

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD
HEALTH
ORGANIZATION



JOINT OFFICE: Viale delle Terme di Caracalla 00100 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

AGENDA ITEM NO. 5 (A)

CX/FL 02/05

E

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

**CODEX COMMITTEE ON FOOD LABELLING
THIRTIETH SESSION
HALIFAX, CANADA, 6 - 10 MAY 2002**

**DRAFT RECOMMENDATIONS FOR THE LABELLING OF FOODS OBTAINED THROUGH
CERTAIN TECHNIQUES OF GENETIC MODIFICATION/GENETIC ENGINEERING (DRAFT
AMENDMENT TO *THE GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS*):
DEFINITIONS (CL 2001/22-FL)
GOVERNMENT COMMENTS AT STEP 6**

COMMENTS FROM:

**ARGENTINA
BRAZIL
CANADA
EUROPEAN COMMUNITY
INTERNATIONAL ASSOCIATION OF PLANT BREEDERS (ASSINSEL)
INTERNATIONAL COUNCIL OF GROCERY MANUFACTURERS ASSOCIATIONS (ICGMA)
MALAYSIA
SPAIN
URUGUAY**

DEFINITION OF TERMS (At Step 6 of the Procedure)

For the purpose of these guidelines:

“Food and food ingredients obtained through certain techniques of genetic modification/genetic engineering” means food and food ingredients composed of or containing genetically modified/engineered organisms obtained through modern biotechnology, or food and food ingredients produced from, but not containing genetically modified/engineered organisms obtained through modern biotechnology.

“Organism” means any biological entity capable of replication, reproduction or of transferring genetic material.

“Genetically modified/engineered organism” means an organism in which the genetic material has been changed through modern biotechnology in a way that does not occur naturally by multiplication and/or natural recombination.

“Modern biotechnology” means the application of:

- a. In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or
- b. Fusion of cells beyond the taxonomic family, that overcome natural physiological, reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.

Argentina:

For the purpose of these guidelines:

“Food and food ingredients ~~obtained through certain technologies of genetic modification / genetic engineering~~ **derived from modern biotechnology**” means food and food ingredients composed of or containing genetically modified / engineered organisms obtained through modern biotechnology, or food and food ingredients produced from, but not containing genetically modified / engineered organisms obtained through modern biotechnology.”

“Organism” means any biological entity capable of replication, reproduction or of transferring genetic material

“Genetically modified ~~/engineered~~ organism” means an organism in which the genetic material has been changed through modern biotechnology in a way that does not occur naturally by multiplication and/or natural recombination.

1

“Modern biotechnology” means the application of:

- a. *In vitro* nucleic acid techniques¹, including recombinant deoxyribonucleic acid

(DNA) and direct injection of nucleic acid into cells or organelles, or

- b. Fusion of cells¹ beyond the taxonomic family, that overcome natural physiological, reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.

~~["is no longer equivalent" / "differs significantly" means food or food ingredients obtained through modern biotechnology where a scientific assessment demonstrates, through an appropriate analysis of data, that the characteristics assessed are different in comparison to those of the corresponding existing food or food ingredients, having regard accepted limits of natural variation for that food or food ingredient"]~~

Brazil:

- (a) Brazil supports the text as drafted.
- (b) Brazil suggests to include the definitions "**Gene Technology**" and "**Threshold Levels**".
- (c) **Justification:** the expressions **Gene Technology** and **Threshold Levels** are being used in the Guidelines, without being defined. The inclusion of these definitions would clarify the understanding of the text.

European Community:

The European Community appreciates the considerable efforts that have been undertaken so far towards reaching international agreement on this difficult and complex issue.

The European Community supports the use of the term "genetically modified" throughout the whole of the text. The European Community notes, however, that this terminology is not consistent with the terminology currently used in the work of the Codex Ad Hoc Task Force on Foods Derived from Biotechnology. At its Second Session, the Task Force maintained its preference for the use of the terms "foods derived from modern biotechnology" as it was of the opinion that consistency with other internationally agreed instruments (notably the Cartagena Biosafety Protocol) was critically important in this case. The Task Force recommended that the CCFL should give consideration to using the same definition in its work (ALINORM 01/34A, para 23).

Recalling the extended discussion at the last Codex Committee on Food Labelling (CCFL) in Ottawa, May 1 B 4, 2001, it is obvious that the CCFL will have certain difficulties to achieve consensus on this issue. In general, The European Community is of the opinion that the Codex Alimentarius Commission and its subsidiary bodies should avoid using different terminology as a matter of principle. The CCFL shall however have full discretion for specifying and defining the terms to be used in the actual labelling of foods and to recommend the terms and definitions most appropriate from a labelling perspective. For labelling purposes, it is pertinent to use terms and definitions that are easier for consumers to understand.

Canada:

Notwithstanding the decision at the 24th session of the Codex Alimentarius Commission to return the Definitions to Step 6 for further comments and consideration by the 30th Session of the Codex Committee on Food Labelling in May 2002, Canada supports the Definitions as currently written.

Canada notes that the definition of **Modern Biotechnology**, as submitted to the Codex Alimentarius Commission, is identical to that found in both the *Proposed Draft Principles for the Risk Analysis of Foods Derived from Modern Biotechnology* being developed by the Codex ad hoc Intergovernmental Task Force on Foods Derived from Biotechnology (CTFBT), as well as the *Cartagena Protocol on Biosafety* under the Convention on Biodiversity. With its adoption of this definition, the CTFBT recognized that while consistency between Codex texts is highly desirable, in this case, consistency with other internationally agreed instruments was critically important. It further recommended that the Codex Committee on Food Labelling give consideration to using the same definition in its work.

