World Health Organization

Frequently asked questions on genetically modified foods

These questions and answers have been prepared by WHO in response to questions and concerns from WHO Member State Governments with regard to the nature and safety of genetically modified food.

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

Genetically modified organisms (GMOs) can be defined as organisms (i.e. plants, animals or microorganisms) in which the genetic material (DNA) has been altered in a way that does not occur naturally by mating and/or natural recombination. 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. Foods produced from or using GM organisms are often referred to as GM foods.

2. 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 and have concentrated on innovations that bring direct benefit to farmers (and the food industry generally).

One of the objectives for developing plants based on GM organisms is 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.

Resistance against insects 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 inherently 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.

3. Is the safety of GM foods assessed differently from conventional foods?
Generally consumers consider that conventional foods (that have an established record of safe consumption over the history) are safe. Whenever novel varieties of organisms for food use are developed using the traditional breeding methods that had existed before the introduction of gene technology, some of the characteristics of organisms may be altered, either in a positive or a negative way. National food authorities may be called upon to examine the safety of such conventional foods obtained from novel varieties of organisms, but this is not always the case.

In contrast, most national authorities consider that specific assessments are necessary for GM foods. 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 conventional foods. Hence there currently exists a significant difference in the evaluation process prior to marketing for these two groups of food.

The WHO Department of Food Safety and Zoonoses aims at assisting national authorities in the identification of foods that should be subject to risk assessment and to recommend appropriate approaches to safety assessment. Should national authorities decide to conduct safety assessment of GM organisms, WHO recommends the use of Codex Alimentarius guidelines (See the answer to Question 11 below).

4. How is a safety assessment of GM food conducted?
The safety assessment of GM foods generally focuses on: (a) direct health effects (toxicity), (b) potential 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.

5. 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 the potentials to provoke allergic reaction (allergenicity), gene transfer and outcrossing.
Allergenicity. As a matter of principle, the transfer of genes from commonly allergenic organisms to non-allergic organisms is discouraged unless it can be demonstrated that the protein product of the transferred gene is not allergenic. While foods developed using traditional breeding methods are not generally tested for allergenicity, protocols for the testing of 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 as markers when creating GMOs, were to be transferred. Although the probability of transfer is low, the use of gene transfer technology that does not involve antibiotic resistance genes is encouraged.

Outcrossing. The migration 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 GM crops, may have an indirect effect on food safety and food security. Cases have been reported where GM crops approved for animal feed or industrial use were detected at low levels in the products intended for human consumption. Several countries have adopted strategies to reduce mixing, including a clear separation of the fields within which GM crops and conventional crops are grown.

6. 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.

7. 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.

8. 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 safety 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 application of safety assessments based on the Codex Alimentarius principles and, where appropriate, adequate post market monitoring, should form the basis for ensuring the safety of GM foods.

9. 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 regulatory 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.

10. What kind of GM foods are on the market internationally?

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. GM crops with higher nutrient content (e.g. soybeans increased oleic acid) have been also studied recently.

11. What happens when GM foods are traded internationally?

The Codex Alimentarius Commission (Codex) is the joint FAO/WHO intergovernmental body responsible for developing the standards, codes of practice, guidelines and recommendations that constitute the *Codex Alimentarius*, meaning the international food code. Codex developed principles for the human health risk analysis of GM foods in 2003 (http://www.codexalimentarius.org/download/standards/10007/CXG_044e.pdf). The premise of these principles sets out 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 also developed three Guidelines for the conduct of food safety assessment of foods derived from recombinant-DNA plants (http://www.codexalimentarius.org/download/standards/10021/CXG_045e.pdf), produced using recombinant-DNA microorganisms (http://www.codexalimentarius.org/download/standards/10025/CXG_046e.pdf) and derived from recombinant-DNA animals (http://www.codexalimentarius.org/download/standards/11023/CXG_068e.pdf).

