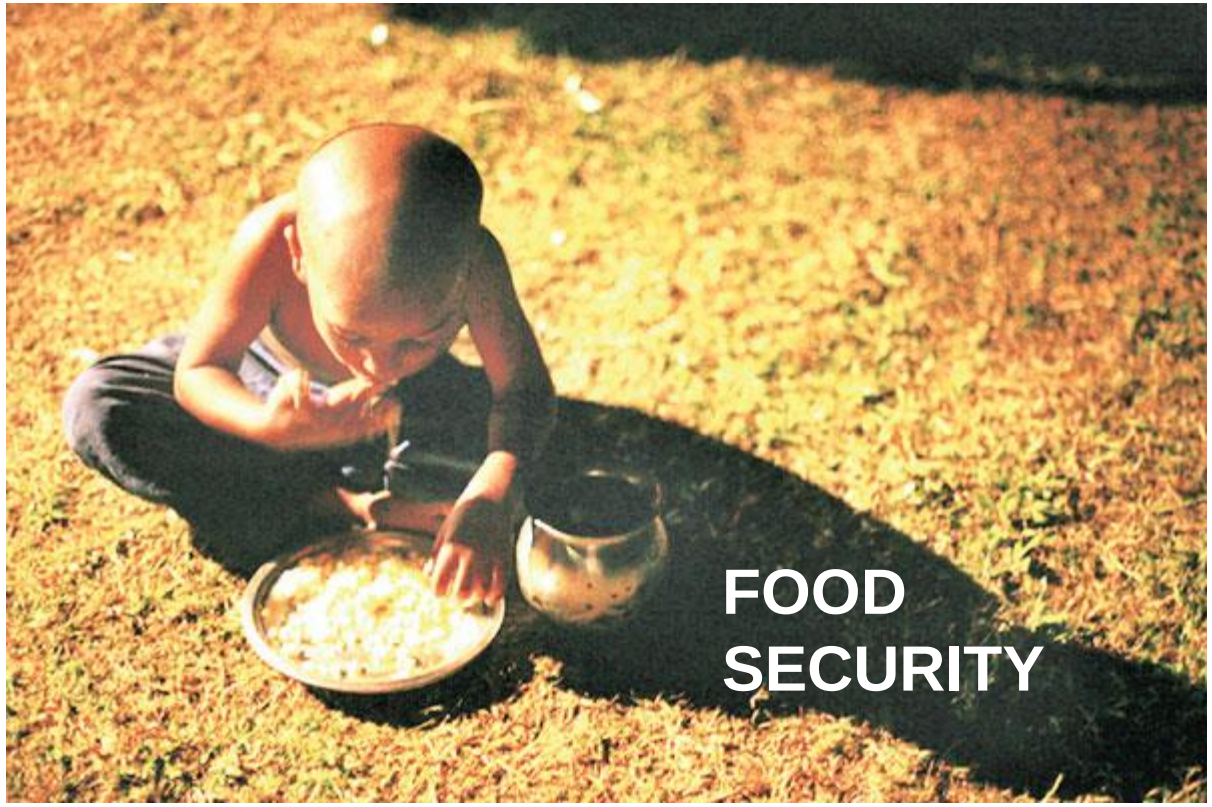
Food and Agriculture Organization of the United Nations

GM food safety assessment and data transportability

MASAMI TAKEUCHI, FOOD SAFETY OFFICER, FAO

28 JUNE 2017

Mandate of FAO



Definition of **food security**

"Food security exists when all people, at all times, have physical, social and economic access to **sufficient**, **safe** and **nutritious** food"

[FAO World Food Summit, 1996]

Food safety and nutrition?

What are they making?

Mud cookies

Food scarcity can coerce populations to consume whatever food is available.

