

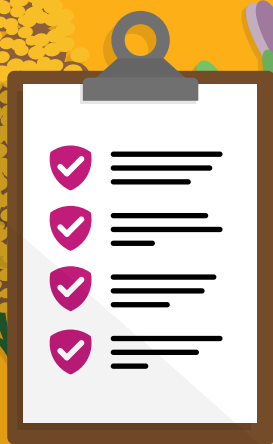


Food and Agriculture
Organization of the
United Nations

Information toolkit on
food biotechnologies
with a focus on
food safety

4

GM food safety assessment



This “Information toolkit on food biotechnologies with a focus on food safety” is a publication consisting of one handbook and ten booklets, referred to as tools. It is strongly recommended to read through the whole set before using the information it contains.

Contents of the information toolkit on food biotechnologies with a focus on food safety

Handbook - Using the information toolkit

Tool 1: Background and guidance

Tool 2: Fundamentals

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Tool 4: GM food safety assessment

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Tool 7: The environment

Tool 8: Practical uses and applications

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Introduction



Tool 4 provides information and examples on the safety assessment for genetically modified (GM) foods, which analysis (FAO, 2020a) and experts' consultations (FAO, 2020b) found to be a key topic that could provide information and assistance for authorities to communicate around food biotechnologies. These examples provided here include information to help inform how, why and by whom GM food safety assessments are conducted. These include:

1. The safety of GM foods is ensured through rigorous scientific risk assessment.
2. Governments are responsible for ensuring that GM foods are safe to eat through GM food safety assessment.
3. Experience, capacities and capabilities in performing GM food safety assessment differ from country to country.
4. All countries that have conducted safety assessment of GM foods have come to the same conclusion: GM foods on the market are safe to eat.
5. GM foods are determined to be as safe as their non-GM counterparts, which have a long history of safe use including in terms of hygiene, additives and residues.
6. All GM foods have to be as safe as their non-GM counterparts in order to go to the market.

In this tool, the safety assessments for GM foods will be considered. There are foods derived from other biotechnologies, e.g. conventional breeding, fermentation and mutagenesis. While these foods do not fall into the category of "GM foods" and do not need to go through the rigorous safety assessment conducted for GM foods, they still need to comply with food safety requirements concerning hygiene, additives and residues, as all foods. The information in this tool may support the purposes of education and general information, and it may also be used to provide an overview of GM food safety assessment for government or other relevant officials who are newly responsible for food safety. Tool 6, addressing the topic of Human Health (FAO, 2021b), can be used to complement the information of this tool. The images show how one may present the materials.

Six examples



The safety of genetically modified (GM) foods is ensured through rigorous scientific risk assessment

GM food safety assessments are based on science and they follow internationally recognized standards from the Codex Alimentarius. Principles and guidelines have been developed for countries that conduct safety assessments of foods derived from biotechnologies (FAO and WHO, 2003, 2008a, 2008b and 2011). To support capacity development, the Food and Agriculture Organization of the United Nations (FAO) published a training tool in 2008 entitled “GM food safety assessment: tools for trainers”: this describes the principles for safety assessment of foods derived from recombinant-deoxyribonucleic acid (DNA) plants, a type of GM food, as guidance for implementing an effective safety assessment framework (FAO, 2008c).

The safety assessment of a food derived from a recombinant-DNA plant follows a stepwise process of addressing relevant factors that include: A) description of the recombinant-DNA plant; B) description of the host plant and its use as food; C) description of the donor organism(s); D) description of the genetic modification(s); E) molecular characterization of the genetic modification(s); F) safety assessment; and G) other considerations. The safety assessment (stage F) is composed of the following analyses: F-i) expressed substances are assessed for potential allergenicity and toxicity; F-ii) compositional analyses of key components; F-iii) evaluation of metabolites; F-iv) food processing; and F-v) nutritional modification.

While this may be too much information to share directly with the general public, it is a good idea for the users of this toolkit to understand the safety assessment process in order to correctly package relevant information for the public and answer any questions.

