



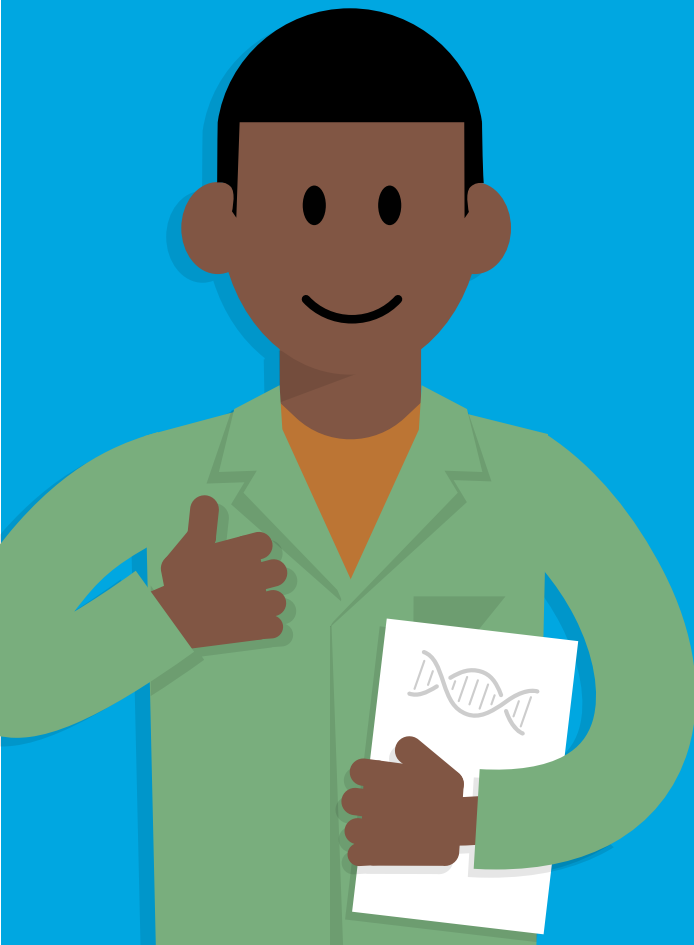
Food and Agriculture  
Organization of the  
United Nations

Information toolkit on  
food biotechnologies  
with a focus on  
food safety

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# Background and guidance

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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

Tool 3: Rationale for potential benefits

Tool 4: GM food safety assessment

Tool 5: Regulations

Tool 6: Human health

Tool 7: The environment

Tool 8: Practical uses and applications

Tool 9: Current innovations

Tool 10: Public engagement

# Introduction



Tool 1 provides general information regarding the background and guidance on food biotechnologies, the safety assessment of foods derived from biotechnologies, and international documents and tools. It contains information on what is meant by food biotechnologies. The principles and guidelines developed through the Codex Alimentarius<sup>1</sup> (FAO and WHO, 2020) are introduced, as well as the FAO GM Foods Platform<sup>2</sup>, an international database where Codex Members can share data and information on the safety assessment of genetically modified (GM) foods. A list of publications is available in the References section that could be used to develop further understanding of the internationally recognized frameworks related to the safety assessment of foods derived from biotechnologies. The following topics are addressed.

1. Food biotechnologies encompass a wide range of biotechnologies.
2. The Codex Alimentarius Commission has been setting international food standards since 1963.
3. The Codex Alimentarius Commission developed principles and guidelines for food safety assessments.
4. Risk managers use risk assessment results to make decisions.
5. The FAO GM Foods Platform is a global online resource that shares information on the GM food safety assessment.

Information in Tool 1 is suitable to be used as a starting point in the communications with the general public, who may have limited technical and scientific knowledge. The information can also help when raising awareness and introducing the topic with policy makers and high-level government officials.

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<sup>1</sup> Principles and guidelines developed through the Codex Alimentarius are available at: <http://www.fao.org/fao-who-codexalimentarius/committees/committee/related-standards/en/?committee=TFFBT>

<sup>2</sup> The FAO GM Foods Platform is available online at: <http://fao.org/gm-platform>

# Five examples

## Food biotechnologies encompass a wide range of biotechnologies

Food and agricultural biotechnologies encompass more than genetically modified organisms (GMO) or GM foods. They cover a wide range of technologies, from culture, fermentation and mutagenesis, to genome editing. All of those biotechnologies have been applied to a broad range of organisms and in sectors that include crops, livestock, forestry, fisheries and aquaculture, and agro-industry (FAO, 2020a). Food biotechnologies are technological applications that use biological systems, living organisms, or derivatives thereof, to make or modify products or processes for human consumption (CBD, 1992).