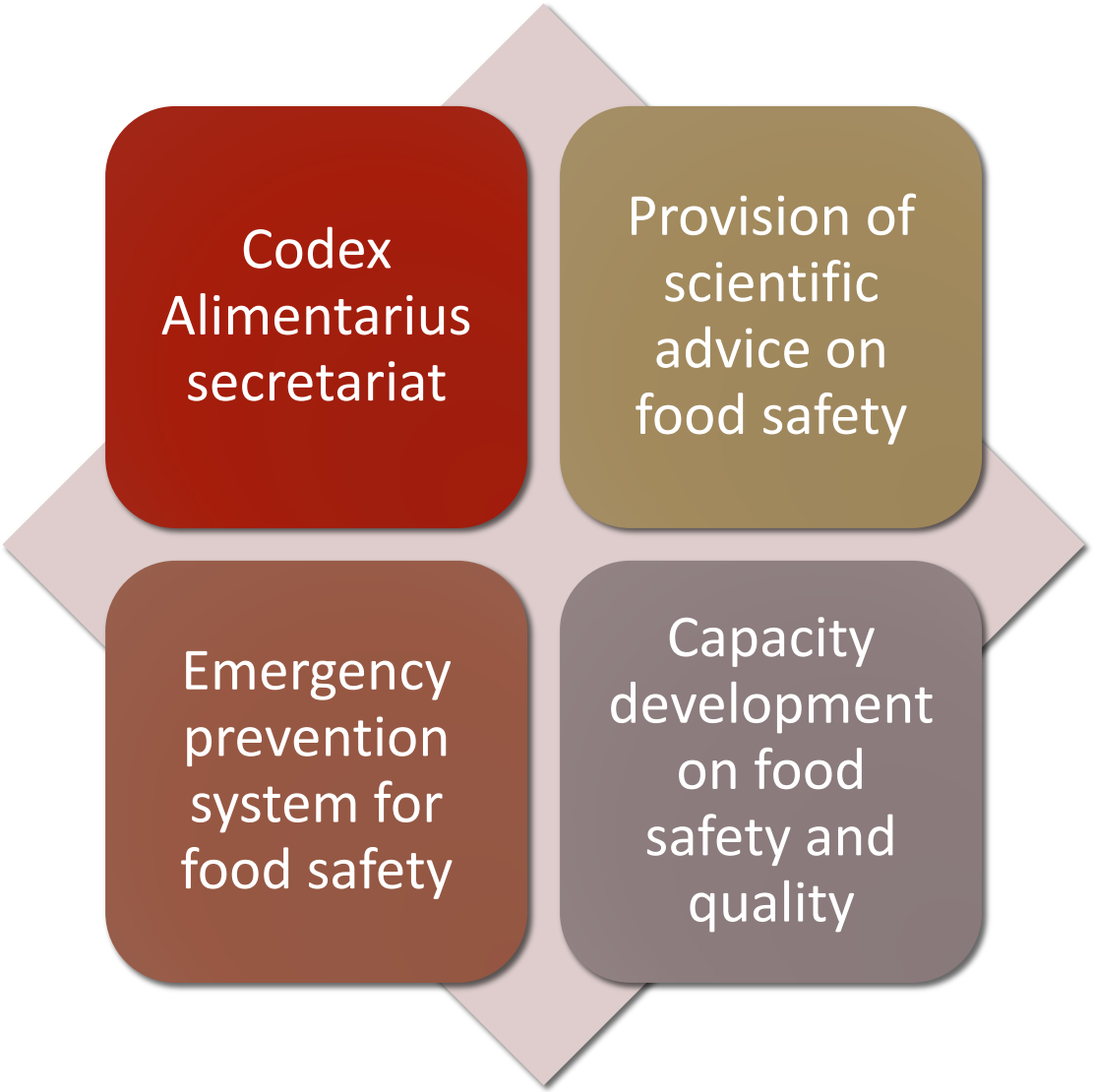
Even if it can be unsafe.

