

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX *Ad HOC* INTERGOVERNMENTAL TASK FORCE ON FOODS DERIVED FROM BIOTECHNOLOGY

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PROPOSED DRAFT GUIDELINES FOR THE LABELLING OF FOOD AND FOOD INGREDIENTS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION/GENETIC ENGINEERING

(At Step 3 of the Procedure)

APPENDIX VI of ALINORM 04/27/22

PURPOSE OF THE GUIDELINES

To provide guidelines to ensure that the labelling of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering provides factual, verifiable, understandable and non-misleading information to protect consumer's health and to ensure fair practices in food trade. Food labelling plays an important role in providing information to consumers and thereby facilitating consumer choice.

These guidelines set out a number of approaches and related information that could be used for the labelling of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering.

1.0 SCOPE

These guidelines recommend procedures for the labelling of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering.

1.1 These guidelines apply to the labelling of such food and food ingredients:

- 1.1.1 when it is demonstrated, through an appropriate analysis of data, that the composition, nutritional value, or intended use of the food or food ingredient differ in comparison to that of corresponding conventional counterparts, having regard to accepted limits of natural variation¹; and /or

¹ This would include products such as oils with altered fatty acid levels, but would not include products such as those with agronomic modifications which contain recombinant DNA and/or protein but no further overall change to composition, nutritional value or intended use.

- 1.1.2 when they are composed of or contain a genetically modified / engineered organism or contain protein or DNA resulting from gene technology²; and/or
- 1.1.3 when they are produced from, but do not contain, genetically modified / engineered organisms, protein or DNA resulting from gene technology.

2.0 DEFINITION OF TERMS³

(At Step 7 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 techniques⁴, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or
- b. Fusion of cells⁵ beyond the taxonomic family,

that overcome natural physiological, reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.

3.0 LABELLING PROVISIONS

In adopting a specific approach to the labelling of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering the following provisions could be used:

3.1 When food and food ingredients obtained through certain techniques of genetic modification/genetic engineering, as defined in Section 2 are [no longer equivalent to / differ significantly] from the corresponding existing food and food ingredients, as regards:

- composition; and/or
- nutritional value; and/or
- intended use;

the characteristics or properties which make it different from the corresponding existing food and food ingredients should be clearly identified on the label as described in Subsection 6.1 on label declarations.

3.2 The presence in any food or food ingredients obtained through certain techniques of genetic modification/genetic engineering of an allergen transferred from any of the products listed in Section

² [Gene Technology: Means a collection of techniques which are used to alter the heritable genetic material of living cell or organisms in a way that does not occur naturally by multiplication an/or recombination]

³ The terminology used in this section on definitions should not determine the terminology which is appropriate for use on food labels

⁴ 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

⁵ 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

4.2.1.4 of the General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985 (Rev.1-1991)) shall be declared⁶

- 3.3 [The presence of substances which may result in physiological or metabolic disorders for certain sections of the population and that are absent in corresponding existing foods[should][shall] be labelled].
- 3.4 In addition to the provisions of Subsection 3.1 to 3.3, when food and food ingredients obtained through certain techniques of genetic modification/genetic engineering as defined in Section 2, are labelled to indicate method of production, labelling declarations should apply (some examples of which are described in Subsection 6.2):
- (a) When they are composed of or contain a genetically modified / engineered organism or contain protein or DNA resulting from gene technology; and/or
 - (b) When they are produced from, but do not contain, genetically modified /engineered organisms, protein or DNA resulting from gene technology even when they do not differ in composition, nutritional value and, intended use.
- 3.5 [Notwithstanding Section 4.2.2.2 of the General Standard⁶, the presence of substances that are absent in corresponding existing food and food ingredients that could be the subject of dietary restrictions, based on religious objections or cultural practices, may be labelled. Where such labelling is used, member countries should establish criteria on how labelling decisions, based on dietary restrictions, will be decided and implemented in a manner that is fair, transparent and consistent.]

