CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 5 **FL/47 CRD06**

Original Language Only

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD LABELLING

Forty-seventh Session

Gatineau, Canada
15 – 19 May 2023

FOOD ALLERGEN LABELLING

(Comments from Burundi, Ghana, Indonesia, Japan, Nigeria, Republic of Korea, South Africa, Uganda, United Republic of Tanzania)

Burundi

Issue 1: Definition
"Food allergy" (New) means "a reproducible adverse health effect arising from an immunoglobulin class E (IgE) antibody or non-IgE antibody immune-mediated response is following oral exposure to a food."

Comment: Burundi supports efforts which have gone towards introducing a new definition for food allergy in the GSLPF. However, Burundi proposes improvement on the definition to read "Food allergy" means a reproducible adverse health effect arising from an immunoglobulin class E (IgE) antibody or non-IgE antibody immune-mediated response following ~~oral exposure to a food."~~**consumption of food.**

Justification: The definition as stated by the EWG does not capture or recognize all forms of feeding such as enteral and parenteral forms of feeding.

Issue 2: List of ingredients 4.2.1.3

Comment: Burundi supports the proposed text on the List of ingredients 4.2.1.3 with the insertions and deletions as followed: Where an ingredient is itself the product of two or more ingredients, such a compound ingredient may be declared as such in the list of ingredients, provided that it is immediately accompanied by a list, in brackets, of its ingredients in descending order of proportion (m/m). Where a compound ingredient (for which a name has been established in a Codex standard or in national legislation) constitutes less than 5% of the food, the ingredients,~~other than~~ need not be declared, except for the foods and ingredients listed in section 4.2.1.4, 4.2.1.6 and where applicable section 4.2.1.5 and food additives which serve a technological function in the finished product, ~~need not be declared~~.

Justification: The changes made allow for the introduction of food allergens to be listed on the label in compound ingredients where food allergens form part of the ingredients. The statement as presented provides clarity on indicating allergens on the label regardless of whether the ingredient constitutes less than 5% of the food or not.

Issue 3: 4.2.1.4
The following foods and ingredients are known to cause ~~hypersensitivity~~ food allergy or coeliac disease[1] and shall always be declared[2] using the name specified:

Comment: Burundi supports the amended text for sections 4.2.1.3, 4.2.1.4, 4.2.1.5 and 4.2.1.6

Justification: The amended texts are based on scientific advice provided by the Ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens (Expert Committee) including the list of ingredients that can cause allergic reactions. Burundi notes that the established criteria of prevalence, severity and potency were primarily applied to IgE-mediated food allergies and coeliac disease, which have well-documented serious adverse public health outcomes. Consequently, the list of priority allergens is represented in section 4.2.1.4, while section 4.2.1.5 includes products that are not listed as priority allergens but may be considered at regional levels as such based on specific populations. Burundi also supports the amended text regarding section 4.2.1.6 as it improves readability and clarity concerning the limit at which added sulphite is declared as an allergen.

Issue 4: Exemption from declaration (new section 4.2.1.7)

Comment: Burundi supports the new provision in section 4.2.1.7, which allows for a generic exemption from labelling of priority allergenic foods. However, this exemption should be treated on a case-by case basis and subject to an established framework for evaluating labelling exemptions for derivatives of priority allergenic foods.

Justification: Regarding ingredients derived from foods on the priority list, some can contain very high levels of protein from the source food, while others may contain almost undetectable levels. This clause allows for flexibility in either increasing or reducing the list in 4.2.1.3 (priority list) based on sound scientific evidence.Therefore, national authorities should use established criteria to determine when an exemption from declaration is appropriate.

Issue 5: Ingredients obtained through biotechnology (section 4.2.2)

Comment: Burundi supports improvement to the text as provided.

Justification: The improvement ensures the lists of food and ingredients in section 4.2.1.4 and new section 4.2.1.5 were referenced.

Issue 6: Ingredient and class names (section 4.2.3 and 4.2.3.1)

Comment: Burundi supports the proposed revised text.

Justification: The proposed changes are minor changes to the GSFLP to reflect the introduction of new sections 4.2.1.5 and 4.2.1.6.