Or possibly contaminated…

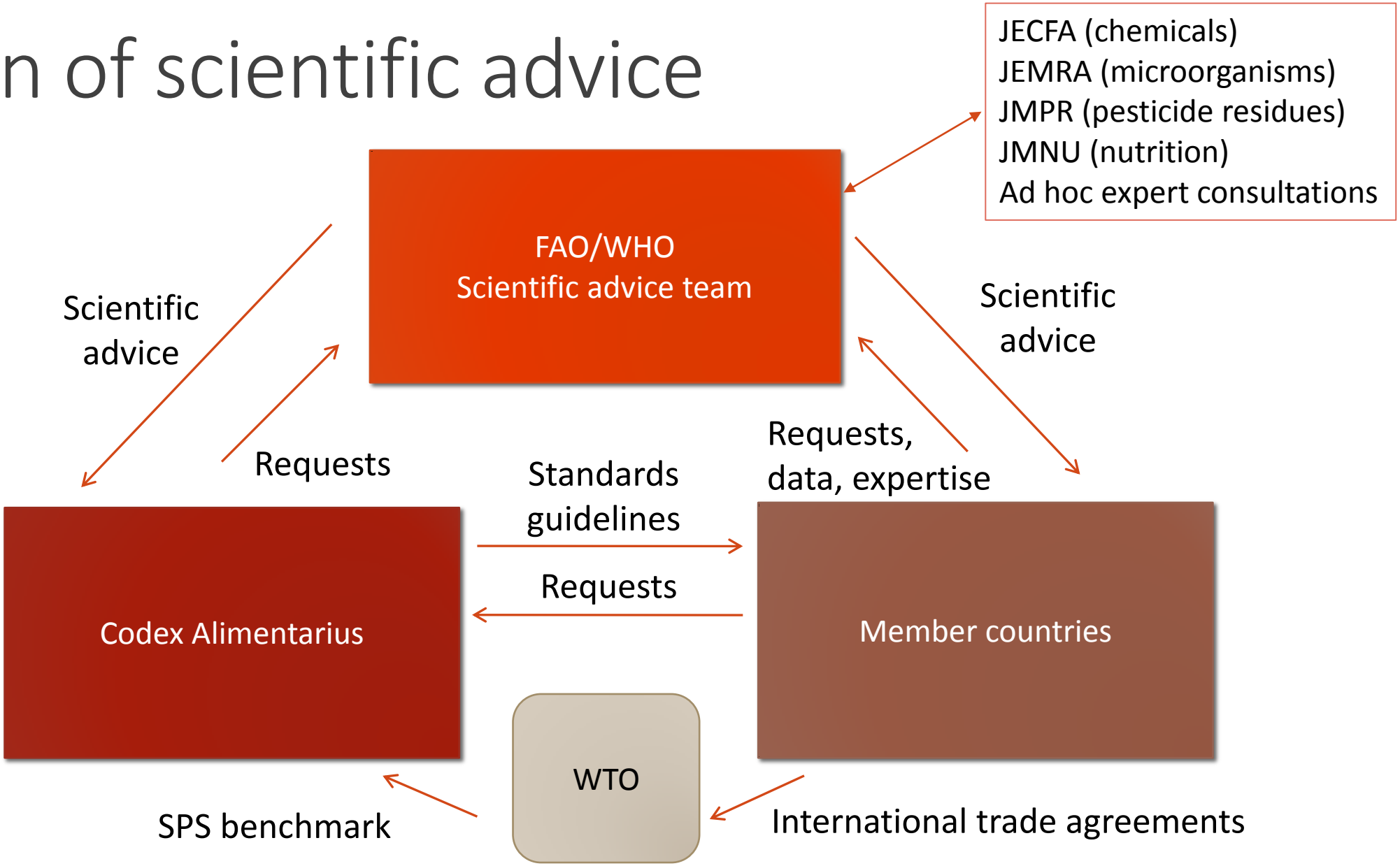
In rare cases, this is valued as a form of culture/traditions.

“ If it’s not safe, it’s not food”

FAO food safety initiatives



Provision of scientific advice



Codex Alimentarius

Intergovernmental food standard-setting body established by FAO and WHO in 1960's

Approx. 190Member Countries + European Union

Approx. 220 Observers

Was established to:

- Protect the health of consumers
- Ensure fair practices in the food trade

http://codexalimentarius.org/

CODEX ALIMENTARIUS

International Food Standards

World Health Organization

Food and Agriculture Organization of the United Nations

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What is the Codex Alimentarius?

The Codex Alimentarius, or "Food

Recent Codex Standards

CAC/GL 2 Nutrition Labelling

Latest news

It's time for fixed definitions for food fraud and food integrity
20 Jun 2017 - We need a food supply system that produces safe food, produces nutritious food, and also [...]

Who is new in the Codex Secretariat?
9 Jun 2017 - Seconded officers provide a valuable contribution to the work of the Secretariat. There are currently five [...]

Codex launches RSS feed for meetings
5 Jun 2017 - Anyone can now follow Codex Alimentarius meetings simply by clicking on the RSS icon. RSS stands [...]

