Chapter 13
Risks and Benefits Associated with Genetically Modified (GM) Plants

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Abstract Genetically modified (GM) plants are those whose genomes have been modified by the introduction of foreign DNA constructs derived from bacteria, fungi, viruses, or animals. The most common genetically modified plants include soybeans, maize/corn, rapeseed mustard, potatoes, cotton, sugarcane, tomato, rice, and aspen/*Populus*.

In this chapter, we list 16 goals of genetic engineers in developing GM plants. These are plants that manifest frost hardiness; insect and herbicide tolerance; virus resistance; altered starch, cellulose, and lignin production; altered levels and kinds of oils and proteins in seed crops; higher levels of antioxidants in edible fruits, synthesis of new metabolites like beta-carotene in rice grains and vaccines in non-edible plants; and sequestration of hazardous wastes from polluted ("brown field") areas.

The next section of this chapter includes a discussion of the purported benefits and risks of GM plants. Our goal here is to present this information in as balanced a fashion as possible.

Lastly, we address important questions and answers concerning GM plants and food products.

13.1 Genetically Modified Plants: What Are They and Goals for Their Production

Genetically modified (GM) plants are those whose genomes have been modified by the introduction of foreign DNA constructs derived from bacteria, fungi, viruses, or animals. The most common genetically modified plants include soybeans, maize/corn, rapeseed mustard, potatoes, cotton, sugarcane, tomato, rice, and aspen/*Populus*. It is important to emphasize here that the generation of transgenic plants can modify natural selection-induced evolution of plants.

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The *goals of genetic engineers in developing genetically modified plants* include the following:

- To develop herbicide-resistant crop plants such as "Roundup Ready"/glyphosate-resistant soybeans with a gene derived from bacteria.
- To develop insect-resistant crop plants such *Bt* (*Bacillus thuringinensis* or milky spore bacterium) cotton (to kill the cotton boll weevil), potatoes (to kill the Colorado potato beetle), and corn/maize (to kill the corn ear worm). *Bt*-containing plants can cause emergence of *Bt*-resistant insects. In "Botany of Desire" by Machael Pollan, he reports that Monsanto Company designed a method to avoid this. They suggest that farmers allot a part of a field for wild-type plants, while most of the field is used for *Bt*-containing transgenic plants. This strategy can cause wild-type insects to outcompete *Bt*-resistant mutant insects.
- To develop viral disease-resistant plants such as papaya and squash that have virus coat protein gene inserted into their genomes. The virus coat protein gene that is inserted into these plants prevents the virus from reproducing because it cannot make coat protein. The mechanism here is called *co-suppression.*
- To develop plants with enhanced levels of an essential vitamin such as "golden rice" that produces significant amounts of B-carotene/vitamin A in the grains based on the introduction of two foreign genes from daffodil and one from a bacterium. "Golden rice" – enrichment with carotenoids (provitamin A): This project produced a rice cultivar with enhanced levels of beta-carotene and other carotenoids, which are metabolic precursors of vitamin A. Vitamin A can be absorbed with fat by the human body. Because rice naturally contains only a negligible amount of beta-carotene, vitamin A deficiency is widespread in regions of the world where rice is a staple food. "Golden rice" was developed for people of underdeveloped countries. However, the primary drawback here is that people who live in underdeveloped countries do not have chance to have such well-nourished foods such as "golden rice" primarily due to its high cost.
- To develop plants with enhanced frost resistance, GM-frost resistance has been achieved by research scientists (Professor German Spangenberg and Dr Ulrik John of the Victorian AgriBiosciences Centre at La Trobe University) in Victoria, Australia, through the use of a gene sequence from Antarctic hairgrass (*Deschampsia antarctica*, *Poaceae*, tribe *Aveneae* (Oats)). The same degree of frost tolerance is achieved in cereals and grasses. Frost tolerance is activated by a protective protein that is activated once the temperature drops below 5°C, and the plant then has the ability to inhibit ice crystal growth which gives the plant its freezing tolerance.
- To develop plants with altered composition of sugars or starch. GM potato plants (EH 92-527-1) have been engineered to have tubers with a higher ratio of branched starch (amylopectin) to straight-chain starch (amylose). These plants have not been approved for human consumption and were developed primarily

for production of starch for industrial purposes. Overexpression of the sucrose-6-phosphate synthase (SPS) gene from maize in tomato, and the same gene from spinach in tobacco and potato, led to significant increases in sucrose biosynthesis in the transgenic plants (see Chapter 4).

