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Food Risk Analysis and Regulatory Excellence Platform

UNIVERSITÉ LAVAL | Faculty of Agriculture and Food Sciences

GFORSS | GLOBAL FOOD REGULATORY SCIENCE SOCIETY

ANALYSIS OF AGENDA ITEMS AND PREPARATION FOR THE 47th SESSION OF THE CODEX COMMITTEE ON FOOD LABELLING (CCFL47)

15-19 May 2023, Gatineau, Québec, Canada

Agenda Item 5: Proposed Draft Guidance on Food Allergen Labelling

Objectives

This document offers a review and analysis of the agenda items planned for discussion at the 47th session of the Codex Committee on Food Labelling, scheduled to take place in Gatineau, Québec, Canada from 15 – 19 May 2023.

The document is intended for possible use by the Codex communities of practice promoted by GFoRSS and PARERA, as part of their contribution to enhancing awareness and supporting effective participation in international food standard setting meetings (Codex meetings) by representatives from members and observers.

The analysis provided in this document offers a factual review of agenda items, their background and a discussion of some considerations. This analysis is indicative in nature and does not represent an official position of the organizations mentioned above (PARERA and GFoRSS), their membership or their management.

This analysis is prepared as part of the **Codex Asia Initiative, part of the Codex Outreach Program** implemented by PARERA and GFoRSS, in partnership with Landolakes Venture 37 and ILSI South East Asia, and funded by the US Codex Office, US Department of Agriculture.

**It is important to note that experts – members of the Expert Working Group (EWG) – do not represent the organizations and / or jurisdictions to which they are affiliated. The selection and participation in the EWG proceedings is based on each expert's own credentials and experience which should not be misconstrued as the country's / delegation's / organization's position to which they belong.*

Agenda Item 5: Proposed draft guidance on Food Allergen Labelling

Documents: ***CX/FL 23/47/5***

Status in Codex Step Process: *Step 3*

Background

- CCFL45 agreed to review and clarify the provisions related to allergen labelling in the General Standard for Labelling of Prepackaged Foods (GSLPF) known as CXS 1-1985 and to develop guidance on precautionary allergen labelling (PAL).
- CAC45 noted that this work is to be associated with the work of CCFH on allergen management and that consistency is needed between both texts.
- CCFL45 also requested scientific advice on:
  - the list of foods and ingredients in **section 4.2.1.4 of the GSLPF** (commonly identified in national regulations as **priority allergens**)
- It was noted that CCFH had also requested scientific advice on threshold levels for the priority allergens to support the Code of Practice on Allergen Management for Food Business Operators (CXC 80-2020). This advice may also be useful to CCFL.
- The scientific advice requested was completed by an ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens, which was convened 4 times and issued full reports currently available:
  - Part 1: Review and validation of Codex priority allergen list through risk assessment
  - Part 2: Review and establish threshold levels in foods for the priority allergens
  - Part 3: Review and establish precautionary labelling in foods of the priority allergens – Summary and conclusions
  - Part 4: Review and establish exemptions for the food allergens – Summary and conclusions
- CCFL46 considered draft revisions to the GSLPF and draft PAL guidelines and agreed **to re-establish an EWG chaired by Australia and co-chaired by the UK and the USA** to continue this work**.**

Analysis

- Expected Work from the Committee:

  The Committee is invited to consider:
  - the overview of EWG discussions in **Appendix I**
  - the proposed draft revision to the GSLPF in **Appendix II**
  - the proposed draft guidelines for the use of PAL in **Appendix III,** including: the proposed location as an annex to the GSLPF and the need to seek advice on analytical methods and sampling from CCMAS,
  - whether to provide advice to CCFH supporting consistency with the Code of Practice on Allergen Management for Food Business Operators (CXC 80-2020)
- There has been significant progress on the development of the draft revision of the GSLFP and on the proposed draft guidelines on precautionary labelling.
- The newly available scientific advice offers the needed guidance that enables to update the current provisions of the GSLFP on food allergens and to consider specific guidelines related to precautionary allergen labelling.

