

# CODEX ALIMENTARIUS COMMISSION



Food and Agriculture  
Organization of the  
United Nations



World Health  
Organization

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Agenda Item 2 (CX/FL 19/45/2)

FL/45 CRD/3  
ORIGINAL LANGUAGE ONLY

## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX COMMITTEE ON FOOD LABELLING

Forty-fifth Session  
Ottawa, Canada, 13-17 May 2019

#### MATTERS REFERRED TO THE COMMITTEE BY THE CAC AND OTHER CODEX SUBSIDIARY BODIES

Comments from Dominican Republic, European Union, India, Nigeria, Panama, Thailand, FoodDrinkEurope

#### DOMINICAN REPUBLIC

##### CCFH

Comité del Codex sobre Higiene de los Alimentos (50.<sup>a</sup> reunión)

Código de prácticas sobre la gestión de los alérgenos alimentarios por parte de los operadores de empresas de alimentos: etiquetado preventivo sobre alérgenos.

Apéndice I.

Anteproyecto de Código de prácticas sobre la gestión de los alérgenos alimentarios por parte de los operadores de empresas de alimentos.

**República Dominicana**, apoya todas las propuestas de párrafos y artículos planteados por la CCFH50, en el Apéndice I, por considerarlas pertinentes al documento propuesto.

##### CCNFSDU

Comité del Codex sobre Nutrición y Alimentos para Regímenes Especiales (40.<sup>a</sup> reunión)

Definición de bioenriquecimiento

Apéndice II - Anteproyecto de definición de bioenriquecimiento

**República Dominicana**, apoya la definición de bioenriquecimiento, al considerar que satisface las necesidades previstas y al igual apoya que esta definición sea incluida en la sección de "**DEFINICIONES PARA LOS FINES DEL CODEX ALIMENTARIUS**" del Manual de Procedimiento del Codex

#### EUROPEAN UNION

*Mixed Competence  
European Union Vote*

##### CCFH

The European Union and its Member States (EUMS) appreciate the work carried out by the Committee on food hygiene (CCFH50) in the field of precautionary allergen labelling. The EUMS are of the opinion that the use of a precautionary allergen labelling needs to be clarified and framed in order to ensure that allergic consumers can benefit from the largest choice of foods.

The EUMS support the proposed definition of precautionary allergen labelling.

With regard to the appropriateness of the use of a precautionary allergen labelling statement, the EUMS are of the view that the proposed code of practice on food allergen management adequately addresses an important issue, namely that certain warning statements such as 'may contain' are present on a number of food labels although no assessments were performed by the food business operator of the likelihood of the accidental presence of the allergen in question in the food and of the risk to consumers. This practice unnecessarily limits food choices to allergic consumers.

Finally, the EUMS wish to note that the terms of reference of the request from CCFH to FAO/WHO *for scientific advice on risk assessment of food allergens* also comprises the setting of threshold levels for the "priority allergens" below which the majority of allergic consumers would not suffer an adverse reaction. The allergens considered as priority correspond to the food and ingredients known to cause hypersensitivity listed in point 4.2.1.4 of the General Standard for Labelling of Prepackaged Foods, with the exception of sulphites. In this regard, the EUMS would like to note that the discussion paper on allergen labelling (under Agenda Item 8) to be discussed at the 45<sup>th</sup> session of CCFL recommends to request a scientific advice from FAO/WHO to the list of foods and ingredients in section 4.2.1.4. and in particular, on whether there are new foods and ingredients that should be added to the list.

## CCNFSDU

### Definition for biofortification

*Mixed Competence  
European Union Vote*

CCNFSDU40 agreed to: **(i)** hold the definition for biofortification at Step 4; and **(ii)** forward the definition to CCFL and request CCFL:

- To consider if the definition would meet their intended needs; and
- To clarify the intended use of the definition and where the definition would be best placed.

The European Union and its Member States (EUMS) appreciate the potential benefits of 'biofortified' foods, i.e. the improvement of nutritional characteristics of foods by other means than conventional nutrient addition such as by plant breeding. This is especially the case for regions where micronutrient deficiencies represent a public health issue.