- To develop tree crops with altered composition of lignin and cellulose in their wood (xylem) tissues through alterations in lignin biosynthesis (e.g., reduction, augmentation and/or structural changes) and cellulose biosynthesis (e.g., augmentation, reduction, and/or quality including high degree of polymerization and crystallinity).
- To develop crop plants whose fruits have longer shelf life due to decreased action of cell wall hydrolases such as cellulases and polygalacturonases (pectinases). The FlavrSavr® tomato is the most famous example. These tomatoes were the first GM fruit sold in the United States and were sold as tomato purée in the UK. Apples, raspberries, and melons with delayed ripening have also been developed.
- To develop seeds with "Terminator" or other sterilizing traits in crops and ornamentals so as to prevent collection of seeds of these plants and thus protect the interests of the owners of patents for such seeds.
- To develop plants with modified oil content and composition (e.g., polyunsaturated fatty acids such as linoleic acid and laureic acid) for maize, soybeans, rapeseed, and other oil crops: These modified crops could be important in the fight against cardiovascular disease, obesity, and certain forms of cancer.
- To develop plants with higher content of protein or amino acids, or modified amino acid composition for enhanced nutritional value: For example, a GM potato was developed in India containing more than one-third of protein including essential, high-quality nutrients. The novel gene came from the protein-rich grain amaranth plant. Another example is LY038, a maize line with enhanced lysine content for improved animal feed quality. It is now awaiting authorization in the EU.
- To develop gluten-free wheat: Celiac sprue patients cannot tolerate the protein gluten (something similar to an allergy).
- To develop higher levels of beneficial antioxidant compounds (e.g., lycopene, flavinols found in tomato) to prevent cardiovascular diseases and certain forms of cancer.
- To eliminate or reduce undesirable substances like allergens or toxic substances (e.g., caffeine, nicotine).
- To develop transgenic "amylopectin potato" that contains almost exclusively amylopectin (an increase from 75 to 98%) rather than a mix of different starches (amylose and amylopectin). This starch will be used for paper, textiles, and adhesives.
- To develop GM rapeseed oil with high erucic acid content. This oil is used in plastics and in high-grade industrial lubricants.
- To develop plants with higher carbon fixation rates via photosynthesis.
- To introduce into C-3 plants C-4 photosynthesis capabilities.

13.2 Benefits and Risks of Genetically Modified Plants

A number of positive and negative issues are associated with plant biotechnology and its applications (Ellstrand, 2000; Gadgil, 2000). The positive issues concern the major benefits that plant biotechnology may contribute to industry, agriculture, and the environment. One of the significant issues is concerned with economically feasible production of crops, pharmaceuticals, and other industrial products (Arber, 2009). We are able to grow more tolerant crops with new traits or produce important vaccines using plant cell factories. Other positive impacts on the environment may involve clearance of contaminated soil by means of phytoremediation as described in Chapter 7. Plants have been found to break down or degrade organic contaminants (similar to microbes), while others are able to extract and stabilize toxic metal contaminants by acting as traps or filters.

Scientists engaged in plant biotechnology should follow all regulatory mandates as well as socially and ethically acceptable targets (Boulter, 1995). Thus, the risks must be evaluated in connection with workplace safety, environmental contamination, and public exposure. In conducting risk assessments, it is important to consider all normal and foreseeable abnormal operations, maintenance, cleaning, and security. Following completion of a risk assessment and risk characterization, development of effective risk management programs, such as implementation through training and selection of risk management tools, is needed.