When presenting this message, it would be advisable to always introduce and use the terms GMO, GM foods, biotechnology and other technical terms alongside their definitions or explanations (acronyms can be used later as part of a continuous communication product, as in the example below). The Terminology section of the Handbook (FAO, 2021a) and at the end of this tool, and the examples in Tool 2 (FAO, 2021b) may be helpful.

**Food biotechnologies mean any technological applications that use biological systems, living organisms, or derivatives thereof, to make or modify products or processes for human consumption.**

These include technologies other than just GMOs and GM foods.

They encompass a wide range of technologies: from fermentation to genome editing.

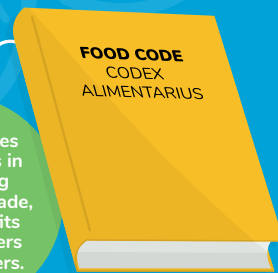
## The Codex Alimentarius Commission has been setting international food standards since 1963

The Codex Alimentarius Commission (Codex) is an international body, jointly managed by FAO and World Health Organization (WHO), that sets food standards. The use of Codex international standards as a basis for national policies, ensures safe foods for consumers and fair practices in the global food trade, which benefits both food producers and consumers (FAO and WHO, 2020).

**The Codex Alimentarius Commission, established jointly by FAO and the WHO, has been setting international food standards since 1963.**

The use of the Commission's standards makes food safe for consumers.

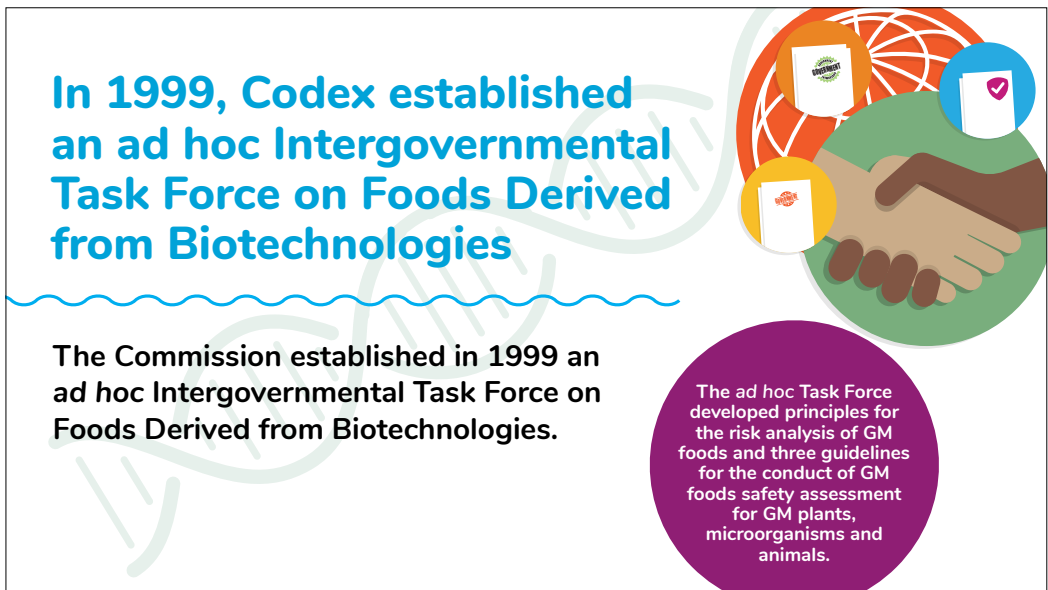
It also ensures fair practices in the growing global food trade, which benefits food producers and consumers.



## The Codex Alimentarius Commission developed principles and guidelines for food safety assessments

When it comes to biotechnology, Codex is primarily concerned with the risk assessment aspects of food safety. Risk assessments include a safety assessment, which is designed to identify whether a hazard, nutritional or other safety concern is present and, if present, to gather information on its nature and severity. In the case of food biotechnologies, safety assessment should include a comparison between the food derived from biotechnologies and its conventional counterpart to determine possible similarities and differences. In 1999, Codex established an ad hoc Intergovernmental Task Force on Foods Derived from Biotechnologies, in which government-designated experts developed standards, guidelines or recommendations for foods derived from biotechnologies or traits introduced into foods by

biotechnological methods. Documents were developed resulting from this task force which discuss principles for the risk analysis of foods derived from modern biotechnology (FAO and WHO, 2011) and guidelines for conducting a food safety assessment of foods derived from recombinant-DNA plants (FAO and WHO, 2008a), recombinant-DNA microorganisms (FAO and WHO, 2003) and recombinant-DNA animals (FAO and WHO, 2008b). Codex texts relevant to labelling foods derived from modern biotechnology were also compiled by another expert group as a useful reference (FAO and WHO, 2010).