Issue 7: Processing Aids and Carry-Over of Food Additives (section 4.2.4)

Comment: Burundi supports the improvement to the text provided.

Justification: This is consistent with the previous texts to ensure that new sections 4.2.1.6 and 4.2.1.5 are reflected.

Issue 8: Exemptions from mandatory labelling requirements (section 6)

Comment: Burundi agrees with the consistency in referencing the labelling of allergenic foods and ingredients regardless of the size of the package.

Justification: Allergen labelling is a safety issue, and therefore declaration of the allergen is an important requirement for the consumer as it provides valuable information despite the size of the package.

Issue 9: Declaration of certain foods and ingredients (new section 8.3)
Comment: Burundi supports the proposed new provisions in section 8.3 and appreciates efforts made to expound on 8.3.2.1. However, Burundi suggestion is to replace the word **"Contains" with "Allergen (s)".**

Justification: The essence of a food label is to provide consumers with critical information regarding the product. The word "Contains" may not clearly communicate the presence of allergens in the product. Clear indication of known allergens on the label helps consumers make informed decisions about the product and removes ambiguity regarding ingredient(s). Additionally, for some consumer populations, the word "Contains" may be misinterpreted as a positive claim.

Agenda Item 5.2

Issue 1: Purpose, Scope and Definitions

Comment: Burundi supports the proposed text as it clearly defines the intention and scope of applicability of PAL.

Justification: The defined captions provide the industry, relevant authorities and consumers, with information on the unintended presence of allergens despite effective allergen management measures being in place.

Issue 2: General Principles (section 4.3)

Comment: Burundi proposes the amendment of 4.3 to read "PAL shall only be used if the presence of a protein from an allergen is ~~equal to or~~above ~~below~~ the action level for this allergen, using the listed reference dose values (RfD) in 4.3.1.

Justification: If the RfD level is equal or above action level, it implies that the product will cause reaction to consumers and thus at that point the labelling should be to inform consumers of the risk of allergenic reaction rather than precautionary. Precautionary labelling should only be applicable once the detected allergen level is below theRfD. This is directly related to 5.2.1 and should be read together as there is a correlation between 4.3.1 and 5.2.1. Hence, amendment of 4.3.1 implies the statement 5.2.1 "May contain' (or equivalent words) and include the identified allergens using the specified names as listed in sections 4.2.1.4 and where applicable 4.2.1.5 of the GSLPF" is justified.

Issue 3: Presentation of PAL (section 5.2.1)

A PAL statement shall commence with the words 'May contain' (or equivalent words) and include the identified allergens using the specified names as listed in sections 4.2.1.4 and where applicable 4.2.1.5 of the GSLPF.

Comment: Burundi does not support the proposed text with phrase "May contain" in the PAL statement as it suggests that the presence of allergen is unknown and proposes replacing "May contain" with "Allergen".

Justification: If an allergen is detected above the reference dose value and consistent with the criteria for use of PAL as stated in the general principles 4.3 and 4.3.1, then the allergen is present in the food. Therefore, the phrase "May contain" is not communicative when the allergen is present above the dosage level". If Burundi's proposal to change the statement in section 4.3.1 from "above" to "below" is acceptable, then Burundi supports section 5.2.1 as presented by the Committee.

Response to the question of the EWG

Response 1: Location of PAL in the GSLPF and the need to request CCMAS for analytical methods and sampling.

Comment: Burundi agrees to the inclusion of the guidelines as an annex to the GSLPF. Regarding the analytical methods and sampling, Burundi agrees to the recommendation to seek expert advice from CCMAS for methods of analysis for determination of the threshold.

Justification: Inclusion of PAL as an annex to GSLPF is primarily for ease of reference and use rather than as a separate document. CCMAS is the relevant expert committee on methods of analysis; hence the request is within their scope of work.

Response 2: Whether to provide any advice to CCFH to ensure consistency with the Code of Practice on Allergen Management for Food Business Operators (CXC 80-2020)

Comment: Burundi appreciates the recommendation offered by the Committee and recommends that CCFH consider the new definition for food allergen in CXC 80-2022.

