

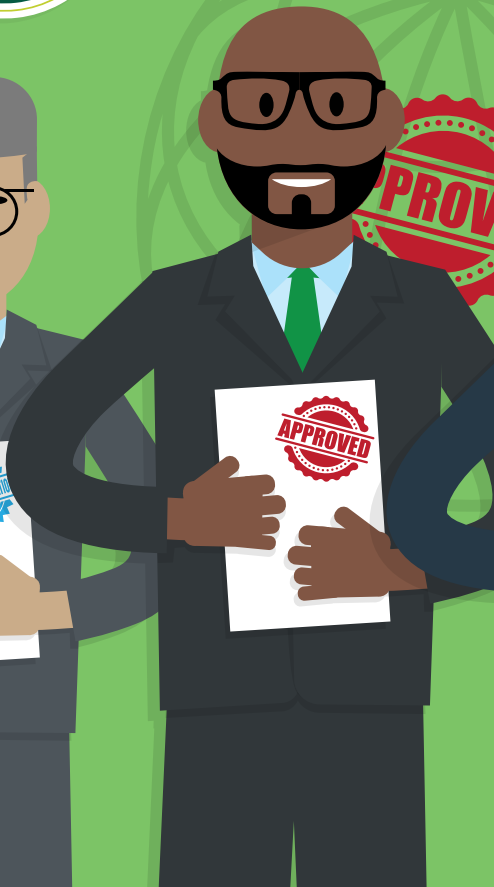


Food and Agriculture
Organization of the
United Nations

Information toolkit on
food biotechnologies
with a focus on
food safety

5

Regulations



Introduction



Tool 5 provides some considerations and examples to deal with regulatory frameworks around food biotechnologies. The examples aim to help users of this toolkit to explain how, why and by whom food biotechnologies are regulated, as well as the purpose of labelling. The first three examples here provided have “food biotechnology products” as the subjects, because governments are responsible for regulating food biotechnology products in general (including GM foods and for example, foods derived from fermentation or genome editing). The last three examples specifically address GM food varieties and GM food labelling, whose information was found to be extremely helpful by the experts’ consultations.

1. Food biotechnology products are regulated to ensure that the foods produced using these technologies are safe for human consumption, animal health and the environment.
2. Each government is responsible for regulating food biotechnology products in their country.
3. Ensuring the safety of food biotechnology products often involves collaboration across multiple government agencies.
4. Approved GM foods may vary from country to country.
5. The status of approval for GM foods varies from country to country.
6. GM food labelling provides information on the method of production.

While information around regulations, legislation and labelling can often already be found on governmental websites, sometimes these texts or formats may not be easy to understand. The examples here provided utilize a simple language and illustrations for effective communication. Regulations differ from one country to another and they may even be different from municipality to municipality. Therefore, it is advisable that texts in the examples target and refer to the different local contexts. Information about intergovernmental efforts and treaties may also be included as a part of the examples. For example, it would be a good idea to highlight the Sanitary and Phytosanitary (SPS) measures (WTO, 2020a) and Technical Barriers to Trade (TBT) agreement (WTO, 2020b) of the World Trade Organization (WTO), which aim to facilitate fair and equitable trading. This tool focuses on regulatory aspects of food safety assessment, but it does not address environmental risk assessments, which are the subject of Tool 7.

Starting from the examples, users can produce their own new materials to introduce regulations and policies on any environmental risk assessment in

their countries. The examples in this tool may be referred to for the regulatory basics of food biotechnologies. Communication materials created using this information, could be shared on platforms including government websites and public education channels. The images alongside the text below can be referred to as example illustrations of how one may present the materials.

Six examples

Food biotechnology products are regulated to ensure that the foods produced using these technologies are safe for human consumption, animal health and the environment

Some people may think that food biotechnology products are regulated because they are unsafe, which is incorrect. They are regulated because, like any other food, they have to be safe to eat, and therefore their safety has to be ensured for human consumption. The information in this tool can be used to dispel this misunderstanding. The first example illustrates why food biotechnology products are regulated, which was suggested to be a key topic to be addressed during the global community meeting of the FAO GM Foods Platform in 2019 (FAO, 2020b).