The criteria for *risk assessment* are based on both genetically modified and original unmodified plants, their potential environmental interactions, as well as the possible effects of plants or their products on the human health (Magaña-Gómez and de la Barca, 2009). Characterization of the novel trait plays a central role in the assessment process and overlaps the assessment of the modified plant. The main criteria assigned pertain to information about the genetic construct (inserted genes, regulatory mechanisms, marker genes, and donors or recipients), the gene functions, complementary and breakdown products, affected metabolic pathways, and potential toxic and allergic effects of the plant product(s). Thus, the negative issues relative to plant biotechnology include potential harm to non-target organisms or potential introduction of regulatory molecules (such as transcriptional factors or hormones) into the same organism with subsequent effects on other genes. The main issue associated with gene biotechnology is that the foreign genes could escape into nature and this process could be uncontrolled. This can lead to loss of biodiversity or to the derivation of new plant organisms with unpredicted properties. The other most serious concern is that pollen from genetically engineered plants could contaminate natural populations due to pollination. In order to escape such difficulties, foreign gene(s) may be transferred to the special organelles, such as chloroplasts or mitochondria, for gene function and possible application, and therefore, the risk assessment with pollination is kept to the minimum.

With the entry of genetically modified (GM) crops into our food chain, consumers are demanding both satisfactory information and choice about GM crops (Parker and Kareiva, 1996; Krebs, 2000; Pimentel et al., 2000). To satisfy this demand, many countries are introducing legislation to control the circulation of GM

crops or to trace the use of approved GM crops. GM plants must go through a rigorous stepwise screening process involving both confined and unconfined field trails. In general, plants with novel traits are regulated on the basis of the characteristics of the product, not the specific process by which the product is made. More specifically, when the next novel plant is assessed, emphasis is placed on the insertion of the novel gene(s) into the plant genome; the number of sites of integration (loci); the copy numbers; presence of rearrangements; the stability; the expression; alterations of metabolic pathways; the activity of an inserted gene product in the plant; and the activity of the gene product in the environment. Potential altered interactions of the novel plants involve identifying changes to the relative phenotype with respect to stress adaptation, composition, toxins, and agronomic characteristics.

A list of potential ecological benefits (Daily, 1999; Dyson, 1999) and risks of selected GM crops is presented in Table 13.1. It provides a framework that makes

Table 13.1 Examples of the potential ecological benefits and risks of selected GM crops

GM modification	Benefits	Risks
Herbicide resistance in crops	Reduced herbicide use Increased opportunities for reduced tillage systems	Increased herbicide use Reduced in-field biodiversity that may reduce the ecological services provided by agricultural ecosystems
Crops with *Bt* toxin	Reduced pesticide use Kills fewer non-target organisms than alternatives such as broad-spectrum pesticides	Promotes development of *Bt* resistance, which will eliminate *Bt* as a relatively safe pesticide Kills non-target caterpillars and butterflies such as monarchs (Pimentel 2000)
Virus resistance in small grains due to coat proteins	Reduced insecticide use to control insect dispersers of pathogens (Hails 2000)	Facilitates the creation of new viruses (Hails 2000) Moves genes into nonagricultural ecosystems where the subsequent increase in fitness of weedy species could eliminate endangered species
Terminator or other sterilizing traits in crops and ornamentals	Prevents the movement of traits to non-target species Prevents the movement of introduced species to other ecosystems (Walker and Lonsdale 2000)	Prevents farmers from developing their own seed supplies adapted to local conditions (Conway 2000)
Synthesis of vitamin A or other nutrients	Improves nutrition of people who depend heavily on rice (Conway 2000)	Disrupts local ecosystems if an ecologically limiting nutrient or protein is produced
Nitrogen fixation by non-legumes	Reduces energy used in fertilizer production and application (Pimentel 2000)	Adds to excess nitrogen leaching from agricultural activities, degrading human health and reducing biodiversity

it easier to screen for the possible combinations of technology, crop, and ecological contexts that are likely to be relatively benign or hazardous. However, constructing such lists is only the first step in a risk assessment. These risks need to be quantitatively assessed for specific organisms in different contexts on a case-by-case basis. Various groups of ecologists have developed a methodology for evaluating the use of GM crops (Tiedje et al., 1989, Scientists' Working Group on Biosafety, 1998). They recommend an incremental, tiered approach to risk assessment that moves from the laboratory to greenhouse and field trials, and finally, to gradually increased, monitored use.