Codex principles do not have a binding effect on national legislation, but are referred to specifically in the Agreement on the Application of Sanitary and Phytosanitary Measures of the World Trade Organization (SPS Agreement), and WTO Members are encouraged to harmonize national standards with Codex standards. If trading partners have the same or similar mechanisms for the safety assessment of GM foods, the possibility that one product is approved in one country but rejected in another becomes smaller.

The Cartagena Protocol on Biosafety, an environmental treaty legally binding for its Parties which took effect in 2003, 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 Protocol is a requirement that exporters seek consent from importers before the first shipment of LMOs intended for release into the environment.

12. Have GM products on the international market passed a safety assessment?

The GM products that are currently on the international market have all passed safety assessments conducted by national authorities. These different assessments in general

follow the same basic principles, including an assessment of environmental and human health risk. The food safety assessment is usually based on Codex documents.

13. Why has there been concern about GM foods among some politicians, public interest groups and consumers?

Since the first introduction on the market in the mid-1990s of a major GM food (herbicide-resistant soybeans), there has been concern about such food among politicians, activists and 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. vaccines, medicines with improved treatment potential or increased safety). In the case of the first GM foods introduced onto the European market, the products were of no apparent direct benefit to consumers (not significantly 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, often without distinguishing between potential environmental impacts and public health effects of GMOs.

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 debated by consumer organizations have included allergenicity and antimicrobial resistance. Consumer concerns have triggered a discussion on the desirability of labelling GM foods, allowing for an informed choice of consumers.

14. What is the state of public debate on GMOs?

The release of GMOs into the environment and the marketing of GM foods have resulted in a public debate in many parts of the world. This debate is likely to continue, probably in the broader context of other uses of biotechnology (e.g. in human medicine) and their consequences for human societies. Even though the issues under debate are usually very similar (costs and benefits, safety issues), the outcome of the debate differs from country to country. On issues such as labelling and traceability of GM foods as a way to address consumer preferences, there is no worldwide consensus to date. Despite the lack of consensus on these topics, the Codex Alimentarius Commission has made significant progress and developed Codex texts relevant to labelling of foods derived from modern biotechnology in 2011 to ensure consistency on any approach on labelling implemented by Codex members with already adopted Codex provisions.

15. 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 may evoke a negative response among consumers, especially in the absence of sound risk communication on risk assessment efforts and cost/benefit evaluations.

16. 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. In the FAO/WHO expert consultation in 2003 (http://www.who.int/entity/foodsafety/biotech/meetings/en/gmanimal_reportnov03_en.pdf?ua=1), WHO and FAO have considered potential problems of the technological divide and the unbalanced distribution of benefits and risks between developed and developing countries and the problem often becomes even more acute through the existence of intellectual property rights and patenting that places an advantage on the strongholds of scientific and technological expertise. Such considerations are likely to also affect the debate on GM foods.

17. 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.

18. What further developments can be expected in the area of GMOs?

Future GM organisms are likely to include plants with improved resistance against plant disease or drought, crops with increased nutrient levels, fish species with enhanced growth characteristics. For non-food use, they may include plants or animals producing pharmaceutically important proteins such as new vaccines.

19. What has WHO been doing to improve the evaluation of GM foods?

WHO has been taking an active role in relation to GM foods, primarily for two reasons:

(1) on the grounds that public health could benefit from the potential of biotechnology, for example, from an increase in the nutrient content of foods, decreased allergenicity and more efficient and/or sustainable 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 in order to protect

public health. Modern technologies should be thoroughly evaluated if they are to constitute a true improvement in the way food is produced.

WHO, together with FAO, has convened several expert consultations on the evaluation of GM foods and provided technical advice for the Codex Alimentarius Commission which was fed into the Codex Guidelines on safety assessment of GM foods. WHO will keep paying due attention to the safety of GM foods from the view of public health protection, in close collaboration with FAO and other international bodies.

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