Codex Secretary Tom Heilandt addresses the 85th OIE General Session
24 May 2017 - May 23rd 2017 Paris. World Organisation for Animal Health Speech: Tom Heilandt The actual speech as [...]

Regional Meeting for Near East begins in Rome
15 May 2017 - The regional meetings provide an incredibly important opportunity for dynamic discussion on major and

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List of Codex Committees

All

Codex Alimentarius Commission		
CAC	Codex Alimentarius Commission	Active
Executive Committee		
CCEXEC	Executive Committee of the Codex Alimentarius Commission	Active
General Subject Committees		
CCCF	Codex Committee on Contaminants in Foods	Active
CCFA	Codex Committee on Food Additives	Active
CCFAC	Codex Committee on Food Additives and Contaminants	Renamed and restablished
CCFH	Codex Committee on Food Hygiene	Active
CCFICS	Codex Committee on Food Import and Export Inspection and Certification Systems	Active
CCFL	Codex Committee on Food Labelling	Active
CCGP	Codex Committee on General Principles	Active
CCMAS	Codex Committee on Methods of Analysis and Sampling	Active
CCNFSDU	Codex Committee on Nutrition and Foods for Special Dietary Uses	Active
CCPR	Codex Committee on Pesticide Residues	Active
CCRVDF	Codex Committee on Residues of Veterinary Drugs in Foods	Active
Commodity Committees		
CCCPC	Codex Committee on Cocoa Products and Chocolate	Adjourned sine die

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List of Codex Committees: Dissolved

Dissolved

ad hoc Intergovernmental Task Forces		
TFAF	Ad Hoc Intergovernmental Task Force on Animal Feeding	Dissolved
TFFBT	Ad Hoc Intergovernmental Task Force on Food Derived from Biotechnology	Dissolved
TFFJ	Ad Hoc Intergovernmental Task Force on Fruit and Vegetable Juices	Dissolved
TFPHQFF	Ad hoc Codex Intergovernmental Task Force on the Processing and Handling of Quick Frozen Foods	Dissolved

Updated on: 18-08-2016

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Ad Hoc Intergovernmental Task Force on Food Derived from Biotechnology (TFFBT)

FAO/WHO ID No:	CX-802
Reference:	CX/FBT
Terms of Reference:	Terms of reference (1999-2003): (a) To elaborate standards, guidelines, or other principles, as appropriate, for foods derived from biotechnology; (b) To coordinate and closely collaborate, as necessary, with appropriate Codex Committees within their mandate as relates to foods derived from biotechnology; and (c) To take full account of existing work carried out by national authorities, FAO, WHO, other international organizations and other relevant international fora. Terms of reference (2004-2008): (a) To elaborate standards, guidelines, or other principles, as appropriate, for foods derived from modern biotechnology, taking account, in particular, of the Principles for the Risk Analysis of Foods derived from Modern Biotechnology; (b) To coordinate and closely collaborate, as necessary, with appropriate Codex Committees within their mandate as relates to foods derived from modern biotechnology; and (c) To take account of existing work carried out by national authorities, FAO, WHO, other international organizations and other relevant international fora.
Status:	Dissolved
Host:	Japan

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Status:	Dissolved
Host:	Japan

Related Meetings

Related Standards

Search:

Reference	Title	Last modified	EN	FR	ES	AR	ZH	RU
CAC/GL 44-2003	Principles for the Risk Analysis of Foods Derived from Modern Biotechnology	2011	✓	✓	✓	✓	✓	⊘
CAC/GL 45-2003	Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants	2008	✓	✓	✓	⊘	⊘	⊘
CAC/GL 46-2003	Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombiant-DNA Microorganisms	2003	✓	✓	✓	✓	⊘	✓
CAC/GL 68-2008	Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals	2008	✓	✓	✓	✓	⊘	⊘