Justification: It is a good practice to ensure that there is consistency in Codex text.

Ghana

Section 4.2.1.3

Position: Ghana supports the proposed text.

Rationale: The statement provides a distinction for ingredients that need to be declared when the food contains a compound ingredient which constitutes less than 5% of the food. The distinction brings clarity to labeling requirements for allergens.

New Sections

Position: Ghana supports the introduction of sections 4.2.1.5, 4.2.1.6 and 4.2.1.7. We would however, propose that, "national or regional authorities" be replaced with competent authorities for consistency.

Rationale: The new sections provide options for competent authorities to take make recommendations based on the risk assessment.

Section 8

Position: Ghana supports the introduction of the section

Rationale: Requirement for declaration of allergens is important to ensure consumer safety and therefore necessary in the standard.

Indonesia

PART B – GUIDELINES ON THE USE OF PRECAUTIONARY ALLERGEN LABELLING

PROPOSED DRAFT ANNEX TO THE GSLPF: GUIDELINES ON THE USE OF PRECAUTIONARY ALLERGEN LABELLING	INDONESIA COMMENT
GUIDELINES ON THE USE OF PRECAUTIONARY ALLERGEN LABELLING	Indonesia agrees with the proposed Title for the draft guidelines on PAL.
1. PURPOSE To facilitate a consistent and harmonized approach to the effective use of precautionary allergen labelling (PAL) for communicating to consumers with food allergy about the risk from the unintended presence of allergens in food due to cross-contact.	Indonesia agrees with the proposed Purpose for the draft guidelines on PAL.
2. SCOPE These guidelines apply to PAL when used to indicate the risk from the unintended presence of allergens caused by cross-contact in prepackaged[1] foods. [1] *As defined in the General Standard for the Labelling of Prepackaged Foods (CXS 1-1985)*	Indonesia agrees with the proposed Scope for the draft guidelines on PAL.

PROPOSED DRAFT ANNEX TO THE GSLPF: GUIDELINES ON THE USE OF PRECAUTIONARY ALLERGEN LABELLING	INDONESIA COMMENT
3. DEFINITIONS For the purpose of these guidelines: *Allergen* means the foods and ingredients listed in sections 4.2.1.4 and where applicable 4.2.1.5 of the *General Standard for the Labelling of Prepackaged Foods (CXS 1-1985).* *Precautionary allergen labelling* is a statement made in the labelling of prepackaged foods to indicate a risk from the unintended presence of an allergen(s) due to cross-contact[2] [2]*Allergen cross-contact* as defined in *Code of Code of Practice on Allergen Management for Food Business Operators (CXC 80-2020)*	Indonesia agrees with the proposed Definitions for the draft guidelines on PAL.
4. GENERAL PRINCIPLES 4.1 Effective management practices and controls to prevent or minimize the unintended presence of allergens caused by cross-contact shall be implemented as outlined in the Code of Practice on Allergen Management for Food Business Operators (CXC 80-2020). The use of PAL shall be restricted to those situations in which the unintended presence of an allergen(s) cannot be sufficiently controlled using these allergen management practices.	Indonesia agrees with the proposed principle in section 4.1.
4.2 The decision to use PAL should be based on the findings of a risk assessment which shall include, but is not limited to, quantitative risk assessment.	Indonesia proposes to replace “shall” with “should” and to add “of food allergen” in principle 4.2 as follows: 4.2 The decision to use PAL should be based on the findings of a risk assessment **of food allergen** which ~~shall~~ **should** include, but is not limited to, quantitative risk assessment. Considering the difference of dietary pattern and habits, individual sensitivity and severity to allergen, limited capacity on allergen quantitative analysis, Indonesia proposes that risk assessment of food allergen is not limited to quantitative analysis but also allow qualitative analysis.
4.3 PAL shall only be used if the presence of a protein from an allergen is equal to or above the action level[3] for this allergen, using the listed reference dose values in 4.3.1. [3]Action level (mg total protein from the allergen / kg food) = Reference dose (mg total protein from the allergen) / Amount of the food (kg)	
4.3.1 References doses	