While field trials are a necessary step in evaluating GM crops on their own, they are insufficient. A more comprehensive analysis is required that includes an assessment of the relative benefits and risks of GM crops for other ecosystems and for people. To illustrate this approach, we provide a partial list of the questions for assessment in Table 13.2. Comprehensive risk assessments could allow people to reap substantial benefits from GM crops while avoiding or mitigating serious risks (Arber, 2009).

Table 13.2 Questions to assess the relative benefits and risks of a GM crop

Impacts	Benefit-related questions	Risk-related questions
Agricultural and industrial	Are alternatives available that provide greater agronomic, economic, social, and ecological benefits? Does the GM crop prevent some specific harm to humans or to ecosystems; e.g., Does it reduce pesticide use?	Are risks minimized through good design; e.g., Is it certain that genes inserted into chloroplast DNA cannot escape through pollen? Has the organism been examined in order to determine whether genetic modifications to produce a desired trait have not also inadvertently produced risky changes?
Ecological	Does the GM crop help to solve an existing environmental problem; e.g., Does it produce sterile feral animals to control pests (Walker and Lonsdale 2000)?	Does the modified trait have the potential to increase the fitness ofthe organism outside of the managed environment; e.g., Does it impart herbivore resistance or increase the reproductive rate? In the locale of release, can the trait spread to other species; i.e., Can the species hybridize with other species nearby?
Social	Will the benefits of this GM organism be widely shared? Does the GM crop provide some specific benefit to humans or ecosystems; e.g., Does it enhance human nutrition or help to restore degraded land?	Is a mechanism in place for surveying possible negative effects after widespread release of the GM crop has occurred? Do institutions exist that could mitigate the potential harmful impacts of GM crops?

13.3 Purported Advantages of GM Food Plants

The world population has now reached six billion people and is predicted to double in the next 50 years. Ensuring an adequate food supply for this booming population is going to be a major challenge in the years to come. GM foods have the potential to meet this need in a number of ways.

Insect Pest Resistance: Crop losses from insect pests can be immense, resulting in substantial financial loss for farmers and starvation of people in developing countries. Farmers typically use many millions of kilos of chemical pesticides annually. Consumers do not wish to eat food that has been treated with pesticides because of potential health hazards and because runoff of agricultural wastes from excessive use of pesticides and fertilizers can poison the water supply and cause harm to the environment. Growing GM foods such as *Bt* corn can help to eliminate the application of chemical pesticides and to reduce the cost of bringing a crop to market.

Herbicide Tolerance: For some crops, it is not cost-effective to remove weeds by physical means such as by tillage. So farmers will often spray large quantities of different herbicides to destroy weeds. This is a time-consuming and expensive process that requires care so that the herbicide does not harm the crop plant or the environment. Crop plants genetically engineered to be resistant to one very powerful herbicide could help prevent environmental damage by reducing the amount of herbicide needed. For example, Monsanto has created a strain of soybeans genetically modified to be not affected by their herbicide product Roundup®. A farmer grows these soybeans which then only require one application of herbicide instead of multiple applications, thus reducing production costs and limiting the dangers of agricultural waste runoff.

Disease Resistance: There are many viruses, fungi, and bacteria that cause plant diseases. Plant biologists are working to create plants with genetically engineered resistance to these diseases.

Frost Resistance: Unexpected frost can destroy sensitive crop seedlings. An anti-freeze gene from cold water fish has been introduced into plants such as tobacco and potato. With this anti-freeze gene, these plants are able to tolerate cold temperatures that normally would kill genetically unmodified seedlings.

Drought Tolerance/Salinity Tolerance: As the world population grows and more land is utilized for housing instead of food production, farmers will need to grow crops in locations previously poorly suited for plant cultivation. Consequently, creating plants that can withstand long periods of drought or high salt content in the soil and groundwater will help people to grow crops in formerly inhospitable places.

