology for food security are often confounded with questions arising from the actual spread of GMOs as commodities through supply chains.

[2] *Transgenic plants and world agriculture.* Published under the auspices of the Royal Society of London. July 2000. Washington, DC, National Academy Press.

A range of opinions in the debate on GMOs

(Quotations from the English-language media)

Food security

"To feed 10.8 billion people by 2050 will require us to convert 15 million square miles of virgin forest, wilderness and marginal land into agrochemical-dependent arable land. GM crops hold the most important key to solve future problems in feeding an extra 5 billion mouths over the next 50 years."

Michael Wilson of the Scottish Crops Research Institute, in 1997

"The greatest threat to food security on earth is the concentration of the food chain in the hands of a few rich and powerful players.... This attempt to control the food chain, through developing genetically modified organisms, threatens to turn them into the hunger merchants of the third millennium."

George Monbiot, journalist with *Socialist Worker*, in 1999

Impact on developing countries

"If imports [of GMO seeds] ... are regulated unnecessarily, the real losers will be the developing nations. Instead of reaping the benefits of decades of discovery and research, people from Africa and Southeast Asia will remain prisoners of outdated technology. Their countries could suffer greatly for years to come. It is crucial that they reject the propaganda of extremist groups before it is too late."

Former United States President Jimmy Carter, in 1998

"There are still hungry people ... but they are hungry because they have no money, not because there is no food to buy ... we strongly resent the abuse of our poverty to sway the interests of the European public."

(In reply to a European scientist's comment that: "those who want GMOs banned are undermining the position of starving people".)

Tewolde Berhan Gebre Egziabher, of the Institute for Sustainable Development in Addis Ababa, Ethiopia, in 1997

Nutrition

"Genetic technology could also improve nutrition. If the 250 million malnourished Asians who currently subsist on rice were able to grow and consume rice genetically modified to contain vitamin A and iron, cases of vitamin A deficiency ... would fall, as would the incidence of anaemia."

Robert Paarlberg in *Foreign Affairs*, in 2000

"A rip-off of the public trust, Asian farmers get (unproved) genetically modified rice, and biotech corporations get the 'gold'."

Rural Advancement Foundation International, in 2000

The global debate on GMOs

Although modern biotechnology over the past few decades has opened up new avenues and opportunities in a wide range of sectors, from agriculture to pharmaceutical production, the scale of the global debate on GMOs is unprecedented. This debate, which is very intensive and at times emotionally charged, has polarized scientists, food producers, consumers and public interest groups as well as governments and policy-makers.

Although it started in small pockets, it has spread rapidly through every region of the world. Consequently, there has been a manifold increase in interest and in the number of proponents and opponents of associated issues – so much so that even local newspapers publish articles on genetically modified (GM) food almost as a routine (for some recent examples, see Box, p. 3).

Aims of this paper

The diverse issues that have been raised in association with GMOs are indicative of some of the broader questions facing agriculture,[3] science, technology and society today. FAO has the responsibility to address issues relevant to food, nutrition and agriculture, and to identify ways for promoting equity and fairness and ensuring food security. As an intergovernmental forum, it facilitates the exchange of ideas and opinions with the aim of promoting food security, rural development and the conservation of natural resources globally, but particularly in the developing countries (adopting an ethical approach). In addition, FAO provides technical assistance, primarily to its member developing countries. It is within this framework that the Organization has an important role in exploring and evaluating the claims that are a critical part of the global debate on GMOs.

This paper[4] seeks to unravel and explore selected facets of the claims made in the ongoing GMO debate from an ethical perspective. The main objective here is to highlight the role of ethical considerations in food and agriculture, both in the light of the discussion on GMOs and in relation to food safety and the environment. The paper also highlights certain actions for consideration by the international community and the public. •

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[3] Agriculture includes forestry and fisheries; however, this paper will primarily use the food production function of agriculture to explore ethical issues associated with the development and use of GMOs.

[4] A draft version of this paper was considered as background material by the Panel of Eminent Experts on Ethics in Food and Agriculture at its first session in September 2000.

GMOs and human rights

FAO/20636/E. YEVES

The right to adequate food implies access to food that is nutritious, safe and culturally acceptable

The right to adequate food

Some ethical aspects of GMOs fall within the context of the right to adequate food, which is derived from the Universal Declaration of Human Rights. At the 1996 World Food Summit, the Rome Declaration on World Food Security and the World Food Summit Plan of Action reaffirmed the right of everyone to adequate food. The UN Committee on Economic, Social and Cultural Rights and the UN Commission on Human Rights have both addressed the right to food in the follow-up to the World Food Summit. In particular, the following quotations related to the right to adequate food are considered to be highly relevant to the analyses of GMOs contained in this paper.

The Committee on Economic, Social and Cultural Rights considers that the core content of the right to adequate food implies:

> "The availability of food in a quantity and quality sufficient to satisfy the dietary needs of individuals, free from adverse substances, and acceptable within a given culture;
> The accessibility of such food in ways that are sustainable and that do not interfere with the enjoyment of other human rights."
>
> **General Comment 12, paragraph 8**
> **(E/C.12/1999/5)**

The Special Rapporteur of the Sub-Commission on the Promotion and Protection of Human Rights of the UN Commission on Human Rights has stated:

> "... State obligations require active protection against other, more assertive or aggressive subjects – more powerful economic interests, such as protection against fraud, against unethical behaviour in trade and contractual relations, against the marketing and dumping of hazardous or dangerous products. This

> protective function of the State is widely used and is the most important aspect of State obligations with regard to economic, social, and cultural rights, similar to the role of the State as protector of civil and political rights;"
>
> **(E/CN.4/Sub.2/1999/12)**

Other important human rights principles that could bear upon GMOs, although not included in the Universal Declaration of Human Rights, are the rights to informed choice and to democratic participation.