Showing 1 to 4 of 4 entries

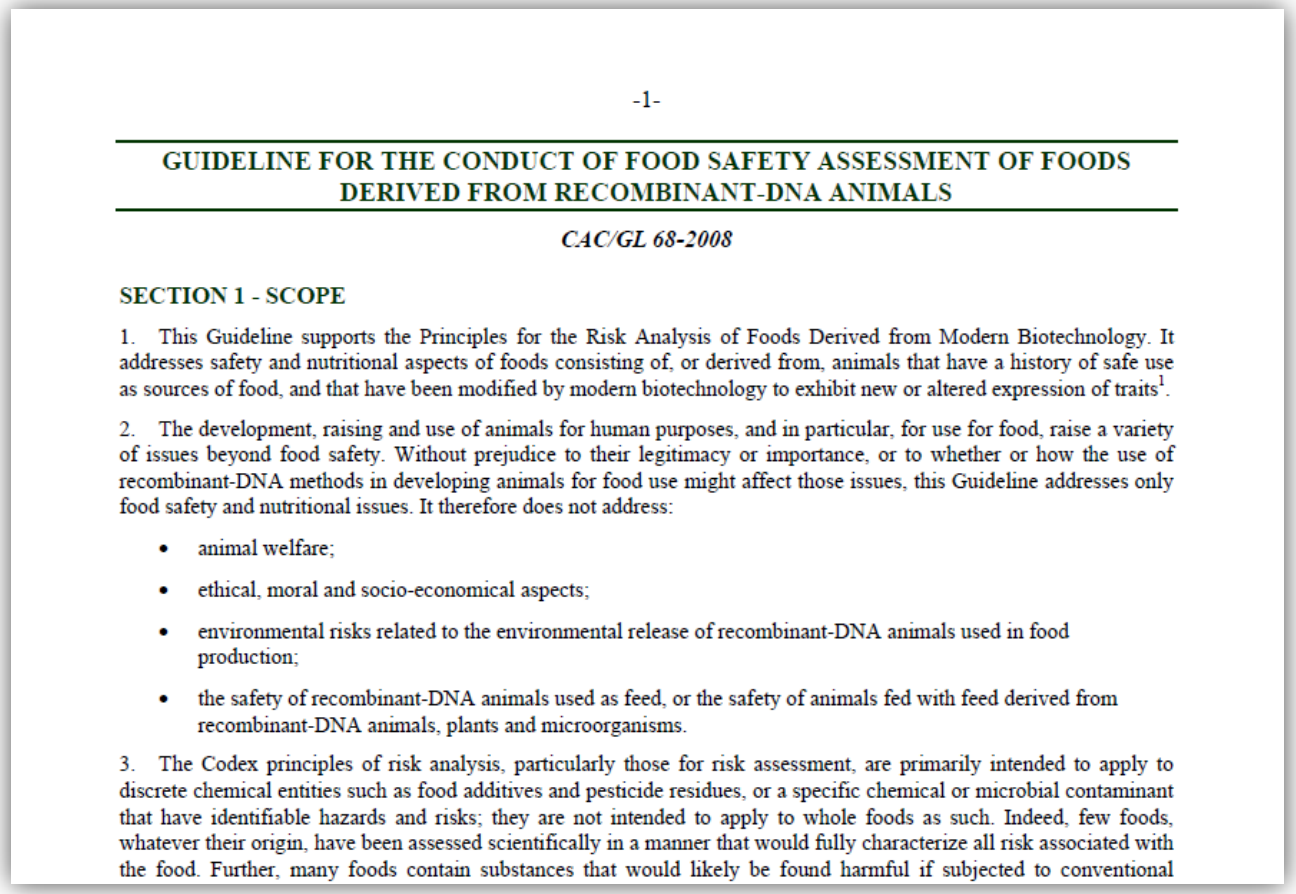
Codex ad hoc intergovernmental task force on food derived from biotechnology

2 terms

- 2000 – 2003 (4 years, 1st – 4th sessions)
- 2005 – 2007 (3 years, 5th – 7th sessions)

4 key documents

- Principles for the risk analysis
- Plants guideline
- Microorganisms guideline
- Animals guideline (including fish)



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GUIDELINE FOR THE CONDUCT OF FOOD SAFETY ASSESSMENT OF FOODS DERIVED FROM RECOMBINANT-DNA ANIMALS

CAC/GL 68-2008

SECTION 1 - SCOPE

1. This Guideline supports the Principles for the Risk Analysis of Foods Derived from Modern Biotechnology. It addresses safety and nutritional aspects of foods consisting of, or derived from, animals that have a history of safe use as sources of food, and that have been modified by modern biotechnology to exhibit new or altered expression of traits[1].