The EUMS would like to recall that the Codex Alimentarius Commission approved the new work on the definition for 'biofortification' and endorsed at the same time the recommendation of the CCEXEC70 to request CCNFSDU to clarify how the definition would be used and where it would be best placed. This recommendation was made to address the concern on how the definition would be used in Codex. The EUMS are of the opinion that a clarification on the placement of the definition and how it would be used was a pre-requisite for meaningful discussions on the development of a definition. However, CCNFSDU has not been able to agree on this issue given the lack of clarity on the expected objective of the exercise.

The EUMS are of the view that CCFL should first discuss the scope and the objective of defining the term 'biofortification' and how it would be used before considering the proposed definition from CCNFSDU. It is indeed very challenging to define and find a consensus on a term in the absence of a clear scope and objective. Furthermore, 'biofortification' is a complex issue that would be captured with great difficulties in the context of a definition.

The EUMS note that the term "biofortification" is not used in any of the Codex texts adopted or texts in the step process that are under the remit of CCFL. Consequently, the EUMS have not identified needs for a definition of the term "biofortification" in the context of CCFL.

The EUMS also note that the text of the proposed draft definition has limited value in terms of labelling harmonisation since the text is so broad that it does not allow to understand which products would be considered as 'biofortified', it allows Member governments to use equivalent terms that are not identified in the proposal and that the process covered by the definition have to be determined by competent national/regional authorities.

While the EUMS have not identified a Codex text where the definition of 'biofortification' could be used, the EUMS note that the concept of 'biofortification' is part of the broader concept of fortification.

## INDIA

### CCFH

India supports the proposal of introducing a “precautionary allergen labelling”, however we do not support text in square bracket in paragraph 72 of Appendix I, which suggests that such labelling can only be used in instances where allergen cross contact cannot be reasonably prevented, therefore putting a restriction on the usage of such labelling. We believe that the precautionary labelling is for safeguarding the consumers and that not using such labelling due to the above restriction may put consumer’s health at risk. Therefore, we propose to delete the text in square brackets

## NIGERIA

Considering the request of CCFH 50 to seek advice of CCFL on;

the appropriateness of the use of a precautionary allergen labelling statement and definition

- (i) the list of foods which cause allergic reactions (see Appendix I to this document),

Nigeria wishes to submit the following considerations;

#### 14. Hazard characterization

[In some instances, it may not be possible to prevent cross-contact, despite the implementation of preventive measures and GHPs, and in such situations, the application of a precautionary allergen statement such as “may contain” is substantiated. However, it may be possible to minimize cross contact to an extent that the amount of allergen present due to cross-contact is below a threshold that could cause an adverse reaction in the majority of consumers allergic to the specific allergen. In these instances, the use of scientifically based threshold levels is a tool to evaluate risk for consumers with food allergies. Threshold levels can be used to reduce precautionary allergen labelling, in turn making precautionary labelling much more meaningful for consumers with food allergies].

***Nigeria agrees that the square bracket in Hazard characterization be removed and the statement be retained.***

#### 2.3 Definitions

**[Precautionary allergen labelling means a label indicating the allergens (other than those that are listed as ingredients) that may be present in the product because of unavoidable cross-contact (e.g. “may contain”).]**

***Nigeria agrees that the square bracket in the definition be removed and the statement be retained.***

#### 5.2.1.4 Monitoring and verification

72. [There should be a regular review of suppliers to ensure that all ingredients, including multi-component ingredients (e.g. sauces, spice mixes), processing aids, or operations, have not changed in a manner that introduces a new allergenic ingredient or that results in allergen cross-contact. **Manufacturers should verify that precautionary allergen labelling is only applied in instances where allergen cross-contact cannot be reasonably prevented (e.g. disassembly of equipment that results in major loss of production time) through GHPs and when such cross-contact could present a risk to allergic consumers.** Periodic product testing for undeclared allergens may also be considered.]