The right to informed choice

The existence of GMOs raises the issue of the right to informed choice, which derives from the ethical concept of autonomy of individuals. This principle can be applied, for example, in the debate on labelling food derived from GMOs to ensure that consumers know what they are consuming and are able to make informed decisions. Informed choice and resulting actions require access to information and resources. Consumers do not all have the same access to information and resources to make informed decisions about GMOs. Particularly in developing countries, the very poor (both women and men) may lack the most basic information to make decisions that may affect their health and capacity to sustain themselves. Appropriate methods to reach the least educated, the poorest and the most disadvantaged groups should form part of any strategy to inform the public so that individuals are able to choose according to their needs.

The right to democratic participation

The right to democratic participation addresses the need for justice and equity, which are of major concern in the context of GMO-related decisions. Principles of justice may include gender equality, need, accountability, liability, and fair and democratic procedures. Many young people, particularly the poor and powerless, have little education and no social entry point to influence decisions about GMOs. They need to be given every opportunity to participate in the debate concerning both the impact of GMOs on their lives and livelihoods and the potential benefits that may arise from the development and use of such products. They should also have the right to choose the product that best suits their needs. Of concern is the fact that future generations have no voice or vote in decisions taken on GMOs today, which means that ways must be found to ensure that their interests are taken into account. Options must be kept open so as to enable future generations to meet their specific needs, including those deriving from unpredictable environmental changes. •

Key issues for ethical consideration

Food safety, the environment and GMOs are linked in the minds of consumers who, through their purchasing, will play a pivotal role in influencing decisions regarding the future of this technology. A number of consumers' concerns can be classified according to the following six issues:

Food safety. The foundation of consumers' concern about GMOs is food safety. Because of experiences with non-GMO food problems such as allergens, pesticide residues, microbiological contaminants and, most recently, bovine spongiform encephalopathy ("mad cow" disease) and its human counterparts, consumers are sometimes wary of the safety of foods produced with new technologies. The approaches being taken by governments to ensure the safety of GMOs are discussed in the sections under Risk analysis, p. 14.

Environmental impact. The potential of GMOs to upset the balance of nature is another concern of the public. GMOs are "novel" products which, when released, may cause ecosystems to adjust, perhaps in unintended ways. There is also concern about the possibility that genetic "pollution" will result from outcrossing with wild populations. As with non-GMOs, an issue is whether pre-release testing (especially when limited to laboratories or computer models) is an adequate safeguard for the environment or whether post-release monitoring is also necessary. The extent of post-release monitoring needed to protect ecosystems, especially with long-lived species such as forest trees, becomes an ethical as well as a technical issue. The current understanding of the environmental impact of GMOs is reviewed in the relevant chapter, p. 19.

Perceived risks and benefits. In forming their views about GMOs, consumers weigh the perceived benefits of accepting a new technology against the perceived risks. Since practically none of the currently available or forthcoming plant and animal GMOs presents obvious benefits to consumers, they question why they should assume possible risks. It is said that consumers take the risks while the producers (or the suppliers or companies) reap the benefits. The science-based methods used to assess risks, together with their relationships with risk management and risk communication, are discussed in the chapter GMOs and human health, p. 14.

Transparency. Consumers have a legitimate interest in and right to information with regard to GMOs in agriculture. This begins with rules for the transparent sharing of relevant information and the communication of associated risks. Science-based risk analysis seeks to enable experts to make decisions that minimize the probability of hazards in the food supply system and the environment. Consumers, however, may also wish for more transparency to protect their right to exercise informed consent on their own. An often-discussed set of means intended to protect these rights is the labelling of products, whether or not they are derived from GMOs. Informed consent and labelling are also discussed in the chapter GMOs and human health, p. 14.

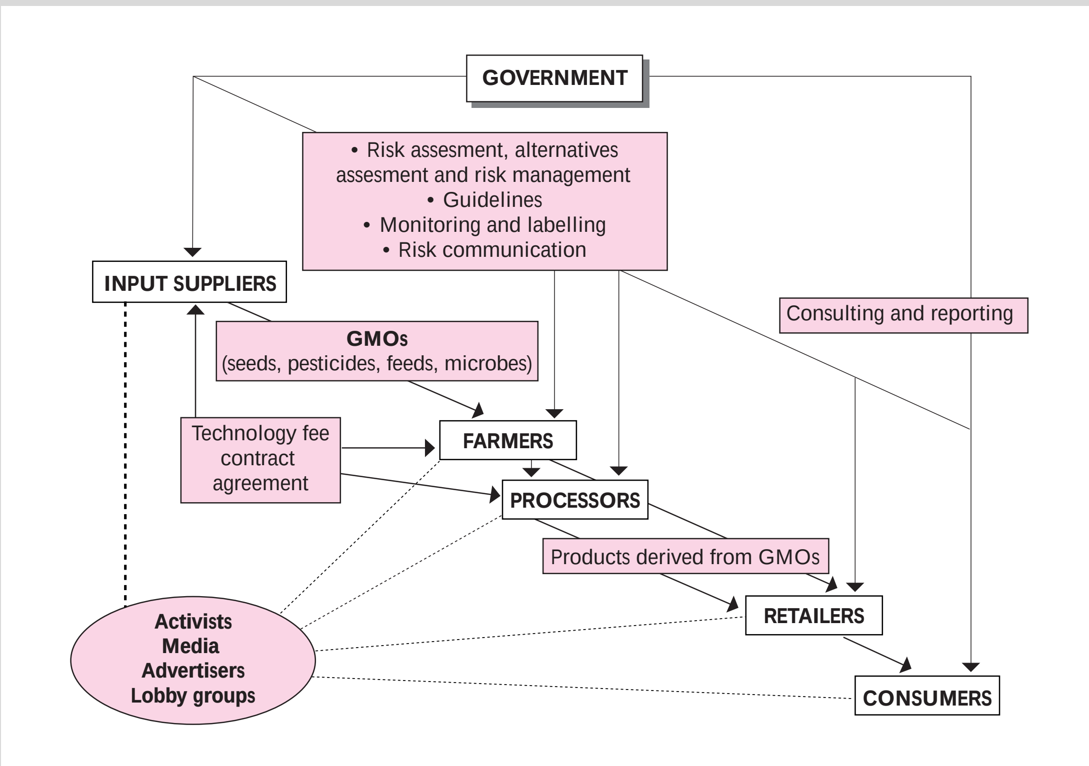
Accountability. Consumers may wish to be more involved in local, national and international debates and in policy guidance. At present, there are very few fora available to the public to discuss the wide range of issues relating to GMOs. A shortage of fora can, understandably, lead to advocates concerned with one aspect of GMOs, such as environmental impact, pushing their concerns into a forum set up for another aspect, such as labelling. A related issue is how to bring the private sector transparently into public fora and, subsequently, how to hold public and private sector agencies accountable.