International Association of Plant Breeders (ASSINSEL):

“No Longer Equivalent” vs “Differs Significantly”

ASSINSEL considers the term “differs significantly” more appropriate since it refers to a scientific and statistical approach. On the contrary, the term “no longer equivalent” is quite vague, and its use could easily lead to the development of trade barriers.

International Council of Grocery Manufacturers Associations (ICGMA):

ICGMA opposes the proposed definition of biotechnology, which is inconsistent and at odds with the definition adopted by the Codex Ad Hoc Intergovernmental Task Force on Biotechnology (at Step 5 in the Codex process). Adopting a different term for labeling would set back the current effort within Codex to create a scientifically supportable and appropriate definition.

The Codex Commission established the Ad Hoc Task Force on Biotechnology to specially address issues for Codex on matters pertaining to biotechnology – including how it is to be defined. The Task Force provides a very precise definition of modern biotechnology that is consistent with the definition used in the Cartagena Biosafety Protocol.

The term “genetically modified/engineered organism,” as used in the labeling document, is scientifically inaccurate for the following reasons: The term “genetic modification” is inaccurate because it technically applies to all forms of genetic manipulation that humans have been practicing on plants, animals, and microorganisms for centuries – including modern day traditional plant breeding.

The use of the terms “organism”, “genetically modified organism”, and “genetically engineered organism” suggest that living organisms of some unusual nature are present in food or food ingredients, and therefore, are confusing and likely to mislead consumers. With very few exceptions, (i.e. yogurt) food does not contain organisms.

Malaysia:

Malaysia is of the view that the definition for “*certain techniques*” should be included in the definition of terms so as to provide consistent understanding of the terms, since at the moment it is subject to interpretation. Although it is clear and understood by the scientific community, for clarity and understanding of the public, Malaysia proposes that the definition of “*certain techniques*” be included in the definition.

In this regard, Malaysia proposes that the definition which was proposed during the early discussions of this agenda item (ALINORM 01/22, Appendix V), be considered. The definition should read as follows:

“Certain techniques” include but are not limited to:

- recombinant DNA techniques that use vector systems
- techniques involving the direct introduction into the organism of hereditary materials prepared outside the organism²
- Cell fusion (including protoplast fusion) or hybridization techniques that overcome natural physiological, reproductive, or recombination barriers, where the donor cells/protoplasts do not fall within the same taxonomic family.

Unless the donor/recipient organism is derived from any of the above techniques, examples of excluded techniques include but are not limited to the following:

- in vitro fertilization
- conjugation, transduction, transformation, or any other natural process,
- polyploidy induction
- mutagenesis
- Cell fusion (including protoplast fusion) or hybridization techniques where the donor cells/protoplasts fall within the same taxonomic family

Spain:

We have the following comment:

We propose to include the following definition regarding “no longer equivalent to/differ significantly”, as in the context of the Proposed Draft Recommendations for the Labelling of Foods obtained Through Certain Techniques of Genetic Modification/Genetic Engineering, this concept is used and should therefore be defined.

We propose therefore the following definition:

“No longer equivalent to / differ significantly”: Means a food or food ingredient obtained through modern biotechnology for which a scientific evaluation demonstrates, through an appropriate analysis of the data, that the evaluated characteristics regarding its composition, nutritive value, metabolism, intended usage and content of undesirable substances are different in comparison to their counterparts in foods or food ingredients already in existence, taking into consideration accepted limits of natural variation for such foods or food ingredients.

Uruguay:

“Organism:” We fully agree with the proposed definition except for the word “reproduction” that is unnecessary. It is similar, in general terms, to the one given under the Biosafety Protocol of the United Nations Environment Program (UNEP).

Genetically modified organism:

We propose using the following definition,

“Is an organism that has a new combination of genetic material obtained through the use of “modern biotechnology”

The proposal in the text is redundant with the definition of modern biotechnology regarding the overcoming of conventional reproductive barriers.

We do not agree with the expression “genetically engineered” as there is no definition of those terms and also because we do not understand how many techniques are covered under such expression.

Modern biotechnology:

The footnotes are considered unnecessary. Furthermore, footnote number 2 introduces two important modifications:

- Because protoplasts are not cells,
- Introducing the concept of hybridization which is not clearly explained (traditional hybridization between plants? of cells?)
- Footnote 2 look more like an option to sentence (b) than a footnote.

We recommend using the exact definition of the Biosafety Protocol:

“Modern Biotechnology” means the application of:

- i. In vitro nucleic acid techniques, including recombinant DNA and direct injection of nucleic acids into cells or organelles, or
- ii. Fusion of cells beyond the taxonomic family, that overcome natural physiological, reproductive or recombination barriers and that are not techniques used in traditional breeding and selection

“Foods or food ingredients obtained through certain techniques of genetic modification”

We do not understand why the word “certain” is used.

It means foods or food ingredients that contain or are made of genetically modified organisms, or foods or food ingredients that are produced from genetically modified organisms but that do not contain them.

We also suggest coordinating the definitions with the Chiba group and other pertinent Codex groups.