Human Nutrition: Malnutrition is common in African countries which face hunger and poverty where impoverished people rely on a single crop such as rice for the main staple of their diet. However, rice does not contain adequate amounts of all necessary nutrients to prevent malnutrition. If rice could be genetically engineered to contain additional vitamins and minerals, nutrient deficiencies could be alleviated. For example, blindness due to vitamin A deficiency is a common problem in third-world countries. Researchers at the Institute for Plant Sciences, Swiss Federal

Institute of Technology, have created a genetically modified strain of "golden" rice containing an unusually high content of beta-carotene (vitamin A).

Phytoremediation: Not all GM plants are grown as crops. Soil and groundwater pollution continues to be a problem in all parts of the world. Plants such as poplar trees have been genetically engineered in order to clean up heavy metal pollution from contaminated soil (see also Chapter 7).

13.4 Genetically Modified (GM) Plants and Foods Derived from GM Plants: Questions and Answers

The questions and answers cited below have been prepared by the *World Health Organization* (*WHO*) in response to questions and concerns by a number of (WHO) Member State Governments with regard to the nature and safety of genetically modified food. They have been modified substantially for presentation here.

Q1. What are genetically modified (GM) organisms and GM foods?
Genetically modified organisms (*GMOs*) can be defined as organisms in which the genetic material (DNA) has been altered in a way that does not occur naturally. The technology is often called "modern biotechnology" or "gene technology", sometimes also "recombinant DNA technology" or "genetic engineering". It allows selected individual genes to be transferred from one organism into another, and also, between non-related species.

Such methods are used to create GM plants – which are then used to grow GM food crops.

Q2. Why are GM foods produced?
GM foods are developed – and marketed – because there is some perceived advantage either to the producer or consumer of these foods. This is meant to translate into a product with a lower price, greater benefit (in terms of durability or nutritional value), or both. Initially GM seed developers wanted their products to be accepted by producers so have concentrated on innovations that farmers (and the food industry more generally) would appreciate.

The initial objective for developing plants based on GM organisms was to improve crop protection. The GM crops currently on the market are mainly aimed at an increased level of crop protection through the introduction of resistance against plant diseases caused by insects or viruses or through increased tolerance toward herbicides.

Insect resistance is achieved by incorporating into the food plant the gene for toxin production from the milky spore bacterium, *Bacillus thuringiensis* (*Bt*). This toxin is currently used as a conventional insecticide in agriculture and is safe for human consumption. GM crops that permanently produce this toxin have been shown to require lower quantities of insecticides in specific situations, e.g., where pest pressure is high.

Herbicide tolerance is achieved through the introduction of a gene from a bacterium conveying resistance to some herbicides. In situations where weed pressure is high, the use of such crops has resulted in a reduction in the quantity of the herbicides used.

In some cases, biotechnology can be used to make virus-resistant crops. The most common way of doing this is by giving a plant a viral gene encoding the virus coat protein. The plant can then produce this viral protein before the virus infects the plant. If the virus arrives, it is not able to reproduce. The explanation for this is called co-suppression. The plant has ways of knowing when the viral coat protein should not be produced, and it has ways of eventually shutting down the protein's expression. When the virus tries to infect the plant, the production of its essential coat protein is already blocked. All genetically modified virus-resistant plants on the market (e.g., papayas and squash) have coat protein-mediated resistance. It may also be possible to confer resistance by taking a resistance gene naturally found in one plant and then transferring it to an important crop.

Q3. Are GM foods assessed differently from traditional foods?

Generally consumers consider that traditional foods (that have often been eaten for thousands of years) are safe. When new foods are developed by natural methods, some of the existing characteristics of foods can be altered, either in a positive or a negative way. National food authorities may be called upon to examine traditional foods, but this is not always the case. Indeed, new plants developed through traditional breeding techniques may not be evaluated rigorously using risk assessment techniques.

With GM foods most national authorities consider that specific assessments are necessary. Specific systems have been set up for the rigorous evaluation of GM organisms and GM foods relative to both human health and the environment. Similar evaluations are generally not performed for traditional foods. Hence, there is a significant difference in the evaluation process prior to marketing for these two groups of foods.