Equity. So far, the development of GMOs in agriculture has mainly been oriented towards cost-reduction at the farm level, primarily in developed countries. Societies have ethical standards that acknowledge the importance of ensuring that those who cannot satisfy their basic food needs receive adequate means to do so. Ethical analysis can consider the moral responsibility of societies, communities and individuals to ensure that economic growth does not lead to an ever-widening gap between the poor majority and the wealthy few. When appropriately integrated with other technologies for the production of food, other agricultural products and services, GMOs may, among other biotechnologies, offer significant potential for assisting in meeting the human population's needs in the future. An ethically salient issue that then emerges is how the development and use of GMOs in agriculture can be oriented towards improving the nutrition and health of economically poor consumers, especially in developing countries. •

GMOs and the food supply chain

The agricultural production and distribution system can be thought of as a supply chain (see Figure): i) goods flow from producers (farmers) through processors and retailers to reach the consumer; ii) advertisers, activists, lobbyists and the media seek to influence choices made by people at each step of the supply chain; iii) government regulatory bodies assess risks, set rules and monitor compliance; iv) producers of food, fish, fibre and forest products purchase inputs such as seeds, planting materials, agrochemicals, fertilizers, feed, fermentation promoters and machinery; v) GMOs reach the public through markets. Consumers, in reality comprising everyone in the world (and including future generations), also have a stake in the process.

GMOs in the food chain



Source: Adapted from *Economic impacts of genetically modified crops on the agrifood sector: a synthesis.* Working document of the Directorate General of Agriculture, European Commission. The literature search for this working document ended 31 March, 2000.

Consumers' choices in the market cannot be ignored: they are not forced to buy something if they choose not to. If consumers decide not to buy a product, the associated production processes will simply wither away. Given the refusal of many consumers in certain countries to buy current GMOs, producers of GM crops are reconsidering their production decisions and the agrifood industry is rapidly restructuring, and even changing the thrust of its research and development efforts, to take this response into account.

The market is not the only place where consumers can express their views or preferences. They may wish to have a more direct "say" in how their food is produced. Increasingly, however, consumers throughout the world now live and work far from the points where their food is grown and processed, and this lack of direct involvement in the production process can result in their views on the agrifood system and its products being largely ignored.

GMOs on the market or under development


J. ESQUINAS

Strawberries growing at -10°C, owing to the insertion of an antifreeze-producing gene from the winter flounder

Tools and techniques used by agricultural input suppliers

Most of the intermediate products and methodologies that allow the development of GMOs, for example molecular fingerprinting and transformation technologies, are currently under intellectual property rights protection in the private sector. Consequently, public sector scientists, especially in developing countries, have less chance of obtaining access to such products and methodologies. This limits their capacity to develop improved strains of crops or animals, including GMOs that could help overcome their particular local or national production constraints. The current situation therefore tends to widen the gap between richer and poorer societies.

In recent years, an increasing number of products derived from GMOs have been developed and made available for public consumption. A small selection of agricultural GMOs that are either on the market or under development are presented in Tables 1 and 2.

GMOs that target insects with *Bacillus thuringiensis* toxins

"Pest-protected" varieties were among the first GM crops to be developed, for the purpose of reducing production costs for farmers. Insect-resistant GMOs have been promoted both as a way to kill certain pests and to reduce the application of conventional synthetic insecticides. For more than 50 years, formulations of the toxin-producing bacteria *Bacillus thuringiensis (Bt)* have been applied by spraying in the same way as conventional agricultural insecticides to kill leaf-feeding insects.

TABLE 1
A selection of GMOs that are currently available

GMO	Genetic modification	Source of gene	Purpose of genetic modification	Primary beneficiaries
Maize	Insect resistance	*Bacillus thuringiensis*	Reduced insect damage	Farmers
Soybean	Herbicide tolerance	*Streptomyces* spp.	Greater weed control	Farmers
Cotton	Insect resistance	*Bacillus thuringiensis*	Reduced insect damage	Farmers
Escherichia coli K 12	Production of chymosin or rennin	Cows	Use in cheese-making	Processors and consumers
Carnations	Alteration of colour	*Freesia*	Production of different flower varieties	Retailers and consumers

TABLE 2
A selection of GMOs currently under development

GMO	Genetic modification	Source of gene	Purpose of genetic modification	Primary beneficiaries
Grapes	Insect resistance	*Bacillus thuringiensis*	Insect control	Farmers
Tilapia fish	Growth hormone	Arctic flounder/ salmon	Increased growth efficiency	Fish farmers
Poplar trees	Herbicide tolerance	*Streptomyces* spp.	Simplified weed control	Forest managers
Salmon	Growth hormone	Arctic flounder/ salmon	Increased growth efficiency	Fish farmers
Eucalyptus	Modified lignin composition	*Pinus* sp.	Pulp and paper processing	Forest managers and paper industry
Rice	Expression of beta-carotene	Daffodil *Erwina*	Added micronutrient	Consumers deficient in Vitamin A
Sheep	Expression of antibody in milk	*H. sapiens*	Fortified milk	Consumers

Studies on the safety of *Bt* for humans have not revealed any adverse effects on health.