Scientific assessment ensures the safety of GM foods by:

- 1 Identifying what changes were made
- 2 Ensuring that new toxic and allergic reactions are not caused by these changes
- 3 Ensuring that GM foods are as nutritious as their non-GM counterparts



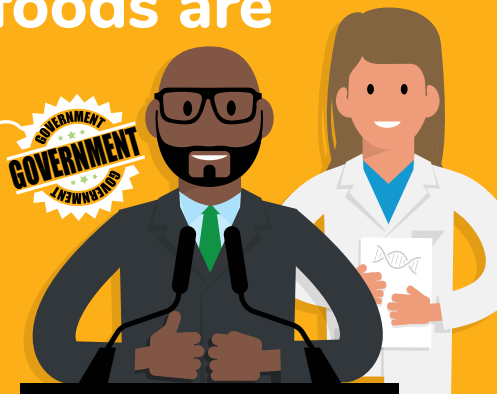
Safety assessments of GM foods are based on science and follow internationally-recognized standards from the Codex Alimentarius.

Governments are responsible for ensuring that genetically modified (GM) foods are safe to eat through GM food safety assessments

Government agencies carry out safety assessments using detailed scientific information from developers and other available sources, e.g. published scientific studies. In some countries, other stakeholders e.g. external expert groups, may be involved in the assessment process. When explaining the food safety assessment process, it can be helpful to list all of the stakeholders, and if applicable, to include the names of their organizations, to clarify the national process. The example below only includes the roles of government agencies in the approval process of GM foods. The word “examine” is used with regards to the safety assessment of GM foods performed by governments. However, several other terms can be used such as “evaluate” and “conduct”, and users of this toolkit may want to modify the texts using the terminology that is used in their country.

Governments examine GM food safety assessments to ensure that the foods are safe to eat.

After the evaluations are done, governments make their decision on whether to authorize use of the GM food.



Experience, capacities and capabilities in performing genetically modified (GM) food safety assessment differ from country to country

Does my country require GM food safety assessments to be conducted? If yes, how many assessments and on which commodities/events have they been conducted? The example reported below can be used as a starting point to develop country-specific information materials responding to these questions. The example provided here only includes generic information, which could apply to any country. Some countries have been conducting safety assessments since the mid-1990s and the outcomes are available online. Other countries have not yet conducted a safety assessment of GM foods, but they may be planning to conduct them in the near future. There are also countries that have never conducted safety assessments of GM food and that will be unable to conduct them in the near future. There may be countries that base their national policy decisions on safety assessments conducted by other governments.

The information about capacities and performance of GM food safety assessments largely varies in the different countries, and when informing about country situations, the national context needs to be captured appropriately. For example, in countries that have not yet conducted GM food safety assessments

or have not yet established the process, materials could highlight any regulatory collaborative initiatives in place to develop capacity to conduct safety assessments. For instance, community members of the FAO GM Foods Platform have established the community of practice and there are ongoing intergovernmental collaborative efforts (FAO, 2020c).

Experience in GM food safety assessments differs from country to country, e.g. how many assessments have been conducted.



Countries that have carried out safety assessments typically make the results publicly available on their governmental websites and international platforms such as the FAO GM Foods Platform.

All countries that have conducted safety assessments of genetically modified (GM) foods have come to the same conclusion: GM foods on the market are safe to eat

Over the past years, various countries have conducted safety assessments of GM foods and they came to the same conclusion: GM foods on the market are safe to eat. In the example below, the number of GM food safety assessments shared on the FAO GM Foods Platform (FAO, 2020d) is used to support this statement. This number is expected to increase over time, and users of this toolkit are invited to visit the Platform to update material with the latest figures. The number of records uploaded is available under the “Global outlook” section of the Platform. The example below is based on data available on the FAO GM Foods Platform.

All countries that have conducted safety assessments of GM foods have come to the same conclusion: GM foods on the market are safe to eat.

As of August 2020, more than 1600 results of the GM food safety assessments are available on the FAO GM Foods Platform.