One of the objectives of the WHO Food Safety Programme is to assist national authorities in the identification of foods that should be subject to risk assessment, including GM foods, and to recommend the correct assessments.

Q4. How are the potential risks to human health determined?

The safety assessment of GM foods generally investigates (a) direct health effects (toxicity); (b) tendencies to provoke allergic reaction (allergenicity); (c) specific components thought to have nutritional or toxic properties; (d) the stability of the inserted gene; (e) nutritional effects associated with genetic modification; and (f) any unintended effects which could result from the gene insertion.

Q5. What are the main issues of concern for human health?

While theoretical discussions have covered a broad range of aspects, the three main issues debated are tendencies to provoke allergic reaction (allergenicity), gene transfer, and outcrossing.

Allergenicity. As a matter of principle, the transfer of genes from commonly allergenic foods is discouraged unless it can be demonstrated that the protein product of the transferred gene is not allergenic. While traditionally developed foods are not generally tested for allergenicity, protocols for tests for GM foods have been evaluated by the Food and Agriculture Organization of the United Nations (FAO) and WHO. No allergic effects have been found relative to GM foods currently on the market.

Gene transfer. Gene transfer from GM foods to cells of the body or to bacteria in the gastrointestinal tract would cause concern if the transferred genetic material adversely affects human health. This would be particularly relevant if antibiotic resistance genes, used in creating GMOs, were to be transferred. Although the probability of transfer is low, the use of technology without antibiotic resistance genes has been encouraged by a recent FAO/WHO expert panel.

Outcrossing. The movement of genes from GM plants into conventional crops or related species in the wild (referred to as "outcrossing"), as well as the mixing of crops derived from conventional seeds with those grown using GM crops, may have an indirect effect on food safety and food security. This risk is real, as was shown when traces of a maize type which was only approved for feed use appeared in maize products for human consumption in the United States. Several countries have adopted strategies to reduce mixing, including a clear separation of the fields within which GM crops and conventional crops are grown.

Feasibility and methods for post-marketing monitoring of GM food products, for the continued surveillance of the safety of GM food products, are under discussion.

Q6. How is a risk assessment for the environment performed?

Environmental risk assessments cover both the GMO concerned and the potential receiving environment. The assessment process includes evaluation of the characteristics of the GMO and its effect and stability in the environment, combined with ecological characteristics of the environment in which the introduction will take place. The assessment also includes unintended effects which could result from the insertion of the new gene.

Q7. What are the issues of concern for the environment?

Issues of concern include the capability of the GMO to escape and potentially introduce the engineered genes into wild populations; the persistence of the gene after the GMO has been harvested; the susceptibility of non-target organisms (e.g., insects which are not pests) to the gene product; the stability of the gene; the reduction in the spectrum of other plants including loss of biodiversity; and increased use of chemicals in agriculture. The environmental safety aspects of GM crops vary considerably according to local conditions.

Current investigations focus on the potentially detrimental effect on beneficial insects or a faster induction of resistant insects; the potential generation of new plant pathogens; the potential detrimental consequences for plant biodiversity and wildlife; a decreased use of the important practice of crop rotation in certain local situations; and the movement of herbicide resistance genes to other plants.

Q8. Are GM foods safe?
Different GM organisms include different genes inserted in different ways. This means that individual GM foods and their safety should be assessed on a case-by-case basis and that it is not possible to make general statements on the safety of all GM foods.

GM foods currently available on the international market have passed risk assessments and are not likely to present risks for human health. In addition, no effects on human health have been shown as a result of the consumption of such foods by the general population in the countries where they have been approved. Continuous use of risk assessments based on the Codex principles and, where appropriate, including post market monitoring, should form the basis for evaluating the safety of GM foods.

Q9. How are GM foods regulated nationally?
The way governments have regulated GM foods varies. In some countries GM foods are not yet regulated. Countries which have legislation in place focus primarily on assessment of risks for consumer health. Countries which have provisions for GM foods usually also regulate GMOs in general, taking into account health and environmental risks, as well as control- and trade-related issues (such as potential testing and labeling regimes). In view of the dynamics of the debate on GM foods, legislation is likely to continue to evolve.