In the late 1980s, scientists began to transfer the genes that produce the insect-killing toxins in *Bt* into crop plants. The intention was to ensure that the toxin was produced by all cells in these GMOs. At present, more than 5 million hectares are currently planted to *Bt* transgenic crop varieties. Although no efforts were made to increase the growth rates or yield potential of the GM crops with these innovations, farmers have welcomed *Bt* crops because of the promise of better insect control and reduced costs. However, in the United States, the impact of *Bt* GMOs on crop yields and the number of conventional insecticide applications have varied widely by location and by year. This is partly because of differences between the intended potential impact of the GM crops on target pests and their actual field performance. Some of these differences were due to the uneven distribution of the toxin within the plants as they grew, some were due to variations in target and non-target pest populations, and others were the result of toxins accumulating in plant-feeding insect pests, causing mortality of predators and parasites that ate those pests.

As with varieties carrying conventionally bred host plant resistance, farmers should manage GM varieties within an ecologically based integrated pest and production management (IPPM) system so as to respond adaptively to environmental variation. In North America, the consensus is now that these varieties have lowered the costs of pest control. They are recommended together with host plant resistance management strategies to slow down the evolution rate of the pests that are able to feed on them.

GMOs for food processors and retailers

Food processors and retailers are also keen to reduce their costs and reap the potential benefits of biotechnology. As the Box shows, GM tomatoes were designed to

GMOs for the benefit of intermediaries in the food supply chain: Flavr Savr tomatoes

The Flavr Savr brand of tomatoes was the first GM food product to be introduced in the fresh food market for public consumption. The tomatoes were genetically modified to delay ripening and they therefore had a prolonged shelf-life in the supply chain. Calgene, in the United States, released this brand of GM tomatoes in 1994.

The aim of this novel product was to offer multiple benefits to tomato producers by:

- **allowing a greater period of time for transportation;**
- **providing an opportunity for mechanical harvesting of tomatoes with little bruising; and**
- **offering consumers the choice of a tomato that is ripened on the vine, unlike those that are picked when still green and that require spraying with ethylene to ripen.**

Since 1996, Flavr Savr tomatoes have been taken off the fresh produce market in the United States. The manipulation of the ripening gene appeared to have had unintended consequences such as soft skin, strange taste and compositional changes in the tomato. The product was also more expensive than non-modified tomatoes.

Flavr Savr tomatoes are still used with success in processed tomato products. Their longer life allows more flexibility in shipping and storage between the field and processing plant.

give processors and retailers more options, but the product did not thrive in the fresh produce market.

The case of the Flavr Savr tomato shows how retailers are sensitive to the opinion of consumers when they are close to them. The concern about consumer confidence may outweigh the prospect of short-term benefits that a processor could gain from using ingredients derived from GMOs. If the public perceives GM foods to be unsafe or harmful to the environment and, therefore, rejects some products, companies may dissociate their products from GMOs. At the present time, some leading food companies have removed ingredients derived from GMOs from their products because they are wary of consumer rejection. Changes in processors' and retailers' demand for ingredients derived from GMOs are carried back up the food supply chain to affect farmers' decisions about whether or not to grow GMOs.

GM farm animals and fish have not entered the food supply chain

Following some initial problems, there was considerable growth in the development and commercialization of GM crops, but products derived from GM farm animals have not reached substantial food production systems. Although more than 50 different transgenes have been inserted experimentally into farm animals, these efforts still require considerable skill and are not as routine as those for plants. Early research in the development of transgenic farm animals has also been accompanied by manifestations of perturbed physiology, including impaired reproductive performance. These experiences raised ethical problems of animal welfare and further damped consumer interest.

So far, the prospect of foods from transgenic farm animals has not been well received by consumers. Surveys consistently show that the public is more accepting of transgenic plants than of transgenic animals. Experimenting with and altering animals is a less acceptable practice and has broader implications. Various cultures and religions restrict or prohibit the consumption of certain foods derived from animals. However, ingesting or being injected with certain pharmaceutical products from transgenic animals seems more acceptable to the public.

Highly successful research has been carried out on GM fish, but no GM fish have entered the market. Most GM fish are aquaculture species that have received genes governing the production of growth hormones, in order to raise their growth rate and yield. Ethical questions on the welfare and environmental impact of these GM fish have been raised, but it is also argued that GM fish share many attributes of conventionally selected alien fish species and genotypes, both of which are proven and accepted means of increasing production from the aquatic environment. •

GMOs and human health

FAO / 19520 / G. BIZZARRI

Consumers need assurance that their food is safe and nutritious

Risk analysis

There is much confusion about the risks of GMOs in terms of food safety and environmental impact. Regulatory agencies formulate their standards according to science-based assessments of risk. Many consider that decision-making based on science is the only objective way to set policy in a world of diverse opinions, values and interests. *Risk analysis* is a process consisting of three components: risk assessment, risk management and risk communication.

