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European Union comments
CODEX COMMITTEE ON FOOD HYGIENE
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Agenda Item 7: Proposed draft code of practice on food allergen management for food business operators (CX/FH 18/50/7)

Mixed Competence
European Union Vote

The European Union and its Member States (EUMS) would like to thank and congratulate Australia, UK and the United States as chair and co-chairs of the EWG for the development of the first version of a draft code of practice on food allergen management for food business operators.

The EUMS are generally satisfied with this initial draft. While it is acknowledged that the draft code follows the format of the General Principles for Food Hygiene and that the concrete examples given are very useful, some simplification of the text might be considered to facilitate the readability. The EUMS would like to see following specific comments addressed:

- Paragraph 3:
With the increasing health burden posed by food allergen, comes the expectation that FBOs take steps to accurately declare the presence of allergenic ingredients, **prevent** and manage unintended allergen presence and ...
Rationale: One of the objectives pursued is also to prevent the cross-contamination, if possible.
- Paragraph 7:
The EUMS propose to keep the same wording and order of allergenic foods as in paragraph 4.2.1.4 of the “General standard for the Labelling of Pre-packaged Foods”.
Rationale: Clarity and consistency
- Paragraph 8: It is proposed to add "**oats**" when mentioning cereal grains.
Rationale: Even though the text says "such as", oats should be included due to its importance worldwide.

- Paragraph 10: It is proposed to replace the term "undeclared allergens in food" by **unintended presence of allergens**
Rationale: clarity/editorial
- Paragraph 11: It is proposed to rephrase the beginning of the sentence in the following way: "Allergen cross-contact **during food processing** can result from a number of factors ~~in processing foods~~ , ..."
Furthermore it is proposed to add the following:
... "The control measures implemented to **prevent or** minimise cross-contact should be based on risk..."
Rationale: One of the objectives pursued is also to prevent the cross-contamination, if possible. This would also be in line with the proposed wording of paragraph 3.
- Paragraph 13, For retail and food service establishments,
 - 4th bullet point: the EUMS propose the addition of the following wording:
 - Inappropriate flow of **or separation** of operations or improper equipment lay-out.
Rationale: Clarity.
 - 8th bullet point: further information needs to be provided as to what "allergy requirements" a food delivery website needs to communicate. The EUMS suggest that such websites need only declare the presence of allergens.
- SECTION II – SCOPE, USE AND DEFINITIONS
Rationale: Editorial
- Paragraph 15: It is proposed to add the following to the second sentence:
"... and ensure accurate allergenic ingredient declaration."
Rationale: Good allergen management is indispensable for ensuring accurate and correct allergenic ingredient declaration.
- Paragraph 16: It is proposed to add the following in dot no 1:
"Prevent or minimise the potential for cross-contact that is of risk to the allergenic consumer;
Rationale: One of the objectives pursued is also to prevent the cross-contamination, if possible.
- Paragraph 24: the last sentence should be deleted and in section 2.3 a definition of "retail" and "food service" should be added.
Rationale: editorial/consistency
- 2.3 Definitions:
 - The following change is proposed to the definition of: "**Allergen Cross-contact** occurs when an allergenic food or **allergenic ingredients** is unintentionally incorporated into ..."

- The following amendment is proposed: "Allergen Profile: means the food allergens present **via intentional addition as well as those inadvertently present** (or the absence of any allergens) in a food".

Rationale: consistency/clarity/precision

- It is proposed to add the definition of "**precautionary allergen labelling" meaning the labelling indicating the allergens (other than those that are listed as ingredients) that may be present in the product because of unavoidable cross contamination (e.g. may contain).**

Rationale: This concept appears several times in the text; therefore it would be useful to include its definition.

- Paragraph 37, end of 1st sentence: the term “most” should be replaced by “all” to read: “... however, this is not feasible in **all** cases”.
- Paragraph 38: the EUMS suggest the following addition: “...provide sufficient separation to **prevent or** minimize the potential for cross-contact ...”
Rationale: One of the objectives pursued is also to prevent the cross-contamination, if possible. This would also be in line with the previous suggestions on similar wording.
- Paragraph 41: the following sentence should be added at the end of the paragraph: "... **allergenic ingredients while ensuring potential spillage management. Storages containing allergens should be clearly labelled.**"
Rationale: to minimise cross-contact as much as possible.
- Paragraph 47: the EUMS suggest the following addition: “... control allergens by **preventing or** minimising the potential...”. It is also suggested to include an additional bullet point stating: “ **the amount of unintentionally present allergen(s), if any, as notified by the supplier**”.
- Paragraph 49: the following changes are proposed in the second and third bullet points:
FBOs should:
 - Implement effective procedures to **prevent or** minimise allergen cross-contact at those steps
 - Monitor, **and when appropriate document,** control procedures to ensure their continuing effectivenessIt is also proposed to include an additional bullet point with the following wording as this would be an important piece of information:
 - **Notify downstream users in a timely manner of any changes to the allergen profile of the product.**
- Section V, PRINCIPLE: It is proposed to change the text in the following way: "The unintentional presence of allergens in food is minimised by taking preventive measures through GHPs and HACCP-based controls at appropriate stages in the operation".
Rationale: clarity/editorial

