CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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AGENDA ITEM NO. 6(a) **CX/FL 11/39/11**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD LABELLING

Thirty-ninth Session

Québec City, Québec, Canada, 9 - 13 May 2011

LABELLING OF FOODS AND FOOD INGREDIENTS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION/GENETIC ENGINEERING:

DRAFT AMENDMENT TO THE GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS: DEFINITIONS (CL 2010/15-FL)

Comments At Step 6

Malaysia
United States
Association of Manufacturers and Formulators of Enzyme Products
Enzyme Technical Association

MALAYSIA

i) Amendments to define "food and food ingredients obtained through biotechnology" for consistency with the terms used in Section 4.2.2 of the General Standard for Labelling of Prepackaged Foods.

Malaysia would like to propose the word "modern" to be inserted before the word "biotechnology" to take into account the intent of the definition which is more specific to modern biotechnology as the word "biotechnology" is too wide and in line with the definition in the Principles for the Risk Analysis of Foods Derived from Modern Biotechnology (CAC/GL 44-2003), as follows:

"Food and food ingredients obtained through ~~certain techniques of genetic modification / genetic engineering~~ ***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.*

ii) Amend the definition for GM/GE in line with the definition in the Principles for the Risk Analysis of Foods Derived from Modern Biotechnology (CAC/GL 44-2003) (CRD 11)

Malaysia is agreeable with the proposal by Japan.

UNITED STATES

The United States is pleased to offer the following comments in response to Codex Circular Letter CL 2010/15-FL regarding the proposed draft amendments to the definition of terms in Section 2 of the General Standard for the Labelling of Prepackaged Foods (ALINORM 10/33/22 paras. 134 to 139 and Appendix IX).

As with the proposed draft Recommendations for the Labelling of Foods and Food Ingredients obtained through Certain Techniques of Genetic Modification/Genetic Engineering (ALINORM 10/33/22 paras. 159 to 161 and Appendix X), the U.S. objects to continuing work on this text. The U.S. recommends discontinuation of work on the "Definitions" as they were developed to apply to a document that is no longer under consideration by the Committee.

Further, the U.S. believes that it would be premature to discuss definitions until any agreement is reached on the draft text that is still under consideration at Step 3 (Recommendations for the Labelling of Foods and Food Ingredients obtained through Certain Techniques of Genetic Modification/Genetic Engineering (ALINORM 10/33/22 paras. 159 to 161 and Appendix X)). The U.S. strongly recommends addressing the need for defining specific, relevant terms and the appropriateness of such definitions only after the consideration of labelling provisions.

At the 38th session of the CCFL the United States and other delegations noted that if a need for a definition exists, the committee could address the issue through a footnote in 4.2.2 of the General Standard for the Labelling of Prepackaged Foods (Codex Stan 1-1985) where biotechnology is mentioned. The footnote could indicate that biotechnology includes modern biotechnology and reference the "Principles for the Risk Analysis of Foods Derived from Modern Biotechnology" since these Principles already defined certain terms of relevance and has been agreed to by the CAC. It should be recognized that the definitions in the document currently at step 6 are not consistent with those in the Risk Analysis document.

SECTION 2. DEFINITION OF TERMS[1]
For the purpose of the General Standard:
"Food and food ingredients obtained through 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.
"Modern biotechnology" means the application of:

[1] The terminology used in this section on definitions should not determine the terminology which is appropriate for use on food labels

a. In vitro nucleic acid techniques[2], including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or
b. Fusion of cells[3] beyond the taxonomic family, that overcome natural physiological, reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.

ASSOCIATION OF MANUFACTURERS AND FORMULATORS OF ENZYME PRODUCTS (AMFEP)

AMFEP (Association of Manufacturers and formulators of enzyme products) would respectfully like to comment on the Draft Amendment to the *General Standard for the Labelling of Prepackaged Foods*: Definitions (para. 139, Appendix IX), which is currently at step 6 of the procedure.

AMFEP is an European non-profit industry association which represents it's member's interests towards international organisations like e.g. various Codex Alimentarious Committees, local authorities and European Institutions. Amfep has a fruitfull co-operation with partner associations in EU, Japan and USA. For further information on AMFEP please see our website http://www.amfep.org.

The members of AMFEP produce and sell enzyme products for use in food manufacturing worldwide, and it is vital for AMFEP and the food industry in general, that the proposed definitions in the Draft Amendment to the General Standard for the Labelling of Prepackaged Foods does not cause confusion that could contribute to creating un-proportional regulatory barriers for the use of enzymes.

