



GM food safety assessment
tools *for* trainers



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- Principles for the Risk Analysis of Foods Derived from Modern Biotechnology CAC/GL 44-2003
- Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants CAC/GL 45-2003

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- Terms of reference for participant selection
- Workshop preparation checklist
- Sample agenda for 3-day workshop
- Sample workshop evaluation form

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Foreword

The Food and Agriculture Organization of the United Nations (FAO) recognizes that biotechnology provides powerful tools for the sustainable development of agriculture, fisheries and forestry, as well as the food industry. When appropriately integrated with other technologies for the production of food, agricultural products and services, biotechnology can be of significant assistance in meeting the needs of an expanding and increasingly urbanized population in the next millennium.

There is a wide array of "biotechnologies" with different techniques and applications. The Convention on Biological Diversity (CBD) defines biotechnology as:

any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.

When interpreted in this broad sense, the definition of biotechnology covers many of the tools and techniques that are commonplace in agriculture and in food production. Interpreted in a more narrow sense, the definition covers specific technologies such as gene modification and transfer, DNA typing and cloning of plants and animals. The definition of modern biotechnology for the purpose of food biosafety analysis is, however, explicitly used for foods derived from genetic engineering and fusion of cells beyond taxonomic families, as adopted from the Cartagena protocol on biosafety by the Codex Alimentarius Commission (CAC). The definitions of biotechnology and modern biotechnology referred to in this document can be found in the Glossary of the Tool.

While there is little controversy about many aspects of biotechnology and its application, recombinant-DNA derived plants, also referred to as genetically modified organisms (GMOs), living modified organisms (LMOs, under the Cartagena Protocol of CBD), genetically engineered crops and transgenic crops, have become the target of a very intensive and, at times, emotionally charged debate. FAO recognizes that genetic engineering has the potential to help increase production and productivity in agriculture, forestry and fisheries. However, FAO is also aware of the concern about the potential risks posed by certain aspects of modern biotechnology. These risks fall into two basic categories: the effects on human and animal health and the environmental consequences. Care must be taken to reduce the risks of transferring toxins from one life form to another, of creating new toxins or of transferring allergenic compounds from one species to another, which could result in unexpected allergic reactions. Risks to the environment include the possibility of outcrossing, which could lead, for example, to the development of increased plant weediness or wild relatives with increased resistance to diseases or environmental stresses, thus upsetting the balance of the ecosystem. As in the case of growing any improved cultivar with improved traits, biodiversity may also be lost, for example as a result of the displacement of traditional cultivars by a small number of genetically modified cultivars.

FAO supports a science-based evaluation system that would determine the benefits and risks of each individual GMO. This calls for a case-by-case approach to address the concerns regarding the biosafety of each product or process prior to its release. The possible effects on

biodiversity, the environment and food safety need to be evaluated, and the extent to which the benefits of the product or process outweigh its risks must be assessed. The evaluation process should also take into consideration experience gained by national regulatory authorities in clearing such products. Careful monitoring of the post-release effects of these products and processes is also essential to ensure their continued safety to human beings, animals and the environment.

Current investment in biotechnological research tends to be concentrated in the private sector and oriented towards agriculture in higher-income countries where there is purchasing power for its products. In view of the potential contribution of biotechnologies to increasing food supply and overcoming food insecurity and vulnerability, FAO considers that efforts should be made to ensure that developing countries, in general, and resource-poor farmers, in particular, benefit more from biotechnological research, while continuing to have access to diverse sources of genetic material. FAO recommends that this need should be addressed through increased public funding and dialogue between the public and private sectors.