***Nigeria suggests that Periodic Product Testing for undeclared allergens shall be considered because of the severity of allergic reaction in some sensitive individuals/consumers.***

#### 9.3 Labelling

160. [Precautionary allergen labelling should only be used after an assessment of the likelihood of allergen cross-contact has been carried out and a risk to consumers has been identified. Following risk assessment, all possible mitigation measures available to eliminate the likelihood should be explored prior to the use of a precautionary allergen label. Precautionary allergen labels that are necessary following this process can help inform FBOs and consumers on the likelihood that the products might contain an allergen (other than those that are listed as ingredients) in situations where:

- Allergen cross-contact for a specific food cannot be prevented using GHPs;
- Allergen cross-contact occurs sporadically; and
- The allergen may be present at levels that, based on an assessment of risk, could result in adverse health consequences to the majority of allergic consumers.]

***Nigeria agrees that the square bracket be removed and the statement be retained.***

**Paragraph 9 from the Proposed draft code of practice on food allergen management for food business operators (list of foods which cause allergic reactions)**

9. [While many different foods can cause allergic reactions in susceptible individuals, the majority of food allergies on a global basis are caused by a variety of proteins in eight foods/ food groups (and derived products). These are:

- cereals containing gluten (i.e., wheat, rye, barley, oats<sup>2</sup>, spelt or their hybridized strains and products of these)
- crustaceans;
- eggs;
- fish;
- milk;
- peanuts;
- soybeans; and
- tree nuts]

## PANAMA

### **Observaciones Generales**

Panamá está satisfecho con la aprobación en CAC41 de la adopción de la “revisión de la Norma general para el etiquetado de los alimentos preenvasados (CXS 1-1985): Marcado de la fecha” y con la aprobación del nuevo trabajo sobre “**directrices para el uso de información nutricional en la parte frontal del envase**”. Está muy interesada en apoyar la evaluación de las diversas posibilidades de gestión de riesgos para la reducción de los “**ácidos grasos trans (AGT)**”, el uso de “**declaración de propiedades “libre de ácidos grasos trans**”, y definición de “**perfiles de nutrientes**” pssssa complementar la labor del CCFL sobre el “**etiquetado nutricional en la parte frontal de los envases**”, y el debate sobre el tema de la “**integridad**” y la **autenticidad de los alimentos**” y el “**fraude alimentario**” que adelanta el CCFICS.

Panamá apoya especialmente la solicitud de asesoramiento al CCFL por parte de CCFH50 sobre la pertinencia del uso de una “**declaración de etiquetado preventivo sobre alérgenos**”, la definición correspondiente, y la petición a la FAO/OMS de convocatoria a una consulta de expertos para proporcionar **asesoramiento científico** sobre los “**umbrales para los alérgenos prioritarios**”, en el marco del desarrollo de un “**Código de prácticas sobre la gestión de los alérgenos alimentarios por parte de los operadores de empresas de alimentos**”.

Panamá apoya la decisión en CCNFSDU40 de retener en el trámite 4 el “**anteproyecto de definición de bioenriquecimiento**” con el propósito de que CCFL determinara si la misma satisface las necesidades previstas, aclarara el uso previsto de la definición y su ubicación adecuada.

## THAILAND

### **General Standard for the Labelling of Prepackaged Foods (CXS 1-1985): Date marking**

Thailand has noted the use of the term “date of minimum durability” throughout several Codex Texts and would like to ask if those would be revised accordingly to the recently revised Codex Stan 1-1985.

### **Free trans-fatty acids**

Thailand appreciated the work of CCNFSDU. In addition, we agree with the suspension of the discussion on the draft condition for a claim for “free” of TFAs as there are some regulations implemented currently do not permit the production, import or sale of hydrogenated fatty acids. If such claim was allowed, it could cause confusion to the consumers.

### **Code of Practice on Food Allergen Management for Food Business Operators: precautionary allergen labelling**

Thailand appreciates the work done by CCFH and in principle agrees with the draft Code of Practice. We also noted that the enforcement of this Code can be quite challenging and are of the view that CCFH should carefully consider the implementation issues that may arise, especially the case of developing countries.