**In 1999, Codex established an ad hoc Intergovernmental Task Force on Foods Derived from Biotechnologies**

The Commission established in 1999 an ad hoc Intergovernmental Task Force on Foods Derived from Biotechnologies.

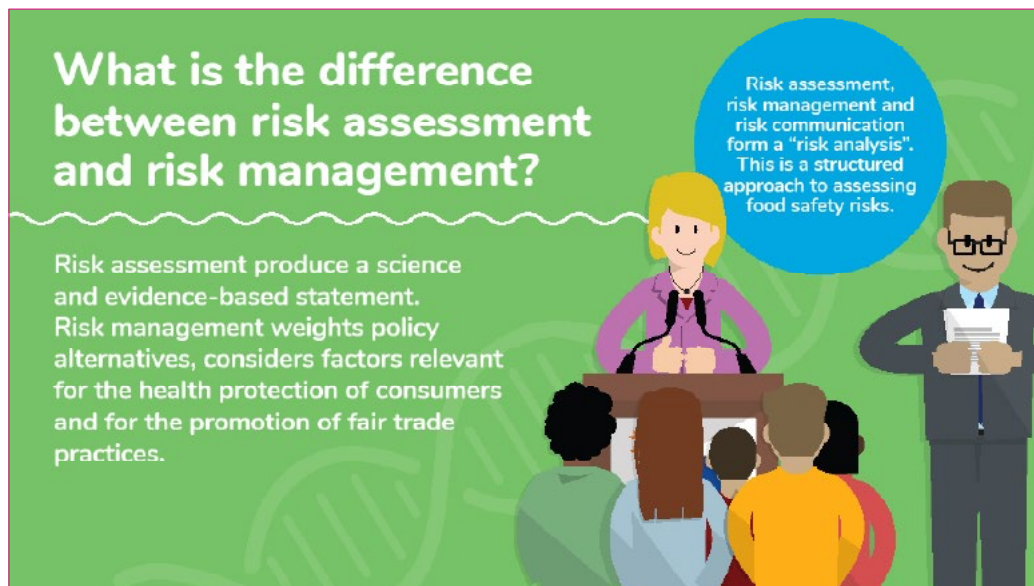
The ad hoc Task Force developed principles for the risk analysis of GM foods and three guidelines for the conduct of GM foods safety assessment for GM plants, microorganisms and animals.

## Risk managers use risk assessment results to make decisions

- **Risk assessments** review evidence, define hazards and evaluate risks with the ultimate goal of producing a science- and evidence-based statement.
- **Risk management** weights policy alternatives in consultation with all interested parties, considers risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selects appropriate prevention and control options.
- **Risk communication** is an exchange of information and opinions throughout the process.

- **Risk analysis** comprises risk assessment, risk management and risk communication. Risk analysis is the structured approach to determine the safety of foods, including for foods derived from biotechnologies.

The Codex Alimentarius Commission Procedural Manual twenty-seventh edition (FAO and WHO, 2019) and the European Food Safety Authority (EFSA, 2013) have produced materials on risk assessment and risk management.



## The FAO GM Foods Platform is a global online resource that shares information on the GM food safety assessment

The FAO GM Foods Platform (FAO, 2020b) is a global online resource where information is shared on safety assessments of foods derived from recombinant-DNA plants authorized in accordance with the Codex Guideline for conducting food safety assessments of foods derived from recombinant-DNA plants (FAO and WHO, 2008a). The Platform also facilitates the effective utilization of food safety assessments in situations of low-level presence (LLP) of recombinant-DNA plant materials in food. The Platform is freely accessible to anyone who wants to browse the information. Registration is required for

those who need to upload information. Only officially nominated Focal Points can register to the Platform, thus only official information/data are shared. As of 30 September 2020, 179 of 188 Codex Members, or 95 percent, have joined the Platform and take part in the community of practice.

## The FAO GM Foods Platform provides information on safety assessment of foods derived from recombinant-DNA plants.

Information on food safety assessments is also available in situations of low level presence (LLP) of recombinant-DNA plant materials in food.

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

The Platform is freely accessible for those who want to browse the information.





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# Terminology

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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).

Food and Agriculture Organization of the United Nations  
FAO-HQ@fao.org  
www.fao.org  
Rome, Italy

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