Risk assessment

Risk in the context of safety includes two elements: i) hazard, an intrinsic factor (e.g. a biological, chemical or physical agent in, or condition of, food, with the potential to cause an adverse effect on health) that indicates the damage if the event occurs; and ii) the probability or chance that the event will occur. Thus, in relation to chemicals, risk is taken to be hazard x chance of exposure; in relation to quarantine, it is the potential damage by the pest x chance of introduction, etc.

Risk assessment is a scientifically based process consisting of the following steps: i) hazard identification; ii) hazard characterization; iii) exposure assessment; and iv) risk characterization. Hazards, and the chance of those hazards occurring, are thereby studied and models constructed to predict the risk. These predictions can be verified afterwards through, for example, statistical (epidemiological) studies.

The two components of risk both contain a measure of uncertainty, and it is this measure of uncertainty that is the focus of many discussions. For example, there is some doubt as to whether risk estimation methodologies used for related purposes (e.g. pesticide residues in food and pest introduction) have sufficient predictive value for GMOs. In particular, the hazard component of risk analysis is subject to close scrutiny.

Risk management and alternatives analysis

Risk management,[5] distinct from risk assessment, is the process of weighing policy alternatives in consultation with all interested parties, considering risk assessment and other factors relevant for the protection of consumers' health and for the promotion of fair trade practices as well as, if necessary, selecting appropriate prevention and control options.

Environmental hazard is probably less easy to quantify than health hazard. It also refers to a common good instead of a private (health) good. In both instances, only long-term experience can show if risk assessment and risk management have been successful. When a sound risk management strategy is applied to environmental problems, as distinct from safety problems, it will begin by describing a problem and the goals, objectives and values to be pursued by solving that problem. An analysis of alternatives is then carried out to consider as many solutions as possible. Rather than narrowing the analysis, this allows the creation of new options or combinations of options. When the benefits and drawbacks of a wider range of solution scenarios can be compared, fuller participation by the concerned society can be better assured.

Risk communication

Risk communication is the interactive exchange of information and opinions among assessors, risk managers, consumers, industry, the academic community and other interested parties throughout the risk analysis process. The information exchange concerns risk-related factors and risk perceptions, including the explanation of risk assessment findings and the basis of risk management decisions. It is vitally important that risk communication with the public comes from credible and trusted sources.

Safety of GM foods

Foods are complex mixtures of compounds characterized by a wide variation in composition and nutritional value. Although priorities vary, food safety is a concern among consumers in all countries. They would like assurances that GM products reaching the market have been adequately tested and that these products are being monitored to ensure safety and to identify problems as soon as they emerge. Because of the complexity of food products, research on the safety of GM foods is still thought to be more difficult to carry out than studies on components such as pesticides, pharmaceuticals, industrial chemicals and food additives. Through the

[5] *Source:* Report of the 23rd session of the Codex Alimentarius Commission, Rome, 28 June-3 July 1999.

Labelling GM food products: two regulatory approaches

The differences between the United States' and the European Union's perspectives on the labelling of GMOs illustrate some of the issues in the debate.

In the United States, the law requires information on food products to be clear and unambiguous. Labels are intended to provide meaningful information and to warn and instruct the consumer. Further misleading or unnecessary information is believed to conflict with the right of consumers to be able to choose wisely, and to lessen the effectiveness of essential label information. If GMOs are not different from their traditional counterparts in terms of nutrition, composition or safety, labelling is considered to be unnecessary and perhaps misleading.

In the European Union, labelling is viewed as a way to ensure the consumers' right to know any fact that they deem important; it is a way to give consumers a choice and to inform them about GMOs. The European Union's approach to labelling attempts to reach a compromise among the industrial, scientific and public sectors. In the European Union, the question is not *whether* to label products of biotechnology, but *how* to label them.

Codex Alimentarius Commission and other fora, countries discuss standards for GMOs and ways to ensure their safety. One approach, which is being used in assessing the risks of GMOs, derives from the concept of *substantial equivalence*.

Substantial equivalence acknowledges that the goal of the assessment is not to establish absolute safety but to consider whether the GM food is as safe as its traditional counterpart, where such a counterpart exists. It is generally agreed that such an assessment requires an integrated and stepwise, case-by-case approach. Factors taken into account when comparing a GM food with its conventional counterpart include:

- identity, source and composition;
- effects of processing and cooking;
- the transformation process, the DNA itself and protein expression products of the introduced DNA;
- effects on function;
- potential toxicity, potential allergenicity and possible secondary effects;
- potential intake and dietary impact of the introduction of the GM food.

If the GMO-derived food is judged to be substantially equivalent to its conventional counterpart, then it is considered to be as safe as the counterpart. If it is not, further tests are conducted.

Labelling of GM products

Consumers have a right to be informed about the products they buy. However, whether or not the labelling of GM foods is the most appropriate and feasible way to enable consumers to make informed choices about such food products is the subject of an active and ongoing debate in number of countries. It is also being debated by the Codex Alimentarius Commission. A number of governments have adopted labelling policies and procedures for GMOs, which vary substantially. Farm-to-consumer labelling protocols may pose insurmountable challenges for countries of limited capacity wishing to earn income in international markets.