[4.0 THRESHOLD LEVELS

- 4.1 Where food and food ingredients obtained through certain techniques of genetic modification/genetic engineering, are labelled to declare the method of production, consideration may be given to:

[Establishment of a threshold level in food and food ingredients for the presence of food and food ingredients obtained from certain techniques of genetic modification/genetic engineering, below which labelling would not apply⁷] and/or

[Establishment of a de minimis threshold level for adventitious or accidental inclusion in food and food ingredients, of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering, below which labelling would not apply]]

[5.0 EXEMPTIONS

- 5.1 Notwithstanding the provisions of Subsection 3.1 to 3.3, consideration may be given to the exemption from labelling of specific categories (for example highly processed food ingredients, processing aids, food additives, flavours) of food and food ingredients obtained through certain techniques of genetic modification / genetic engineering.]

6.0 LABEL DECLARATIONS

In accordance with the General Principles section of the Codex General Standard for the Labelling of Prepackaged Foods and the Codex General Guidelines on Claims, prepackaged food shall not be described on any label or in any labelling or presented in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character or safety in any respect.

- 6.1 Where food and food ingredients obtained through certain techniques of genetic modification/genetic engineering are labelled to indicate final product characteristics, the following

⁶ This provision was adopted at Step 8 by the Codex Alimentarius Commission at its 24th Session (July, 2001)

⁷ Consideration of a threshold must address existing provisions of the *Codex General Standard for the Labelling of Prepackaged Foods*, e.g. Section 4.2.1.3 (Compound Ingredients)

requirements should apply:

- (a) if the composition or nutritional value of food and food ingredients is [no longer equivalent to/ differs significantly] from the corresponding existing food and food ingredients, the label should provide, in conjunction with, or in close proximity to, the name of the food and food ingredients, such additional words or phrases as necessary to inform the consumer as to its changed composition or nutrient content in conformity with Sections 4.1 and 4.2.2 of the General Standard. In addition, nutrient declaration should be provided in conformity with the Codex Guidelines on Nutrition Labelling.
- (b) if the mode of storage, preparation or cooking is [no longer equivalent to / differs significantly] from the corresponding existing food and food ingredients, clear instructions for use should be provided.

6.2 In accordance with Section 6.0 and in addition to the provisions in Subsection 6.1, food labels should be meaningful to the [intended] consumer. Where food and food ingredients obtained through certain techniques of genetic modification/genetic engineering are labelled to declare the method of production, examples of label declaration(s) include but are not limited to:

- (a) ["Produced from genetically modified (naming the source)"] e.g. "produced from genetically modified soya"
- (b) If the ingredient is already listed as produced from the source, ["genetically engineered (naming the food)"], e.g. "genetically engineered maize flour"
- (c) ["Grown from seeds obtained through [modern] plant biotechnology"]
- (d) If the ingredient is designated by the name of a category, ["contains (name of the ingredient) produced from genetically modified (source)"], e.g. starch ("contains starch produced from genetically modified maize")
- (e) ["Genetically engineered (naming the characteristic) (naming the food)"] e.g. "genetically engineered high oleic soybean oil"
- (f) ["Product of plant / animal biotechnology"]
- (g) ["Naming the food/food ingredient (genetically modified)"] e.g. "soybean (genetically modified)"
- (h) ["Naming the food/food ingredient (genetically modified food/food ingredient (not segregated)"] e.g. "soybean (genetically modified soybean not segregated)"
- (i) ["Product of gene technology"]

6.3 Where the presence of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering is declared on the label, the following would apply:

- (a) In the case of single-ingredient foods, or where there is no list of ingredients, the information should appear clearly on the label of the food; or
- (b) In the case of a food ingredient(s) in a multi-ingredient food, the information should be shown in the list of ingredients or in parentheses immediately following the ingredient(s). Alternately, the ingredient(s) may be identified by an asterisk and the required wording should appear in a statement immediately following the list of ingredients.

[7.0 IMPLEMENTATION

Consistent with the approach(es) adopted under Section 3, additional consideration should be given to procedures and methodologies for the identification of food and food ingredients produced using certain techniques of genetic modification/genetic engineering and verification of label declarations. These include, but are not limited to: development of validated detection methods; establishment of verification (for example, documentation) systems; and efforts for the development of supporting capacity and infrastructure.]

[Optional Labelling: Without prejudice to the acceptance of the approach to method of production labelling as a “legitimate concern”* of governments in establishing their national legislation, the following is provided
as optional considerations to member countries:]

[*Statements of Principle Concerning the Role of Science in the Codex Decision-Making Process and the Extent to Which Other Factors are Taken Into Account]