<table>
<tr><th>PROPOSED DRAFT ANNEX TO THE GSLPF: GUIDELINES ON THE USE OF PRECAUTIONARY ALLERGEN LABELLING</th><th>INDONESIA COMMENT</th></tr>
<tr><td>
<table>
<tr><th></th><th>Reference dose (RfD) (mg total protein from the allergen)</th></tr>
<tr><td>Walnut (and Pecan)</td><td>1.0</td></tr>
<tr><td>Cashew (and Pistachio)</td><td>1.0</td></tr>
<tr><td>Almond</td><td>1.0</td></tr>
<tr><td>Peanut</td><td>2.0</td></tr>
<tr><td>Egg</td><td>2.0</td></tr>
<tr><td>Milk</td><td>2.0</td></tr>
<tr><td>Sesame</td><td>2.0</td></tr>
<tr><td>Hazelnut</td><td>3.0</td></tr>
<tr><td>Wheat</td><td>5.0</td></tr>
<tr><td>Fish</td><td>5.0</td></tr>
<tr><td>Crustacea</td><td>200</td></tr>
</table>
</td><td></td></tr>
<tr><td>4.3.2 Where a reference dose is not established for a particular allergen by 4.3.1 above, national authorities can establish a reference dose consistent with recognized principles[4] for the purposes of determining an action level.

4
FAO and WHO (2022). Ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens: Part 2:
Review and establish threshold levels in foods of the priority allergens. https://doi.org/10.4060/cc2946en.</td><td></td></tr>
<tr><td>4.4 PAL should be accompanied by education/information programs to ensure understanding and appropriate use of PAL by consumers, health care providers and food business operators.</td><td></td></tr>
<tr><td>5. PRESENTATION OF PAL</td><td></td></tr>
<tr><td>5.1 Section 8.1.1, 8.1.2 and 8.1.3 and 8.2 of the General Standard for the Labelling of Prepackaged Foods (GSLPF) (CXS 1-1985) apply to PAL labelling.

5.2 PAL should appear as a separate statement in the same field of vision as the ingredient list (when present), and contrast distinctly from surrounding text, such as through the use of font type, style or colour in the same manner as Section 8.3.1 in the GSLPF.

5.2.1 A PAL statement shall commence with the words ‘May contain’ (or equivalent words) and include the identified allergens using the specified names as listed</td><td>Indonesia agrees with the proposed Section 5 for the draft guidelines on PAL.</td></tr>
</table>

PROPOSED DRAFT ANNEX TO THE GSLPF: GUIDELINES ON THE USE OF PRECAUTIONARY ALLERGEN LABELLING	INDONESIA COMMENT
in sections 4.2.1.4 and where applicable 4.2.1.5 of the GSLPF.	

Japan

Proposed draft revision to the *General Standard for the Labelling of Prepackaged Foods* – Provisions relevant to allergen labelling

SUMMARY

This document outlines

1. a proposal to the Committee to, as the next step, begin the discussion of how authorized detection methods for allergen(s) can be established within each country/region when new sections 4.2.1.3 and 4.2.1.4 are incorporated into its national/regional legislation.
2. Introduction of Japan's detection methods for each allergen designated to be labelled mandatorily when 'included' in prepackaged foods for consideration by member countries/regions and NGOs.

INTRODUCTION

Japan appreciates the work of Australia, the UK and the United States in guiding the draft forward to the current state. Japan's comments on the 2023 CL are summarized in CX/FL 23/47/5 Add.1 (Part A), where Japan supports the new sections 4.2.1.3 and 4.2.1.4.

For member countries/regions to promote the effectiveness of such labelling regulation, Japan thinks that it is a good idea to incorporate "authorized detection methods" (ADMs) into the legislation of each country/region, because they would make it easier for food business operators (FBOs) to comply with the regulation, while they would make it easier for national authorities to enforce the regulation. We think that, as a result, this scheme of ADMs enables food allergy patients to gain more accurate information. So, Japan proposes to the Committee, as the next step, to begin the discussion about how ADMs can be established. Japan also would like to introduce its food allergen labelling system based on such detection methods for allergen(s), hoping Japan's experience is helpful anyway to the countries/regions which are going to establish/revise their system of allergen labelling.