GMOs and allergens

Genetic modification offers the opportunity to decrease or eliminate the protein allergens that occur naturally in specific foods. With the objective of assuring food safety, greater attention has been given to the potential risks of genetic modifications that may add allergens to the food supply. All products that contain allergens, irrespective of their origin, should be managed similarly – for example by labelling – to ensure the consumers' right to informed choice and the possibility to avoid allergens in foods. The Brazil nut-soybean (see Box) provides an example of how a potential health problem was avoided by testing before marketing.[6]

Brazil nut allergens

The possibility of transferring allergens with genetic engineering came to light when a methionine-producing gene from the Brazil nut was incorporated into soybean to enhance its nutrient content. The process was experimented by Pioneer Hi-bred in the United States. The tests conducted by their scientists on allergens, however, confirmed that consumption of the transgenic soybean could trigger an allergic response in sensitive subjects. The nature of the allergic reactions was the same as those triggered by Brazil nuts in sensitive subjects. The company, therefore, decided not to release the transgenic soybean for sale. This particular case was significant in raising awareness about the potential dangers associated with the transfer of genes in the absence of a better understanding of their functional characteristics.

[6] This paper is based on information collected up to July 2000. In September 2000, a GM maize containing a gene for a particular strain of *Bt*, which had been cleared for use as animal feed but not as human food, was found to be commercially available in a human food product. The public regulatory response was rapid, and the longer-term implications of this case are now being determined.

Golden rice and the alleviation of vitamin A deficiency

Recently, rice was genetically engineered by the insertion of three genes (from daffodil and bacteria) that generate enzymes that make the rice grains produce beta-carotene, which can be converted into vitamin A in the body. This transgenic rice produces golden-coloured grains containing enough beta-carotene to meet a person's daily requirement of vitamin A.

The potential to create rice with an enhanced micronutrient content illustrates one way in which genetic engineering can contribute to reducing malnutrition. Vitamin A deficiency, which is widespread in the developing world, can lead to morbidity and blindness and contribute to child mortality.

There are a number of alternative ways to address the problem of vitamin A deficiency, for example promotion of foods that are naturally rich in vitamin A, supplementation and fortification. These technologies are already being used and, although experts debate the merits of each approach, they are found to be effective in treating the illness. The value of GM golden rice therefore needs to be assessed in relation to these other options.

Use of GMOs in solving nutrition problems

The recent announcement that GM crop varieties can be made to produce the precursor of vitamin A (see Box on golden rice) generated considerable anticipation that products from these crops could contribute to solving the serious public health problem of vitamin A deficiency. This anticipation expanded the public debate on the role of GMOs as part of strategies to address global nutrition problems.

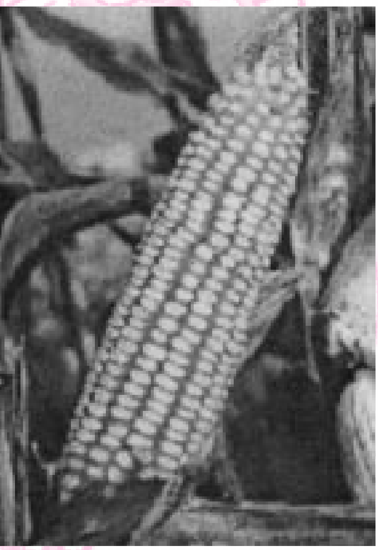
Scientists are also experimenting with genetic engineering techniques to prevent food safety problems. For example, genetically modified *Bt* maize, which is resistant to attacks from toxin-producing fungi, has been associated with decreased mycotoxin contamination. Mycotoxins are carcinogens and they can lead to liver cancer in humans. The fact that fewer feeding punctures from insects are found on *Bt* maize is thought to mean that there are fewer openings for fungal infection. •

GMOs and the environment

Although the global debate on GMOs has usually allied disparate groups concerned about food safety and the environment, environmental risks are perceived to differ from food safety risks in several ways. Experience built up through decades of environmental impact studies suggests that the impact of new biological elements in ecosystems may take years or decades to be understood. The environmental impacts of introduced GMOs can be either ecological or genetic and may include:

- unintended effects on the dynamics of populations in the receiving environment as a result of impacts on non-target species, which may occur directly by predation or competition, or indirectly by changes in land use or farming practices;
- unintended effects on biogeochemistry, especially through impacts on soil microbial populations that regulate the flow of nitrogen, phosphorus and other essential elements;
- the transfer of inserted genetic material to other domesticated or native populations, generally known as gene flow, through pollination, mixed matings, dispersal or microbial transfer.

Bt *maize – Problems associated with insect-resistant* **Bt** *crops are under intensive research*



Because these potentially adverse effects have been documented in the field with non-GMO species, and because the consequences of these effects could be serious, it is important to regulate and monitor all introductions of GMOs effectively. Field experiments in ecology take months or years to become valid. Furthermore, current data on GMOs in the field should be viewed as location-specific, and extrapolations from laboratory or computer simulation to the field must be made cautiously.

Environmental issues and GM crops

GM crops are commercially available and planted on more than 40 million hectares across six continents. These plantings represent the largest-scale experience in the introduction of GMOs into ecosystems, and they have become the focus of environmental concerns. Activists, worried about GMOs being released into the biosphere, have destroyed test plots in at least four continents. This may show the depth of their commitment, but it also prevents anyone from learning from the data that should have been collected from those tests.

The majority of the area under GM crops is planted with varieties resistant to herbicides. These herbicides are associated with a shift towards less mechanical tillage in large-scale arable crops, which reduces primary soil erosion. Early on, weed

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Monarch caterpillar – The Monarch butterfly has generated the most detailed research into the impacts of GMOs on wild species

scientists appreciated and studied the environmental consequences of introducing GM crops, especially for weed control.

A 1998 international technical meeting, organized by FAO on Benefits and Risks of Transgenic Herbicide-Resistant Crops, found that:

1. The repeated use of one herbicide causes a shift in the weed flora because there is very high selection pressure on weeds to evolve biotypes that are resistant to the herbicides associated with transgenic plants bred to be tolerant of those herbicides.
2. Gene flow occurs with the spread of genes through pollen and outcrossing from herbicide-resistant crops to related weed species. In the absence of the particular herbicide, the possession of this trait is unlikely to improve the strength of the weeds but, when the herbicide is applied, it would improve the weeds' strength and could reduce the economic benefits of herbicide resistance.
3. The risks of gene transfers are higher in areas of origin and diversification. Care needs to be taken to ensure that native germplasm, including weed and wild crop relatives, is not affected by the transfer of herbicide-resistant genes.