Q10. What kind of GM foods are on the market internationally?
All GM crops available on the international market today have been designed using one of three basic traits: resistance to insect damage; resistance to viral infections; and tolerance toward certain herbicides. All the genes used to modify crops are derived from microorganisms.

Q11. What happens when GM foods are traded internationally?
No specific international regulatory systems are currently in place. However, several international organizations are involved in developing protocols for GMOs.

The *Codex Alimentarius Commission* (*Codex*) is the joint FAO/WHO body responsible for compiling the standards, codes of practice, guidelines, and recommendations that constitute the Codex Alimentarius: the international food code. Codex is developing principles for the human health risk analysis of GM foods. The premise of these principles dictates a premarket assessment, performed on a case-by-case basis and including an evaluation of both direct effects (from the inserted gene) and unintended effects (that may arise as a consequence of insertion of the new gene). Codex principles do not have a binding effect on national legislation, but are referred to specifically in the *Sanitary and Phytosanitary Agreement of the World Trade Organization* (*SPS Agreement*), and can be used as a reference in case of trade disputes.

The *Cartagena Protocol on Biosafety* (*CPB*), an environmental treaty legally binding for its parties, regulates transboundary movements of living modified organisms (LMOs). GM foods are within the scope of the protocol only if they contain

LMOs that are capable of transferring or replicating genetic material. The cornerstone of the CPB is a requirement that exporters seek consent from importers before the first shipment of LMOs intended for release into the environment.

Q12. Have GM products on the international market passed a risk assessment?
The GM products that are currently on the international market have all passed risk assessments conducted by national authorities. These different assessments in general follow the same basic principles, including an assessment of environmental and human health risk. These assessments are thorough; they have not indicated any risk to human health.

Q13. Are there implications for the rights of farmers to own their crops?
Yes, intellectual property rights are likely to be an element in the debate on GM foods, with an impact on the rights of farmers. *Intellectual property rights* (*IPRs*), especially patenting obligations of the TRIPS Agreement (an agreement under the World Trade Organization concerning trade-related aspects of intellectual property rights), have been discussed in the light of their consequences on the further availability of a diversity of crops. In the context of the related subject of the use of gene technology in medicine, WHO has reviewed the conflict between IPRs and an equal access to genetic resources and the sharing of benefits. The review has considered potential problems of monopolization and doubts about new patent regulations in the field of genetic sequences in human medicine. Such considerations are likely to also affect the debate on GM foods.

Q14. What further developments can be expected in the area of GMOs?
Future GM organisms are likely to include plants with improved disease or drought resistance, crops with increased nutrient levels, fish species with enhanced growth characteristics, and plants or animals producing pharmaceutically important proteins such as vaccines. At the international level, the response to new developments can be found in the expert consultations organized by FAO and WHO in 2000 and 2001, and the subsequent work of the Codex ad hoc Task Force on Foods Derived from Biotechnology. This work has resulted in an improved and harmonized framework for the risk assessment of GM foods in general. Specific questions, such as the evaluation of allergenicity of GM foods or the safety of foods derived from GM microorganisms, have been covered and an expert consultation organized by FAO and WHO will focus on foods derived from GM animals in 2003.

Q15. What is WHO doing to improve the evaluation of GM foods?
WHO will take an active role in relation to GM foods, primarily for two reasons: (1) on the grounds that public health could benefit enormously from the potential of biotechnology, for example, from an increase in the nutrient content of foods, decreased allergenicity, and more efficient food production and (2) based on the

need to examine the potential negative effects on human health of the consumption of food produced through genetic modification, also at the global level. It is clear that modern technologies must be thoroughly evaluated if they are to constitute a true improvement in the way food is produced. Such evaluations must be holistic and all-inclusive and cannot stop at the previously separated, non-coherent systems of evaluation focusing solely on human health or environmental effects in isolation.

Work is therefore under way in WHO to present a broader view of the evaluation of GM foods in order to enable the consideration of other important factors. This more holistic evaluation of GM organisms and GM products will consider not only safety but also food security, social and ethical aspects, access, and capacity building. International work in this new direction presupposes the involvement of other key international organizations in this area.

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