BACKGROUND

When Japan firstly introduced the allergen labelling system in 2001, it had already been considered that, for the proper enforcement of such a mandatory labelling regulation system, the establishment of scientific methods to detect allergens within foods is essential. Because it is a mandatory labelling regulation system, it is necessary to enable authorities to apply punishment(s) properly. Furthermore, as the production process of a food product is more and more complex, it is more and more difficult for FBOs to recognize the existence of allergen(s) within the final food product precisely (e.g. cases in which minute amount of allergen(s) is contained within a so-called "compound ingredient"). Therefore, it was also considered that, for FBOs responsible for food labelling to provide consumers with allergen information accurately, they need practical methods to check the existence of allergen(s) by themselves. Detection methods such as an enzyme-linked immunosorbent assay (ELISA) or a polymerase chain reaction (PCR) were investigated as possible ways to provide authorities with scientific evidences.

Based on such considerations, Japan's food allergen labelling regulation system was established, in which the Consumer Affairs Agency (CAA) designates and publishes quantitative and qualitative[1] "authorized detection methods" (ADMs) for each allergen item within mandatory labelling items. Test kits used in ADMs are readily available, and authorities conduct monitoring using ADMs. FBOs also check their products using ADMs by themselves. Note that, in qualitative ADMs, when the detected value of the amount of protein deriving from an

[1] Quantitative ADMs sometimes detect protein that actually derives from other items than the targeted allergen, which results in "false positive". Thus, when the value over 10 ug/g was detected by a quantitative ADM, the qualitative ADM for the targeted item is used to confirm the DNA area that is unique to that item.

allergen ingredient is over 10 ug per 1g of processed food,[2] the result is "positive". If a product is regarded as a violation of the mandatory labelling requirement, authorities apply punishment(s), but because authorities use ADMs in monitoring and inspections, this value of 10 ug/g is important when considering applying punishment(s).

MANDATORY LABELLING AND RECOMMENDED LABELLING/PERIODIC REASSESSMENT

In other words, a food allergen shall not be designated as a mandatory labelling item without the ADMs for that allergen, even if such an allergen is important in view of its frequency, severity, etc. Such allergens are designated as "recommend labelling items" to be labelled voluntarily.

For example, we recently designated 'walnut' as a mandatory labelling item. "Walnut" had been classified as a "recommended labelling" item, but based on the result of the periodic reassessment in 2021, the CAA concluded that walnut should be designated as a mandatory labelling item due to the frequency, severity, etc. of its allergen symptom. Through the necessary procedures for the revision of the "Food Labelling Standards", we took the designation of walnut as a mandatory labelling item into force on March 9, 2023, and on the same date, we published the ADMs for walnut, which was developed accompanying with this policy revision.

Mandatory Labelling Items (8 items): Shrimp, crab, wheat, buckwheat, egg, milk, peanut and walnut
Recommended Labelling Items (20 items): Almond, abalone, squid, salmon roe, orange, cashew nut, kiwi fruit, beef, sesame, salmon, mackerel, soybean, chicken, banana, pork, matsutake mushroom, peach, yam, apple, and Gelatin

The CAA has the periodic reassessment that has been conducted for approximately 20 years every 3 years in which doctors specialized in allergy monitor patients who had symptoms of immediate allergy. 6,080 cases were examined in the latest reassessment in 2021.

DETECTION METHODS

Below you can find Japan's ADMs for all mandatory labelling items (8 items)
(Sorry, only in Japanese available):
https://www.cao.go.jp/consumer/history/02/kabusoshiki/syokuhinhyouji/doc/130530_shiryou2-6-1.pdf

Shrimp and crab are distinguished from each other by name to be labelled. "Crustacean" is not used. The ADMs for shrimp and crab are also distinguished. This is not to narrow consumers' food choices too much. It is reported that over 35 per cent of patients with shrimp allergy do not have the symptom of crab allergy (2005 domestic research report).[3]

So far, the Japanese regulation system has proven to be effective. Notably, more than 20 years have passed since we set the demarcation of positive/negative in qualitative ADMs at 10ug/g, but regarding this value of 10ug/g, there are not strong opinions that a lower value should be adopted to prevent serious food allergy. Japan hopes that its experience is helpful anyway to the countries/regions which are going to establish/revise their system of allergen labelling.