Food biotechnology products are regulated to ensure that the foods produced using these technologies are safe to eat.

Governments ensure that all foods derived from biotechnologies are safe for human consumption, animal health and the environment. Regulation supports public confidence in the decisions governments make.



Each government is responsible for regulating food biotechnology products in their country

National governments hold the responsibility to regulate food biotechnology products, and the example below illustrates this information by setting who is in charge of regulating food biotechnology products. Given the opportunity to clarify regulatory activities that governments conduct, there may be relevant aspects to highlight other than those listed in the example. There may be countries in which legislations and policies around food biotechnologies are currently being developed or updated. Such countries may like to develop materials that introduce the government efforts to establish regulatory frameworks.

Each government is responsible for regulating food biotechnology products in their country.

Regulations are informed by international standards and guidelines and may include:

- setting health and safety standards
- conducting safety assessments
- communicating with the public.



Ensuring the safety of food biotechnology products often involves collaboration across multiple government agencies

The way food biotechnology products are regulated may vary from one country to another. The example below can be used as a starting point when informing about how food biotechnology products are regulated, and which government agencies are involved. In many countries multiple ministries and competent

authorities are responsible for regulating food biotechnology products, e.g. Ministry of Agriculture, Ministry of Health and the Food Safety Authority. Information may also include clarification of the roles, responsibilities and tasks. In countries where only one government agency is responsible for regulation, information to provide may include regulatory collaborations at the national, regional or global level, as applicable.

Ensuring the safety of food biotechnology products often involves collaboration across multiple government agencies.

Governmental agencies ensure foods derived from biotechnologies are safe for humans and animals to eat, and ensure they are safe for use in the environment.

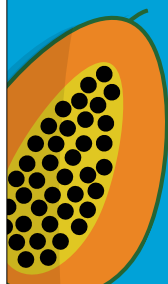


Approved genetically modified (GM) foods may vary from country to country

Different varieties of GM foods may be approved in different countries, and the example below may help users of this toolkit introduce which GM foods are approved for use in their country. The varieties listed in the example are just some of the foods available in some countries. Users may like to refer to the commodities that are popular and often consumed in their country. It is also possible to highlight some varieties that are in the process of being approved for human consumption. The type of approval differs for marketing, importing and cultivation, so communicators may want to distinguish between these. While the text of the example below focuses on GM varieties for human consumption, countries may like to introduce some varieties that are used mainly for animal feed, e.g. corn and sorghum.

Approved GM foods may vary from country to country.

Some authorized GM foods include varieties of corn, soybean, canola, sugar beet, apple, alfalfa, plum, potato and papaya.



The status of approval for genetically modified (GM) foods varies from country to country

The timing required to approve GM foods, the demands for certain particular foods, and other policy or regulatory issues are different in each country. This may create the situation where a type of GM food approved in one country may not be approved in another. This situation of asynchronous approvals is a management issue rather than a safety issue, because the GM food was already considered safe by one country following Codex guidelines. However, this could be wrongly perceived as a reason to be concerned for health and safety issues between countries.

The status of approval for GM foods varies from country to country. A GM food approved in one country may not be approved in another country.

This is typically because of differences such as the timing of approvals and demand for a particular food in each country.



Genetically modified (GM) food labelling provides information on the method of production

The purpose of labelling GM foods is to provide information about the method of production. GM food labelling is not intended to imply that labelled foods differ in safety from foods that do not carry GM labelling. The example below may help clarifying the rationale behind GM food labelling and to correct any possible misconception. Labelling helps consumers know where their food comes from and how it has been produced. Over the last years, an increasing number of consumers worldwide are showing an interest in obtaining such information. GM food labelling standards and practices vary between countries, e.g. they can be voluntary or mandatory, and criteria and requirements may differ. In some countries, GM foods do not require labelling. As with any food label, GM labels must be truthful and not misleading. Users of this toolkit may use the example below as a starting point to inform about GM foods labels, and they are encouraged to tailor the labelling designs to the actual designs used in their countries so that the audience can become more familiar with the design.

GM food labelling provides information on the method of production.

Even though GM food labelling varies among countries, in all cases labelling should be truthful and not misleading.



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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 genome 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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