- Precautionary allergen labelling has been widely used in food labeling practices for over two decades, yet these practices are not subject to international guidance such as Codex guidance. The proposed **GUIDELINES ON THE USE OF PRECAUTIONARY ALLERGEN LABELLING** would help address this gap.
- Some considerations are to be made to support the development of national positions in relation with the proposed **APPENDIX II (PROPOSED DRAFT REVISION OF THE *GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS* (CXS 1-1985) RELEVANT TO ALLERGEN LABELLING**)

a) The proposed list of priority allergens (identified in section **4.2.1.4** of the allergen labelling provisions) reflects the most up-to-date scientific advice globally and offers change to the list of what was known as "the Big eight".

b) While this list is indeed of global relevance, as established by the scientific opinion provided to CCFL, it may be useful that a mention be made of **the criteria** that led to update this list, as this may support food regulators in their effort(s) to review the adaptability of the ingredients included in this list for their national jurisdictions. A sentence to this effect could be added at the end of the list such as :

"the list of food identified to cause food allergy was set based on a scientific evaluation that considered the criteria of prevalence, severity and/or potency"

c) It is noteworthy that the list of the **new big eight are protein containing ingredients** and that allergic reactions are related to exposure to the protein fraction of these ingredients. Therefore, the trigger of declaration on food labels should be the **deliberate presence of any protein fraction** of these ingredients in the food, as part of the recipe. Any other extract of these ingredients that excludes the protein fraction (e.g. Wheat derived Maltodextrin), should not cause an allergic reaction and would not / should not trigger the mandatory labelling provision, as this would lead to "over labelling" and therefore restrict food choices unduly to allergic consumers. The identification of the protein fraction, as the basis for mandatory labelling, would support a lesser reliance on the process of exemption from mandatory declaration (discussed later) when the ingredient derived from these foods is well known to exclude the protein fraction.

Moreover, the way the mandatory declaration of these ingredients is warranted in section 4.2.1.4 implies that any source of these foods or ingredients are to be declared in the food, regardless of whether this is an intended presence or unintended one (cross-contact). It may be beneficial to explicitly specify that this provision is to be applied in the context of **deliberate addition of the ingredient**.

To account for these considerations, a proposed wording for Section **4.2.1.4** could be as follows:

"The following foods and ingredients are known to cause hypersensitivity: **food allergy or coeliac disease1 when any protein fraction of these foods and ingredients is present as a result of deliberate addition to the food (composition),** and shall, **as result of such presence**, always be declared2 **using the name specified"**

d) Section 4.2.1.5 is an addition to the existing Codex text and offers more guidance on foods known to cause food allergies but not of global relevance, rather of regional importance. However, the way the statement frames the ingredients of this list seems to indicate that only these foods should be considered of regional relevance:

"In addition to the foods and ingredients listed in section 4.2.1.4, national or regional authorities may also require the declaration of any of the following foods and ingredients using the name specified, based on an assessment of risk of food allergy or coeliac disease in their respective population(s)".

It may be beneficial to add, that other foods beyond those included in the list recommended of regional relevance, could be considered for addition to the list requiring mandatory labelling, based **on a risk assessment** by national/regional jurisdictions that **uses the criteria of national /regional prevalence, severity of the reaction induced and/or its potency**, as established by the FAO/WHO ad hoc expert consultation.

e) The list of regional relevance includes "Oats and other *Avena* species (and their hybridized strains) and products thereof". However, based on the scientific evidence available, pure oats are not harmful to food allergic consumers nor to the majority of celiac individuals, therefore it may be useful to remove oats from this list. Reactions to oats, observed both with allergic consumers or with celiac patients is mainly due to issues of cross-contamination with other cereals, such as wheat.

f) In the way the declaration is to be made on food labels, a proposed specified name is listed for the English declaration, based on the common name of the ingredient known to cause the food allergy. **It may be beneficial to provide guidance, that such specified names need to be adapted to regional and national relevance**, supported by evidence that corroborates the way consumers are to refer to the ingredients more commonly.