2. The development, raising and use of animals for human purposes, and in particular, for use for food, raise a variety of issues beyond food safety. Without prejudice to their legitimacy or importance, or to whether or how the use of recombinant-DNA methods in developing animals for food use might affect those issues, this Guideline addresses only food safety and nutritional issues. It therefore does not address:

- animal welfare;
- ethical, moral and socio-economical aspects;
- environmental risks related to the environmental release of recombinant-DNA animals used in food production;
- the safety of recombinant-DNA animals used as feed, or the safety of animals fed with feed derived from recombinant-DNA animals, plants and microorganisms.

3. The Codex principles of risk analysis, particularly those for risk assessment, are primarily intended to apply to discrete chemical entities such as food additives and pesticide residues, or a specific chemical or microbial contaminant that have identifiable hazards and risks; they are not intended to apply to whole foods as such. Indeed, few foods, whatever their origin, have been assessed scientifically in a manner that would fully characterize all risk associated with the food. Further, many foods contain substances that would likely be found harmful if subjected to conventional

Guideline for the conduct of food safety assessment of foods derived from r-DNA animals

The development, raising and use of animals for human purposes, and in particular, for use for food, raise a variety of issues beyond food safety.

Without prejudice to their legitimacy or importance, or to whether or how the use of recombinant-DNA methods in developing animals for food use might affect those issues, this Guideline addresses only:

- **food safety** and
- **nutritional issues**.

It therefore does not address:

- animal welfare;
- ethical, moral and socio-economical aspects;
- environmental risks related to the environmental release of recombinant-DNA animals used in food production;
- the safety of recombinant-DNA animals used as feed, or the safety of animals fed with feed derived from recombinant-DNA animals, plants and microorganisms.

General principles and considerations

Conventional foods are generally considered to be safe, if provided properly prepared and handled

Novel foods, including r-DNA foods, are required to undergo mandatory pre-market safety assessment in some jurisdictions

An explicitly cautious approach is applied to foods, such as r-DNA foods with no history of safe use

Safety assessments are undertaken according to 4 key principles:

- Safety assessments use scientific and risk-based methods
- Safety assessments are conducted on a case-by-case basis
- Both intended and unintended effects are considered
- Where exist, comparisons are made with conventional counterparts (comparative approach)

Assessment decisions with respect to safety are based on the totality of the evidence

Essential understanding of safety assessment of r-DNA animals

Food safety assessment approach should take into account all of the following:

- The nature of the r-DNA construct and its expression product(s), if any
- The health status of the r-DNA animals
- The composition of foods produced from r-DNA animals including key nutrients

Two key definitions (in addition to the ones defined for the overall principles and the guideline for r-DNA plants):

- **Recombinant-DNA anima**l: an animal in which the genetic material has been changed through in vitro nucleic acid techniques, including r-DNA and direct injection of nucleic acid into cells or organelles
- **Conventional counterpart**: an animal breed with a known history of safe use as food from which the r-DNA animal line was derived, as well as the breeding partners used in generating the animals ultimately used as food, and/or food derived from such animals

Introduction to safety assessment

No assessment on traditional/conventional food

Issues around safety assessment of a single substance vs. whole foods

Difficulty in applying traditional toxicological tests for whole foods

Substantial equivalence and comparative approach

Unintended effects – focuses, what to look for and how

Framework of food safety assessment (step-wise approach)

General description of the r-DNA animal

Description of the recipient animal prior to the modification and its use as food or for food production

Description of the donor organism or other source(s) of the introduced r-DNA

Description of the genetic modification(s) including the construct(s) used to introduce the r-DNA

Description of the methods used to produce the initial r-DNA animal and the processes to produce the r-DNA animal ultimately used as food or for food production