Monarch butterflies and alternatives analysis of *Bt* maize

Monarchs (*Danaus plexippus*), migratory Lepidoptera that feed on milkweeds, are the best-known butterflies in North America. A well-publicized study of GMOs showed that *Bt* maize pollen was toxic to laboratory-fed Monarch butterfly larvae. A study later collected pollen-covered milkweed plants, which were found growing naturally next to *Bt* maize fields. A significantly larger proportion of Monarch butterfly larvae that fed on these field-collected plants died compared with those fed pollen-free plants.

Conventional insecticides, which are the dominant alternative for controlling pest Lepidoptera now employed in maize production in North America, also kill Monarchs and other wild butterflies. Tested alternatives within an IPPM framework include:

- **encouraging predators with intercrop management, refuges and additional food during food-scarce months;**
- **timing planting to avoid pest immigration flights (especially in tropical maize production);**
- **rotating crops to discourage the build-up of target pests;**
- **using pheromones to confuse and trap pests, reducing mating success and concentrating pests to allow lower doses of insecticides;**
- **using trap plantings to concentrate pests away from commercial crops – usually combined with better targeted applications of conventional insecticides.**

While the total area planted to insect-resistant *Bt* crops is less than one-fourth of that planted to herbicide-tolerant crops, commonly recognized problems are under intensive research. This research focuses on the applied aspects of managing agro-ecosystems for intensified production, but public attention to GMOs has also encouraged scientists in academic and other public sector institutions to carry out more basic ecological studies, especially concerning the impact of GMOs on non-target species. For example, *Bt* varieties have been found to secrete *Bt* toxins into soil root zones; these zones then produce higher concentrations of *Bt* toxins than are normally found, which may affect populations of soil insects that do not eat crops.

The prominence of the Monarch butterfly as a much-loved insect in North America, where the largest areas of GM crops are now grown, has generated the most detailed research into the impact of GMOs on wild species, as well as considerable consumer attention.

Regulatory issues, especially those related to quarantine, invasive species and biosafety become very important when GM crops move internationally, as facilitated by trade. International treaty bodies such as the International Plant Protection Convention, the Convention on Biological Diversity and the Cartagena Protocol on Biosafety are actively engaged in constructing a suitably workable framework. More specific regulatory mechanisms include the draft Code of Conduct on Biotechnology as it relates to Genetic Resources for Food and Agriculture, under development by countries through FAO.

Principle 15 of the Rio Declaration on Environment and Development (adopted at the time of the United Nations Conference on Environment and Development in 1992) states:

> "In order to protect the environment, the precautionary approach shall be widely applied by States according to their capacities. 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."

The Cartagena Protocol on Biosafety was adopted early in 2000, with the following objective:

> "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 ... the Parties shall ensure that the development, handling, transport, use, transfer and release of any living modified organisms are undertaken in a manner that prevents or reduces the risks to biological diversity, taking also into account risks to human health."

Environmental issues and GM forest trees

Research on the genetic modification of forest trees is undertaken almost exclusively with a view to application in plantation forestry. Today, forest plantations supply approximately 25 percent of the world's wood requirements. The area of forest plantations, which currently represents less than 5 percent of the global forest area, is expected to increase and to provide one-third of the total wood supply by the year 2010.

One of the first reported trials with GM forest trees was initiated in 1988 using poplars. Since then, there have been more than 100 reported trials in at least 16 countries, involving at least 24 tree species – mostly timber-producing species for use in intensively managed plantations. There is no reported commercial-scale production of GM forest trees.

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Regenerating shoots of transgenic poplars – Genetic modification of forest trees is studied almost exclusively for application in plantation forestry

Traits for which genetic modification can realistically be contemplated in the near future include insect and virus resistance, herbicide tolerance and modified lignin content. Modification of lignin is a potentially important objective for species grown for the production of pulp and paper. Wood with modified lignin requires less processing with harsh chemicals and is thus environmentally benign. It has also been pointed out that, as lignin content is associated with resistance to insect feeding, the overall impacts of modified lignin should be carefuly investigated. Monitoring should include possible secondary effects, such as changes in the incidence of insect damage, including in surrounding forests.

A major technical factor limiting the application of genetic modification to forest trees is the currently low level of knowledge regarding the molecular control of traits that are of most interest, notably those relating to growth, stem form and wood quality.

Investments in GM technologies should be weighed against the possibilities of exploiting the large amounts of generally untapped genetic variation that are available within forest tree species in nature.

Biosafety aspects of GM trees need careful consideration because of the long generation time of trees, their important roles in ecosystem functioning and the potential for long-distance dispersal of pollen and seed.

Environmental issues and GM fish

In the fisheries sector, most GMOs show increased growth rates; therefore, concerns about environmental risk focus more on predation, competition and genetic pollution. GM fish may pose risks to the environment because of their increased rates of feeding on prey species; their wider environmental tolerances, which allow them to invade new territories and possibly to displace local native populations; and their potential for genetic mixing with, and thus the altering of, the composition of natural fish populations. Proponents of GM fish maintain that these fish will be very domesticated and will not survive well in nature.