<http://fao.org/gm-platform>



Genetically modified (GM) foods are determined to be as safe as their non-GM counterparts, which have a long history of safe use including in terms of hygiene, additives and residues

How is the safety of GM foods demonstrated? The example below addresses this question by using a question-and-answer format. To ensure the safety of GM foods, these have to go through a rigorous GM food safety assessment. For the assessments, a comparison is made with their non-GM counterparts, which have a much longer history of safe use. This information could be presented together with the first example of this tool, which introduces GM food safety assessments by listing its components, and by showing that the assessment process derives from Codex, an internationally-recognized standard setting body. The example below shows that after the safety of GM foods is established, compliance with all the other food safety requirements concerning hygiene, additives and residues is also necessary, as for all non-GM foods.

How is the safety of GM foods demonstrated?

GM foods undergo rigorous food safety assessments.

Once their safety is established, GM foods, like all non-GM foods have to comply with the other food safety requirements, e.g. in terms of hygiene, additives and residues.



All genetically modified (GM) foods have to be as safe as their non-GM counterparts

“Why do we need to assess the safety of GM foods?” The example below addresses this question in a question-and-answer format. The answer is: because all foods have to be safe to eat, and GM foods are not an exception. All GM foods need to be as safe as their non-GM counterparts in order to go to the market. GM foods have a history of safe use spanning more than 20 years. During the safety assessment process, comparison is made with non-GM counterparts, which have been used for centuries.

Why do we need to assess GM foods?

All foods have to be safe to eat, and GM foods are not an exception. All GM foods need to be as safe as their non-GM counterparts in order to go to the market.

To ensure safety, all GM foods have to pass a rigorous GM food safety assessment. GM foods have a history of safe use spanning more than 20 years.



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Terminology

Biosafety	Set of measures or actions addressing the safety aspects related to the application of biotechnologies and to the release into the environment of transgenic plants and other organisms, particularly microorganisms, that could negatively affect plant genetic resources, plant, animal or human health, or the environment (FAO, 2001).
Biotechnology	Any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for a specific use. In this document, the words “food biotechnology” are used when biotechnology is applied to make or modify foods for human consumption (FAO, 2001).
Conventional counterpart	A related organism/variety, its components and/or products for which there is experience of establishing safety based on common use as food (FAO and WHO, 2009).
Deoxyribonucleic acid	Deoxyribonucleic acid (DNA) is a long chain polymer of deoxyribonucleotides. DNA constitutes the genetic material of most known organisms and organelles, and is usually in the form of a double helix, although some viral genomes consist of a single strand of DNA, and others of a single- or a double-stranded ribonucleic acid (RNA) (FAO, 2001).
Gene	The unit of heredity transmitted from generation to generation during sexual or asexual reproduction. More generally, the term is used in relation to the transmission and inheritance of particular identifiable traits. The simplest gene consists of a segment of nucleic acid that encodes an individual protein or RNA (FAO, 2001).
Genome editing	Techniques utilized by scientists to correct or to introduce specific mutations at a particular site (locus) within the DNA of an organism. The techniques used to accomplish these site-specific corrections or directed mutations (base substitution, addition or deletion) include living modified organism (LMO) genome editing and transcription activator-like effector nucleases (TALEN). The term gene editing may be used interchangeably (FAO, 2019).
Genetic modification	Altering the genetic material of cells or organisms with the intention of making them capable of producing new substances or performing new functions (FAO, 2020a). The term genetic engineering may be used interchangeably.
Genetically modified food	Food produced for human consumption and derived from organisms whose genetic material (DNA) has been modified in a way that does not occur naturally, e.g. through introducing a gene from a different organism (FAO, 2020a).
Genetically modified organism	An organism that has been transformed by inserting one or more transgenes (FAO, 2001).
Living modified organism	A living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology. It is a synonym of GMO, but is restricted to organisms that can endanger biological diversity (FAO, 2001).
Modern biotechnology	Application of: i) <i>In vitro</i> nucleic acid techniques, including r-DNA and direct injection of nucleic acid into cells or organelles, or ii) fusion of cells beyond the taxonomic family that overcome natural physiological reproductive or recombinant barriers and that are not techniques used in traditional breeding and selection (FAO, 2001).

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