❖ Other considerations were identified in relation with the new guidance proposed as **Appendix III: (GUIDELINES ON THE USE OF PRECAUTIONARY ALLERGEN LABELLING)**

a) It is appreciated that the guidance proposed relies upon the same definitions adopted as part of CXC 80-2020, ensuring the consistency of Codex texts (e.g., definition of cross-contact)

b) While principle 4.1 addresses situations of over-use of Precautionary Labelling by indicating that 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*", it does not go as far as **to mandate the reliance on these statements** when the conditions of use are encountered or met.

The absence of mandatory requirement to use Precautionary labelling is leading **to a patchwork of regulatory actions internationally,** where some jurisdictions would take recall actions when these statements are missing and the allergen is proven to be present, and others would be silent on the matter. This, in turn is leading to an unpredictable food regulatory environment.

It is the opinion of the expert team developing this analysis, that the guidance for the use of precautionary statements need to be consistent with and mirror that on the labelling of deliberately added ingredients when they have an allergenic potential. The Codex text ought to be directive enough and **mandate reliance upon these statements** when allergen control measures for cross-contact situations conclude to a possible risk for allergic consumers.

A proposed change to the wording of Principle 4.1, based on the above considerations would read:

"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. **When such situations are met, the mandatory declaration of the foods and ingredients warranted by section 4.2.1.4 of the GSLPF shall apply using a Precautionary Allergen Labelling instead of an ingredient declaration. The same would apply for food and ingredients identified in Section 4.2.1.5 where relevant.**"

c) Principle 4.2 offers more guidance as to the requirement of a risk assessment supporting this labelling practice.

It is important that the guidance proposed refers to the way **thresholds or reference doses** are to be applied in supporting the decision to adopt a PAL. However, setting the reference doses as being those recommended by the FAO/WHO expert consultation which used the ED05 approach, would lead to consider that all consumers have the same level of perception of the threshold information relied upon (and have the same level of sensitivity globally). It is suggested that a more flexible approach be adopted in this principle, while ensuring the harmonized practice desired through a Codex guidance.

Reference Doses could therefore be suggested to be those adopted by the Adhoc Expert Consultation, or other reference doses established by national jurisdictions based on their own risk assessments.

It would be however warranted that these RfDs be publicly disclosed when they are different from the recommended ones.

A proposed re-wording of Principle 4.2 could therefore read as follows:

"PAL shall only be used if the presence of a protein from an allergen is equal to or above the action level for this allergen, which is defined as:

Action level (mg total protein from the allergen / kg food) = Reference dose (mg total protein from the allergen) / Amount of the food (kg)

The reference dose may be chosen from the listed reference dose values in 4.3.1 or be developed by national jurisdictions based on their own risk assessments.

Should the Reference Dose chosen by a given competent authority be different from the listed values in 4.3.1, it would need to be disclosed and made available to industry and consumers, with the relevant justification."

d) The provision 5.2.1 states that PAL statements ought to be "may contain" or equivalent words. This provision supposes that all consumers globally would react in the same fashion to this type of statement.

   Other iterations such: "may be present" or similar wording may be adopted, so long that they meet the requirement of being informative to consumers (through documented consumer surveys or studies)

   As a result, it may be recommended to have a more flexible approach indicating that the wording chosen for PAL needs to be validated with consumer behavior data **and may include** the following wording " may contain" or equivalent wording

e) Given that the decision to adopt a PAL on the food label is based on a risk assessment, which accounts for possible occurrence data (level of presence of allergens and their marker protein in prepackaged food), it is important that **guidance be provided** (by CCMAS) on the **performance of food allergen testing methods** to enable access to reliable analytical methods supporting the implementation of this guideline.

Conclusion

Considerable progress has been made in the development of the proposed texts. The analysis provided in this document draws on the experience of various jurisdictions internationally. It attempts to introduce either more clarity or flexibility to the proposed text, considering its global nature.

Based on the comments received, there does not seem to be any polarizing issues in relation with the proposed text. Any consensus reached would constitute an improvement of the way food allergic consumers are informed and therefore protected (particularly in relation with the use of PAL). As a result, delegations are encouraged to support reaching such consensus and enable the recommendation of the possible adoption of this text through the accelerated procedure 5/8.