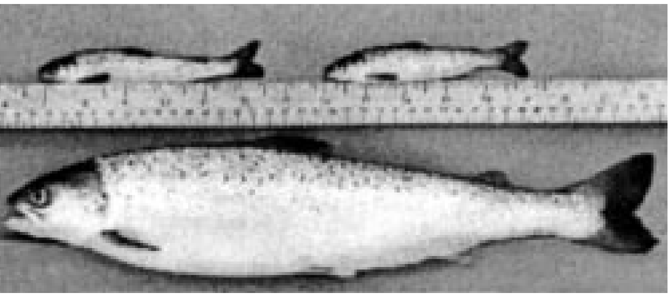
Alien species and genotypes that are used throughout the world, such as tilapia

Applying a precautionary approach to GMOs in fisheries

The North Atlantic Salmon Conservation Organization (NASCO), with more than 12 member countries, negotiated and recently began to apply elements of a precautionary approach to aquaculture and genetic modification of Atlantic salmon. Formulated during a Sweden-FAO technical meeting in 1995, the various elements are part of a dynamic process to organize regulations, standards, management and research. They force managers or policy-makers to think about what is known and unknown, what is reasonable and unreasonable, what is practical and what is impractical, and then to plot a course of action accordingly. The following are elements in this precautionary approach:

- **the lack of full scientific certainty should not be used as a reason to put off management efforts;**
- **reference points should be established to help determine desirable situations and undesirable impacts – for example limit reference points, such as a maximum percentage of GMO seed in a shipment, and target reference points, such as reduction in the use of pesticides;**
- **action plans should be identified, agreed on and implemented when limit reference points are approached or when adverse impacts are apparent;**
- **priority should be given to maintaining the productive capacity of the resource or ecosystem;**
- **the impacts should be reversible within the time frame of two to three decades;**
- **the burden of proof should be placed according to the above requirements and the standard of proof should be commensurate with risks and benefits.**

The establishment of reference points is critical and will indicate where much of the uncertainty lies as well as, therefore, where much of the monitoring, research or study is needed. In the course of NASCO discussions about the conservation of Atlantic salmon, it transpired that there were no reference points for allowable levels of genetic introgression between farmed and wild stocks of salmon.



A transgenic Atlantic salmon, containing an antifreeze protein promoter, measured against control siblings

and domesticated salmon, present these same risks. The process of evaluating the risks of farming GMOs should be the same as for the farming of any aquatic species that is new to a local ecosystem. It should be based on an ecosystem approach that considers the spreading of impacts once a species is introduced.

Precautionary principle: an example from fisheries

Although no GM fish have been commercially released, countries concerned with salmon fishing in and around the North Atlantic have agreed to apply a precautionary approach. Earlier experiences with the collapse of populations of several species of fish of economic value in that region may have prepared fisheries policy-makers from these countries to attempt this negotiation and application of the precautionary principle. •

Conclusion

During the process of development of any agricultural or food technology, there are always questions and concerns to be tackled at every stage, ranging from the yields of the product and economic gain to consumer safety and societal response. Questions such as "why is the particular product being developed?", "what are its uses?", and "who decides what is useful?" are important and need to be answered as transparently as possible.

This review of GMOs shows that the technology has the potential to affect a wide range of plant and animal products and could have many consequences. It also implies that the application of GMOs can extend beyond the food production function of agriculture.

Modern biotechnology, if appropriately developed, could offer new and broad potential for contributing to food security. At the same time, the speed of genetic change made possible by genetic engineering may represent a new potential impact on the biosphere. However, it is not possible to make sweeping generalizations about GMOs; each application must be fully analysed on a case-by-case basis. Through complete and transparent assessments of GMO applications, and recognition of their short- and long-term implications, the debate can be less contentious and more constructive.

During the relatively brief period that genetic engineering has existed, close scrutiny of the research and commercialization process has proved to be beneficial in terms of raising important issues and improving our understanding.

Citizens have a direct interest in technological developments, yet there are obstacles to their participation in decision-making that must be acknowledged and overcome. The public has not been adequately informed about the application of gene technology to food production or the consequent potential impacts on consumers' health and the environment. With the confusing array of claims, counter claims, scientific disagreement and misrepresentation of research that is present in the media, the public is losing faith in scientists and government.

Scientists, governments and the agrifood industry have now realized the need to inform the public about GMOs, yet there is relatively little information available to enable the lay person to make decisions. Widely communicated, accurate and objective assessments of the benefits and risks associated with the use of genetic technologies should involve all stakeholders. Even where access to information exists, this does not guarantee that the lay person will have sufficient knowledge and training to interpret and make use of the technical documents.

Experts have the ethical obligation to be proactive and to communicate in terms that can be understood by the lay person. Some professional associations have recognized this and have called for the education of the general public on genetic technologies and principles.

There need to be more opportunities enabling the exchange of information among scientists, corporate representatives, policy-makers and the public at large. Including members of the public on advisory committees set up for the formulation of laws, regulations and policies would help to ensure that their perspectives were fairly represented.

Fora that enable citizens to voice their views can be a routine and integral part of analysing GMO issues and making decisions. National, regional and international fora need to be clearly identified and their respective roles clarified to provide efficient mechanisms for discussing specific issues, reaching relevant agreements and devising appropriate instruments for their implementation.

The right to adequate food, as understood today, carries with it obligations on the part of states to protect individuals' autonomy and capacity to participate in public decision-making fora, especially when other participants are more powerful, assertive or aggressive. These obligations can include the provision of public resources to ensure that those fora take place in a spirit of fairness and justice. •

Abbreviations

Bt
Bacillus thuringiensis

DNA
deoxyribonucleic acid

GM
genetically modified

GMO
genetically modified organism

IPPM
integrated pest and production management

LMO
living modified organism

NASCO
North Atlantic Salmon Conservation Organization

NGO
non-governmental organization