FAO briefly summarizes Japan's experience below (pp.13-19);
https://www.fao.org/3/cb2868en/cb2868en.pdf

PRECAUTIONARY ALLERGEN LABELLING (relating to AGENDA 5.2)

Japan welcomes that the need to seek advice on standardized analytical methods and sampling from CCMAS are to be discussed in Agenda 5.2, wishing the information described above also contributes anyhow to the discussion of Agenda 5.2.

RECOMMENDATIONS

The Committee:

1. Begins the discussion of how ADMs for allergen(s) can be established within each country/region when new sections 4.2.1.3 and 4.2.1.4 are incorporated into its national/regional legislation.

[2] This value refers to the amount of protein deriving from an allergen ingredient within a processed food. It was set as the minimum value which (i) inspection institutes everywhere in the country can apply with sufficient reliability and accuracy, and (ii) can be detected in almost all of food products.

[3] Japanese Journal of Allergology, 55, 1536-1542 (2006)

2. Refers/Considers the experience of member countries/regions who have already implemented ADMs for allergen(s), including 20 years old Japan's case.

Nigeria

FOOD ALLERGEN LABELLING CX/FL 23/47/5

General comment

Nigeria would like to thank Australia, United Kingdom and the United States of America for leading the work of the electronic working group (EWG) on the review of the provisions relevant to allergen labelling in the General Standard for the Labelling of Prepackaged Foods (CXS 1-1985) (GSLPF) and ~~also~~ for developing the guidance on precautionary allergen labelling (PAL).

PART A – REVIEW OF ALLERGEN LABELLING PROVISIONS IN THE GSLPF (APPENDIX I)

- **SPECIFIED NAME**

Para 18 **-** 21. Nigeria supports the use of commonly known name such as "Wheat" as "cereal containing Gluten" in the allergen food labelling instead of using specified name "Gluten"
Rationale: This will provide a better understanding of the source of the allergen to the consumer

- **LACTOSE AND SULPHITES (NEW SECTION 4.2.1.6)**

Para 24. Nigeria supports the removal of 'Lactose' from the revised list of section 4.1.2.4 and the use of common name "Milk" instead of using the specific name containing "Lactose"

Rationale: The use of the term 'Milk' provides a better understanding to a consumer and also acts as a signal for individuals with lactose intolerance.

PART B – GUIDELINES ON THE USE OF PRECAUTIONARY ALLERGEN LABELLING

- **LOCATION OF THE PAL GUIDELINES**

Para 40. Nigeria supports the inclusion of PAL guideline as an Annex to GSLPF
Rationale; For better application to ensure consistency with the document and so that provisions relevant to allergen labelling including PAL are located within the same text.

- **EDUCATION PROGRAMES**

Para 57. Nigeria supports the inclusion of a principle for the use of Education Programs
Rationale: For training to enable countries especially the developing countries to carry out their regional food allergy reference dose.

Republic of Korea

The Republic of Korea proposes the opinion about principle 4.3 in "PROPOSED DRAFT ANNEX TO THE GSLPF: GUIDELINES ON THE USE OF PRECAUTIONARY ALLERGEN LABELLING". Additional review with the advisory committee and other CODEX committees is required because evaluation factors, such as 'age', 'intake' and others, to be considered for establishing Reference Dose(RfD) and criteria(Action Level(AL) 3 times) of Precautionary Allergen Labelling(PAL) may be different by each countries.

South Africa

5.1 Proposed draft revision to the General Standard for the Labelling of Pre-packaged Foods- Provisions relevant to allergen labelling (CX/FL 23/47/5): (Part A)

5.2 Proposed draft Guidance on Precautionary Allergen Labelling (CL/FL 23/47/5): (Part B)

APPENDIX II AND APPENDIX III

Recommendations:
Noting the available scientific advice from FAO/WHO to date and the consumer evidence provided by ISSLG, the Committee is invited to consider:

(a) the overview of EWG discussions in Appendix I

- South Africa supports the overview of the EWG discussions.

