# 20 questions on genetically modified foods

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## 20 QUESTIONS ON GENETICALLY MODIFIED (GM) FOODS

**Q1. What are genetically modified (GM) organisms and GM foods?**

These questions and answers have been prepared by 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.

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, 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 towards herbicides.

Insect resistance is achieved by incorporating into the food plant the gene for toxin production from the 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.

Virus resistance is achieved through the introduction of a gene from certain viruses which cause disease in plants. Virus resistance makes plants less susceptible to diseases caused by such viruses, resulting in higher crop yields.

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.

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 food.

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 of America. 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

induction of resistant insects; the potential generation of new plant pathogens; the potential detrimental consequences for plant biodiversity and wildlife, and 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 labelling 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 towards 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). The principles are at an advanced stage of development and are expected to be adopted in July 2003. 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. The Protocol will enter into force 90 days after the 50th country has ratified it, which may be in early 2003 in view of the accelerated depositions registered since June 2002.

**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.

consumers, especially in Europe. Several factors are involved.

In the late 1980s – early 1990s, the results of decades of molecular research reached the public domain. Until that time, consumers were generally not very aware of the potential of this research. In the case of food, consumers started to wonder about safety because they perceive that modern biotechnology is leading to the creation of new species.

Consumers frequently ask, "what is in it for me?". Where medicines are concerned, many consumers more readily accept biotechnology as beneficial for their health (e.g. medicines with improved treatment potential). In the case of the first GM foods introduced onto the European market, the products were of no apparent direct benefit to consumers (not cheaper, no increased shelf-life, no better taste). The potential for GM seeds to result in bigger yields per cultivated area should lead to lower prices. However, public attention has focused on the risk side of the risk-benefit equation.

Consumer confidence in the safety of food supplies in Europe has decreased significantly as a result of a number of food scares that took place in the second half of the 1990s that are unrelated to GM foods. This has also had an impact on discussions about the acceptability of GM foods. Consumers have questioned the validity of risk assessments, both with regard to consumer health and environmental risks, focusing in particular on long-term effects. Other topics for debate by consumer organizations have included allergenicity and antimicrobial resistance. Consumer concerns have triggered a discussion on the desirability of labelling GM foods, allowing an informed choice. At the same time, it has proved difficult to detect traces of GMOs in foods: this means that very low concentrations often cannot be detected.

**Q14. How has this concern affected the marketing of GM foods in the European Union?**

The public concerns about GM food and GMOs in general have had a significant impact on the marketing of GM products in the European Union (EU). In fact, they have resulted in the so-called moratorium on approval of GM products to be placed on the market. Marketing of GM food and GMOs in general are the subject of extensive legislation. Community legislation has been in place since the early 1990s. The procedure for approval of the release of GMOs into the environment is rather complex and basically requires agreement between the Member States and the European Commission. Between 1991 and 1998, the marketing of 18 GMOs was authorized in the EU by a Commission decision.

As of October 1998, no further authorizations have been granted and there are currently 12 applications pending. Some Member States have invoked a safeguard clause to temporarily ban the placing on the market in their country of GM maize and oilseed rape products. There are currently nine ongoing cases. Eight of these have been examined by the Scientific Committee on Plants, which in all cases deemed that the information submitted by Member States did not justify their bans.

During the 1990s, the regulatory framework was further extended and refined in response to the legitimate concerns of citizens, consumer organizations and economic operators (described under Question 13). A revised directive will come into force in October 2002. It will update and strengthen the existing rules concerning the process of risk assessment, risk management and decision-making with regard to the release of GMOs into the environment. The new directive also foresees mandatory monitoring of long-term effects associated with the interaction between GMOs and the environment.

Labelling in the EU is mandatory for products derived from modern biotechnology or products containing GM organisms. Legislation also addresses the problem of accidental contamination of conventional food by GM material. It introduces a 1% minimum threshold for DNA or protein resulting from genetic modification, below which labelling is not required.

In 2001, the European Commission adopted two new legislative proposals on GMOs concerning traceability, reinforcing current labelling rules and streamlining the authorization procedure for GMOs in food and feed and for their deliberate release into the environment.

The European Commission is of the opinion that these new proposals, building on existing legislation, aim to address the concerns of Member States and to build consumer confidence in the authorization of GM products. The Commission expects that adoption of these proposals will pave the way for resuming the authorization of new GM products in the EU.

**Q15. What is the state of public debate on GM foods in other regions of the world?**

a way to address consumer concerns, there is no consensus to date. This has become apparent during discussions within the Codex Alimentarius Commission over the past few years. Despite the lack of consensus on these topics, significant progress has been made on the harmonization of views concerning risk assessment. The Codex Alimentarius Commission is about to adopt principles on premarket risk assessment, and the provisions of the Cartegena Protocol on Biosafety also reveal a growing understanding at the international level.

Most recently, the humanitarian crisis in southern Africa has drawn attention to the use of GM food as food aid in emergency situations. A number of governments in the region raised concerns relating to environmental and food safety fears. Although workable solutions have been found for distribution of milled grain in some countries, others have restricted the use of GM food aid and obtained commodities which do not contain GMOs.

**Q16. Are people's reactions related to the different attitudes to food in various regions of the world?**

Depending on the region of the world, people often have different attitudes to food. In addition to nutritional value, food often has societal and historical connotations, and in some instances may have religious importance. Technological modification of food and food production can evoke a negative response among consumers, especially in the absence of good communication on risk assessment efforts and cost/benefit evaluations.

**Q17. 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.

**Q18. Why are certain groups concerned about the growing influence of the chemical industry on agriculture?**

Certain groups are concerned about what they consider to be an undesirable level of control of seed markets by a few chemical companies. Sustainable agriculture and biodiversity benefit most from the use of a rich variety of crops, both in terms of good crop protection practices as well as from the perspective of society at large and the values attached to food. These groups fear that as a result of the interest of the chemical industry in seed markets, the range of varieties used by farmers may be reduced mainly to GM crops. This would impact on the food basket of a society as well as in the long run on crop protection (for example, with the development of resistance against insect pests and tolerance of certain herbicides). The exclusive use of herbicide-tolerant GM crops would also make the farmer dependent on these chemicals. These groups fear a dominant position of the chemical industry in agricultural development, a trend which they do not consider to be sustainable.

**Q19. 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.

**Q20. 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:

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. As a first step, the WHO Executive Board will discuss the content of a WHO report covering this subject in January 2003. The report is being developed in collaboration with other key organizations, notably FAO and the United Nations Environment Programme (UNEP). It is hoped that this report could form the basis for a future initiative towards a more systematic, coordinated, multi-organizational and international evaluation of certain GM foods.