For the definition of precautionary allergen labelling, we propose a small amendment as follows: "Precautionary allergen labelling means ~~a label indicating~~ **labelling that indicates** the allergens (other than those that are listed as ingredients) that may be present in the product because of unavoidable cross-contact (e.g. "may contain")

We also propose to add this definition, once it is adopted by the Commission, to Codex Stan 1-1985.

Thailand agrees with the labelling provision in paras. 158 and 159 of this Code.

### **Definition of Biofortification**

In principle, Thailand really appreciates the hard work of CCNFSDU in developing the definition of biofortification and thus does not oppose the proposal. Nevertheless, we would like to propose a few amendments.

1. Thailand is of the opinion that the processes of biofortification are very varied and in certain cases may involve genetic modification. Therefore, we would like to propose addition of a footnote to explicitly mention that if genetic modification is involved in the biofortification of a food, by all means it shall undergo safety assessment and be correctly labelled according to relevant laws and regulations of importing countries.

2. Thailand would like to propose addition of "essential" in the definition of biofortification as follows:

"any process other than conventional **essential** nutrient addition to food<sup>3</sup>"

We are of the view that it should be in line with the document this clause is referring to, which is the *General Principles for the Addition of Essential Nutrients to Foods* (CXG 9-1987).

## **FOODDRINKEUROPE**

### **General comments**

FoodDrinkEurope supports the request from CCFH to seek advice of CCFL on the use of a precautionary allergen labelling statement and definition. We also support CCFH's request to FAO/WHO to convene an expert consultation to provide scientific advice on threshold levels for the priority allergens.

### **Detailed comments**

Please find below specific comments to CX/FL 19/45/2 Appendix 1 (suggested amendments highlighted in yellow).

- **Hazard Characterization, Paragraph 14:**

[In some instances, it may not be possible to prevent cross-contact, despite the implementation of preventive measures and GHPs, and in such situations, the application of a precautionary allergen statement such as "may contain **allergen**" is substantiated. However, it may be possible to minimize cross-contact to an extent that the amount of allergen present due to cross-contact is below a threshold that could cause an adverse reaction in the majority of consumers allergic to the specific allergen. In these instances, the use of scientifically based threshold levels is a tool to evaluate risk for consumers with food allergies. **Officially validated** threshold levels can be used to reduce precautionary allergen labelling, in turn making precautionary labelling much more meaningful for consumers with food allergies.]

<i>Rationale:</i> Provide clarity to the text. Add requirement that threshold levels be officially validated.
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- **Section 2.3 Definitions, Paragraph 28:**

[*Precautionary allergen labelling* means a label indicating the allergens (other than those that are listed as ingredients) that may be present in the product because of unavoidable cross-contact (e.g. "may contain **allergen**").]

<i>Rationale:</i> Provide clarity to the text.
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- **Section 5.2.1.4 Monitoring and verification, Paragraph 72:**

[There should be a regular review of suppliers to ensure that all ingredients, including multi-component ingredients (e.g. sauces, spice mixes), processing aids, or operations, have not changed in a manner that introduces a new allergenic ingredient or that results in allergen cross-contact. Manufacturers should verify that precautionary allergen labelling is only applied in instances where allergen cross-contact cannot be reasonably prevented (e.g. disassembly of equipment that results in major loss of production time) through GHPs and when such cross-contact could present a **significant** risk to allergic consumers. **In case of doubt, occasional Periodic** product testing for undeclared allergens may also be considered.]

*Rationale:* Provide clarity to the text. Promoting manufacturers to do periodic testing of 'undeclared' allergens in supplied materials is not appropriate. However, manufacturers and suppliers must work collaboratively, and allergen information provided by suppliers must be reliable and trustworthy.

- **Section 9.3 Labeling, Paragraph 160:**

[Precautionary allergen labelling should only be used after an assessment of the likelihood of allergen cross-contact has been carried out and a **significant** risk to consumers has been identified. Following risk assessment, all possible mitigation measures available to eliminate the likelihood should be explored prior to the use of a precautionary allergen label. Precautionary allergen labels that are necessary following this process can help inform FBOs and consumers on the likelihood that the products might contain an allergen (other than those that are listed as ingredients) in situations where: [...]]

*Rationale:* Provide clarity to the text.