Rationale: The work of the EWG was well structured and evidence based.

(b) the proposed draft revision to the GSLPF in Appendix II

- South Africa supports the proposed draft revision to the GSLPF in Appendix II.

Rationale: The draft revision contains appropriate requirements that will assist consumers to make safe food choices, and also increase harmonization and facilitate trade.

(c) the proposed draft guidelines for the use of PAL in Appendix III

- South Africa supports the proposed draft guidelines for the use of PAL in Appendix III.

Rationales:

- Consistent and harmonised approaches to the use of PAL would be helpful in communicating allergen risks and provide more guidance on allergen management to consumers so they can make informed choices when purchasing food products.

- It will also help in ensuring fair trade because currently there is no harmonised precaution allergen labelling since food industry uses various forms of “may contain” statement which are often inconsistent.

(i) the proposed location as an annex to the GSLPF.

- South Africa supports the inclusion of the proposed draft guidelines as an annex to the GSLPF.

Rationale: To ensure consistency with the GSLPF and so that provisions relevant to allergen labelling including PAL are located within the same text.

(ii) the need to seek advice on standardised analytical methods and sampling from CCMAS.

- South Africa agrees that it is always beneficial to seek advice from CCMAS.

Rationale: CCMAS is the only relevant expert Committee on methods and analysis.

(d) whether to provide any advice to CCFH to ensure consistency with the Code of Practice on Allergen Management for Food Business Operators (CXC 80- 2020).

- South Africa agrees that it is necessary to provide advice to CCFH to ensure consistency with the Code of Practice on Allergen Management for Food Business Operators e.g., around definitions of terms such as “food allergy”.

Rationale: Since it is proposed that the GSLPF should include PAL as an Appendix, the Code of Practice on Allergen Management for Food Business Operators should be amended accordingly to ensure consistency.

Specific comments:

PROPOSED DRAFT REVISION OF THE GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS (CXS 1-1985) RELEVANT TO ALLERGEN LABELLING (APPENDIX II)

Section 4.2.1.6*:*

4.2.1.6 When added sulphite is present in a food, and the total concentration exceeds 10 mg/kg, it shall always be declared using the specified name 'sulphite.

- South Africa request clarification for section 4.2.1.6 as to whether the 10 mg/kg is as sold or as consumed.

Rationale: This may cause confusion with products that require preparation (e.g., dry soups and bouillon powder) before consumption.

Section 8.3.2.1:

- South Africa suggests the addition of the word "allergens" after "contains", to help consumers to make safe informed choice about the presence of allergens in a food. The statement should read as follows:

*8.3.2.1 The statement shall commence with the word "Contains **Allergens"** (or equivalent word) and must declare all the foods and ingredients which are declared in the list of ingredients as applicable in accordance with section 8.3.1.*

PROPOSED DRAFT ANNEX TO THE GSLPF: GUIDELINES ON THE USE OF PRECAUTIONARY ALLERGEN LABELLING (APPENDIX III)

Section 4.1:

- South Africa suggests replacing the word "controlled" with "reduced or maintained below the reference dose" as shown below.

Rationale: There may be various interpretations of what "control" means, including whether if PAL is indeed used, then presence of allergens does not need to be controlled.

*4.1 Effective management practices and controls to prevent or minimize the unintended presence of allergens caused by cross-contact shall be implemented as outlined in the Code of Practice on Allergen Management for Food Business Operators (CXC 80-2020). The use of PAL shall be restricted to those situations in which the unintended presence of an allergen(s) cannot be sufficiently ~~controlled~~ **reduced to or maintained below the reference dose** using these allergen management practices.*

Section 4.2:

- South Africa suggests the inclusion of the following text to this section.

*4.2 The decision to use PAL should be based on the findings of a risk assessment which shall include, **where possible and** ~~but is~~ not limited to, quantitative risk assessment.*

Rationale: While quantitative risk assessments should be encouraged, they are not always possible. For example, the limit of quantification for some test methods may be above the reference dose so it is not possible to know whether the level of above or below the reference dose. Calculations are also not always possible given that ingredient suppliers may not always provide information on the level of allergens in their ingredients.