Enzymes produced **by** the use of Genetically Modified Microorganisms (GMMs) are produced under contained use conditions and the GMMs are therefore not present in the final enzyme product, and accordingly not in the food in which the enzymes have been used. Enzymes made by use of GMMs under contained used conditions have a long history of safe use – since the beginning of the early 1980's – and are today widely accepted.

The situation in The European Union is that such products are not within the scope of the European GM Food/feed regulation[4] and accordingly need no approval in accordance with this regulation, nor do they need to be labeled as GM product. In annex, for your information a document from AMFEP informing about the European situation:

In the proposed definitions in the Draft Amendment to the *General Standard for the Labelling of Prepackaged Foods*, it is said that:

"**Food and food ingredients obtained through 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.

AMFEP respectfully requests that a foot-note is attached clarifying that substances produced **by** microorganisms under contained use and used as additives or processing aids, including enzymes, are not considered to be in the scope of this definition.

Such clarification would be consistent with the fact that the Codex Alimentarius "Principles for the risk assessment for foods derived from modern biotechnology"[5] says in section 3, art. 13 that ".. the risk assessment approach for these food is based on considerations …taking into account the factors mentioned in the accompanying Guidelines", which are one regarding foods derived from GM plants[6], and one regarding foods derived from GM microorganisms[7].

[2] These include but are not limited to: recombinant DNA techniques that use vector systems and techniques involving the direct introduction into the organism of hereditary materials prepared outside the organism such as micro-injection, macro-injection, chemoporation, electroporation, micro-encapsulation and liposome fusion
[3]Fusion of cells (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

[4] Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22.9.2003 on genetically modified food and feed
[5] Codex Alimentarius guideline CAC/GL 44-2003 – also attached to the mentioned 2008 guideline
[6] Guideline for the Conduct of Food Safety Assesment of Foods Derived from Recombinant-DNA Plants - CAC/GL **45-2003**
[7] 4Guideline for the Conduct of Food Safety Assesment of Foods Derived from Recombinant-DNAMicroorganisms - CAC/GL **46-2003**

The guideline concerning foods derived from GM microorganisms specifically excludes from the scope (section 1, art. 2) "substances produced **by** microorganisms that are used as additives or processing aids**, including enzymes used for food production".**

ENZYME TECHNICAL ASSOCIATION (ETA)

The Enzyme Technical Association (ETA) would respectfully like to comment on the draft Amendment to the *General Standard for the Labelling of Prepackaged Foods*: Definitions (para. 139, Appendix IX), which is currently at step 6 of the procedure.

ETA is a trade association that represents manufacturers and marketers of enzyme products in the United States, Canada and Mexico. The ETA has been in existence since 1970 and has taken an active role in assisting in the development of regulations and policies that affect the enzyme industry. Its membership represents a majority of the North American enzyme industry.

The members of ETA produce and sell enzyme products for use in food manufacturing worldwide, and it is important for ETA and the food industry that the proposed definitions in the Draft Amendment to the *General Standard for the Labelling of Prepackaged Foods* does not cause confusion that contribute to creating regulatory barriers for the use of enzymes.

Enzymes produced **by** the use of Genetically Modified Microorganisms (GMMs) are produced under contained use conditions and the GMMs are therefore not present in the final enzyme product, and accordingly not in the food in which the enzymes have been used. Enzymes made by use of GMMs under contained use conditions have a long history of safe use – since the beginning of the early 1980's – and are today widely accepted.

The situation in North America is that such products do not need to be labeled as GM products.

In the proposed definitions in the Draft Amendment to the *General Standard for the Labelling of Prepackaged Foods*, it is said that:

> "**Food and food ingredients obtained through 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.

ETA respectfully requests that a foot-note is attached clarifying that substances produced **by** microorganisms under contained use and used as additives or processing aids, including enzymes, are not considered to be in scope of this definition.

Such clarification would be consistent with the fact that the Codex Alimentarius "Principles for the risk assessment for foods derived from modern biotechnology"[8] says in section 3, art. 13 that "the risk assessment approach for these food is based on considerations … taking into account the factors mentioned in the accompanying Guidelines," which are one regarding foods derived from GM plants[9], and one regarding foods derived from GM microorganisms[10].

The guideline concerning foods derived from GM microorganisms specifically excludes from the scope (section 1, art. 2) "substances produced **by** microorganisms that are used as additives or processing aids**, including enzymes used for food production"**.

[8] Codex Alimentarius guideline CAC/GL 44-2003 – also attached to the mentioned 2008 guideline
[9] Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants - CAC/GL 45-2003
[10] Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Microorganisms - CAC/GL 46-2003