FAO continues to assist its member countries, particularly developing countries, to reap the benefits derived from the application of biotechnologies in agriculture, forestry and fisheries. It also assists developing countries to participate more effectively and equitably in the trade in international commodities and food. FAO provides technical information and assistance, as well as socio-economic and environmental analyses, on major global issues related to new technological developments. For instance, together with the World Health Organization (WHO), FAO provides the secretariat to the Codex Alimentarius Commission (CAC), which has established an *ad hoc* Intergovernmental Task Force on Foods Derived from Biotechnologies (TFFBT). Government-designated experts in the task force will develop standards, guidelines or recommendations, as appropriate, for foods derived from biotechnologies or traits introduced into foods by biotechnological methods. The CAC is also considering approaches that will allow the consumer to make informed choices.

FAO is constantly striving to determine the potential benefits and possible risks associated with the application of modern technologies to increasing plant and animal productivity and production. However, the responsibility for formulating policies towards these technologies rests with the member governments themselves. To be in a position to take full advantage of the technology, countries must have the necessary infrastructure, financial support and expertise. In the case of GMOs, countries will also need to put the necessary regulatory framework in place to minimize potential risks. To this end, FAO provides technical advice for the establishment of appropriate regulatory frameworks in the fields of biosafety, food safety and intellectual property rights.

We welcome comments and feedback on this training tool as part of our ongoing commitment to support member countries to strengthen their capacity to assess the safety of foods derived from modern biotechnology and to manage better all relevant issues in protecting public health, agricultural production and the environment, in the concept of “Biosafety¹ within the Biosecurity² framework” ●

¹ Biosafety is defined as: “Means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health.” UNEP/CBD. 1992. Convention on Biological Diversity: Article 8(g).

² Biosecurity is defined as: “A strategic and integrated approach to analyzing and managing relevant risks to human, animal and plant life and health and associated risks to the environment.” FAO. 2007. FAO Biosecurity Toolkit. ISBN 978-92-5-105729-2.



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Acronyms

AGN	Nutrition and Consumer Protection Division of the FAO
AGNS	Food Quality and Standards Service of the FAO
All	Allergy and Immunology Institute of the ILSI
APUA	Alliance for the Prudent Use of Antibiotics
BCIL	Biotechnology Consortium of India Limited
CAC	Codex Alimentarius Commission
CBAC	Canadian Biotechnology Advisory Committee
CBD	Convention on Biological Diversity
CPB	Cartagena Protocol on Biosafety
Defra	United Kingdom Department for Environment, Food and Rural Affairs
DNA	Deoxyribonucleic acid
EC	European Commission
ELISA	Enzyme-linked immunosorbent assay
FAO	Food and Agriculture Organization of the United Nations
FSANZ	Food Standards Australia and New Zealand
GC-MS	Gas chromatography coupled to mass spectrometry
GLP	Good laboratory practice
GM	Genetically modified
GMO	Genetically modified organism
HPLC	High-pressure liquid chromatography
HPLC-NMR	Liquid chromatography coupled to nuclear magnetic resonance
ICGEB	International Centre for Genetic Engineering and Biotechnology
IFBC	International Food Biotechnology Council
IFBiC	ILSI International Food Biotechnology Committee
IFIC	International Food Information Council
IHCP	The Institute for Health and Consumer Protection of Director General JRC
ILSI	International Life Sciences Institute
INFOODS	International Food Data Systems Project
ISP	Independent Science Panel
JRC	Joint Research Center
LMO	Living modified organism
NDL	Nutrient Data Laboratory of the USDA
NOEL	No observed (adverse) effect level
OECD	Organisation for Economic Co-operation and Development
ORF	Open reading frame
PCR	Polymerase chain reaction
RNA	Ribonucleic acid
SDS-PAGE	Sodium dodecylsulphate polyacrylamide gel electrophoresis
T-DNA	Transfer-DNA

TFFBT	Codex <i>ad hoc</i> Intergovernmental Task Force on Foods Derived from Biotechnologies
Ti	Tumour-inducing plasmid
UN	United Nations
UNIDO	United Nations Industrial Development Organization
USDA	United States Department of Agriculture
US FDA	United States Food and Drug Administration
US NAS	United States National Academy of Sciences
VAD	Vitamin A deficiency
WHO	World Health Organization