- We are also of the opinion that there should be an information source provided about conducting a Quantitative Risk Assessment (QRA) by food businesses operators. A source such as an expert guidance or interpretation for QRA should be referenced to assist national governments and food business operators in the best practices for conducting a QRA. This would ensure a consistent, robust approach is applied globally.

Section 4.3:
South Africa suggests the inclusion of the following amendment to this section:

*4.3 PAL shall only be used if the presence of ~~a~~ **the total** protein from an allergen is equal to or above the action level for this allergen, using the listed reference dose values in 4.3.1.*

Rationale: The use of "a" implies a single protein. It is recommended to rephrase the clause to echo the units of the reference doses – mg total protein from the allergen.

- South Africa is also of the opinion that Section 4.3 suggests that only a quantitative risk assessment justifies the use of precautionary allergen labelling (PAL). However, the presence of allergen residues in particulate form - which in essence cannot be quantified- may also justify PAL. We would therefore recommend the section to be reworded as follows:

*4.3 **Where all allergens or allergen residues can be quantified**, PAL should only be used if the presence of the total protein from an allergen is equal to or above the action level for this allergen, using the listed reference dose values in 4.3.1.*

Footnote 3, page 16:

- South Africa proposes inclusion of the following amendments to footnote 3:

*"Action level (mg total protein from the allergen / kg food) = Reference dose (mg total protein from the allergen) / ~~Amount of the food~~ **Food exposure amount** (kg)".*

Rationale: It is not clear what is meant by "Amount of the food".

Section 5.2:

- We suggest inclusion of the following amendments to this text, to ensure consistency with similar information.

*5.2 PAL should appear as a separate statement in **immediately proximity after the end of** ~~the same field of vision as~~ the ingredient list (when present), and contrast distinctly from surrounding text such as through the use of font type, style and/or colour ~~in the same manner as Section 8.3.1 in the GSLPF~~. **The same font format used for the allergens in the ingredient list shall be used for PAL**.*

Uganda

The Uganda appreciates the opportunity to provide comments on the different agenda items to be discussed by the 47th Session of Codex Committee on Food Labelling.

AGENDA ITEM 5: FOOD ALLERGEN LABELLING, (CX/FL 23/47/5 (CX/FL 23/47/5 (CX/FL 23/47/5 (Part A) and CX/FL 23/47/5 (Part B))

General comment: Uganda acknowledges the contribution of the EWG on both parts of CX/FL 23/47/5.

Part A
proposed draft revisions to the GSLPF: provisions relevant to allergen labelling

1. comment on:
   i. the proposed draft revision to the GSLPF in Appendix II of CX/FL 23/47/5:

      Position: Uganda supports the new proposed additions and deletions wherever made in the draft revision as presented by the EWG
      Rationale: More clarity will be brought out in the GSLPF.

Part B
proposed draft guidelines on precautionary allergen labelling

1. Comment on:

i. the proposed draft guidelines for the use of PAL in Appendix III of CX/FL 23/47/5, including:
   a) the proposed location as an annex to the GSLPF (i.e. whether the guidelines should be incorporated as an annex to the GSLPF to ensure consistency with the GSLPF).

Position: Uganda proposes that this guideline is annexed to the GSLPF

Rationale: It will ease reference of use by the industry and consumers as well as ensuring consistence with the GSLPF

United Republic of Tanzania

Appendix II

The URT supports the endorsement of the proposed draft revision to the GSLPF

Appendix III
The URT support the proposal of the EWG members to locate the appendix III as annex on the GSLPF.
The URT support the need to seek advice on standardized analytical methods and sampling from CCMAS.

Justification:
To verify the levels of allergens declared in a label of pre-packaged food, a standardized analytical method is essential to protect the health and safety of the consumers.

Advice to CCHF:
The URT recommends that the CCFH should have to consider the work done by CCFL on PAL for consistency purposes.

Justification
The work done by the CCHF on the Code of Practice on Allergen Management for Food Business Operators (CXC 80-2020) is important in protecting consumers, but there are issues concerning allergens that are not similar to those discussed by CCFL in Appendix III something which might confuse the users of the two documents.