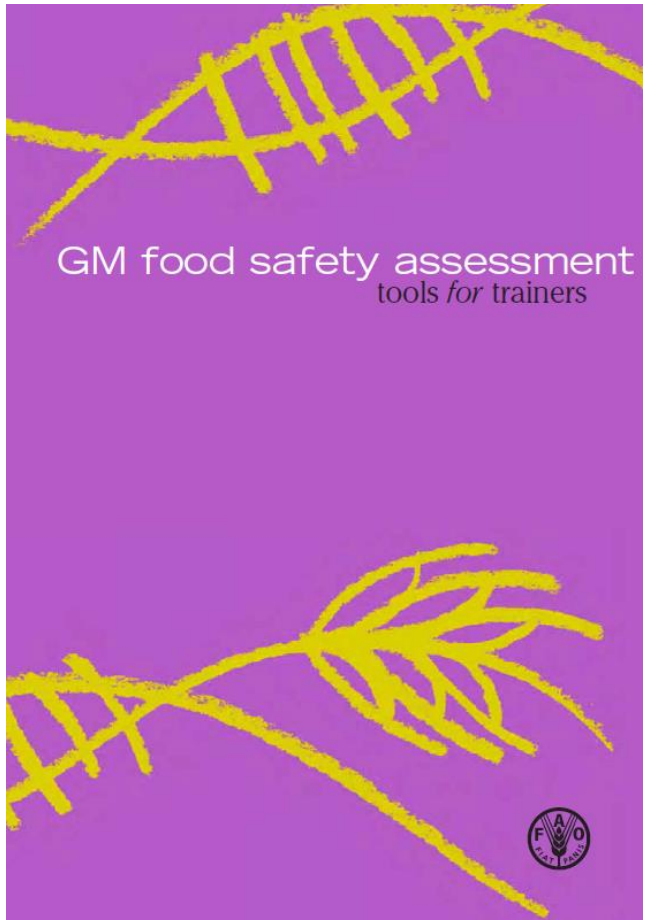
Characterization of the genetic modification(s) in the r-DNA animal ultimately used as food or for food production

Safety assessment:

- Health status of the r-DNA animal
- Expressed substances (non-nucleic acid substances)
- Compositional analyses of key components
- Food storage and processing
- Intended nutritional modification

Other considerations (i.e., allergenicity)

FAO Training tool



FAO GM food safety assessment tools for trainers

Available in English, French and Spanish

Includes relevant Codex guidelines

Training kit CD (agenda template, presentations, worksheets)

3 Example dossiers for GM food safety assessment (plants)

Supported by Canada, Australia and USA

Currently being updated (support from EFSA)

Adding a section on r-DNA animals is being considered

New version will be available in 2018

Data transportability

Plant guidelines Annex III (food safety assessment in situations of low level presence (LLP) of r-DNA plant material in food), Section 3 – guidance on data and information sharing (para 27-29):

27. In order for Codex Members to use this Annex, **it is essential that they have access to requisite data and information**.

28. Codex Members should make available to a publicly accessible central database to be maintained by FAO **information on recombinant-DNA plants authorized in accordance with the Codex Plant Guideline**. (see next slide)

29. This process should facilitate **rapid access by importing Codex Members to additional information relevant to the assessment of food safety assessment** in situations of low-level presence of recombinant-DNA plant material in foods in accordance with this Annex.

Paragraph 28

Codex Members should make available to a publicly accessible central database to be maintained by FAO information on recombinant-DNA plants authorized in accordance with the Codex Plant Guideline. This information should be presented in accordance with the following format:

a. name of product applicant;

b. summary of application;

c. country of authorization;

d. date of authorization;

e. scope of authorization;

f. unique identifier;

g. links to the information on the same product in other databases maintained by relevant international organizations, as appropriate;

h. summary of the safety assessment, which should be consistent with the framework of food safety assessment of the Codex Plant Guideline;

i. where detection method protocols and appropriate reference material (non-viable, or in certain circumstances, viable) suitable for low-level situation may be obtained37; and

j. contact details of the competent authority(s) responsible for the safety assessment and the product applicant.

Questions for you: Food safety assessment data sharing for r-DNA animals

Is safety for human consumption one of the main concerns?

- Scientifically
- Perception-wise

Is food safety assessment data sharing beneficial? If yes, who benefit the most?

Would individual countries make the safety assessment results (summarized version to protect IPR) available to public?

Is standardization of data for the international community possible?

Is it possible or needed to have mutual recognition of food safety assessment among different countries?

Which is better/easier: having bilateral hotline systems to discuss safety assessment results/considerations or having multinational IT-based data/information sharing system?

Merci

¡Gracias

谢谢

Спасибо

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