- Paragraph 75 : The following changes are proposed:
Retail and food service personnel should ~~ask customers if they have any food allergies, even if they are not told by the customers.~~ **be able to inform on allergenic content of food, when asked by the customers.**
Rationale: the possibility for allergic consumers to be able to ask and receive the information they need, especially as some allergies can trigger serious reactions.
- Paragraph 86: typo: “presenting”
- Paragraph 87 the following change is proposed:
~~Suppliers should have~~ **Manufacturers must ensure that their** suppliers have good allergen management practices to minimise the risk of cross-contact between foods with different allergen profiles.
Rationale: Manufacturers are those who will need the most accurate information possible to ensure appropriate consumer information.
- Paragraph 100: it is proposed to delete the last sentence
Rationale: the code of practice is on food allergen management, not on food allergy management.
- Paragraph 102: it is proposed to add the following bullet points:
"Records could include those for:"
 - **Control of allergen cross contamination SOP**
 - **Order process SOP (how are orders for someone with an allergy handled?/ how are meals made for someone with an allergy)**
 Furthermore, the acronym SOP should be spelled out.
Rationale: completeness.
- Section VI: it is proposed to amend the title in the following way:
"ESTABLISHMENT: MAINTENANCE AND ~~SANITATION~~CLEANLINESS".
Rationale: In certain languages (e.g. Spanish) there is not a term with the same meaning of "sanitation". Therefore it is considered that terms such as "cleaning", "cleanliness" or "cleaning and disinfection" are more appropriate. Consistency with the draft revision of the *General Principles of Food Hygiene* should be ensured.
- Paragraph 115: The EUMS prefer the short original wording subject to the following change: "Manufacturers should develop **validated** cleaning procedures designed to remove food allergens to the extent possible."
Rationale: Cleaning validation is an important aspect but no need to go into further detail.
- Paragraph 125: It is proposed to delete "rapid ATP (adenosine triphosphate)". In addition, the following sentence could be added at the end: "**FBOs shall be aware of that only accredited laboratories have fully validated test methods.**"

- Paragraph 130: The following change is proposed: "Where it is not feasible to assign one individual to prepare an allergenic food (e.g. deveining prawns/shrimps), ensure that the individual's hands are thoroughly cleaned **and when appropriate change clothing** before handling another food."
- **Rationale:** avoid cross contamination.

- **SECTION IX – CONSUMER AWARENESS AND PRODUCT INFORMATION**

The EUMS propose to reverse the order in line with the title of Section IX in the General Principles of Food Hygiene CAC/RCP 1-1969.

Rationale: consistency

- Paragraph 144-145: the EUMS are in favour of paragraph 145, however, it is proposed to replace the last sentence of that paragraph by: **"Nevertheless, any form of precautionary allergen indication should only be used when an (prior) associated and appropriate risk assessment has been carried out."**
Rationale: The statement in paragraph 145 is not precise enough as to the type of information related to allergens present in foods (it refers only to allergens used as ingredients). Information on unintentional presence of an allergen in food should also be covered. The proposed sentence is a more precise statement in order to avoid any confusion as to the message to be conveyed.
- Paragraph 147: It is proposed to make the following changes in the second sentence: "Restaurants should ensure that any allergen information ~~on the menu~~, both on site and online, is current."
Rationale: The site of the allergen declarations in restaurants can vary; on site covers menus.
- Paragraph 149 the EUMS propose the addition of the following text:
 Self-service areas where consumers handle unpackaged food products may pose a particular risk for cross-contact. **Separation of allergenic food items and non-allergenic food as well as Pprovision** of information on the risk of cross-contact should be considered in these instances ...
Rationale: avoid cross-contamination as much as possible.
- Paragraph 153: the following changes are proposed: "Precautionary allergen labelling (e.g. "may contain **[allergen]...**") **should only be used after a risk assessment has been carried out and risk has been identified. Following risk assessment, all possible mitigation measures available to remove the risk should be explored prior to the use of a precautionary label. Precautionary labels that are necessary following this process can help to** be used to inform FBOs and consumers on the risk that the products might contain an allergen (other than those that are listed as ingredients) in situations where (...)"

Rationale: clarity/risk assessment is at the heart of all precautionary labelling and it should not be used as a simple means to avoid litigation rather than to protect consumers.

Furthermore, in the 3rd bullet point, the following change is proposed: “the allergen is detected at levels that, based on an assessment of risk, could result in adverse health consequences to **the majority of** allergic consumers”.

Rationale: This has to do with Eliciting doses (ED1, etc.) applied in risk assessment rather than a zero-tolerance approach.

- Paragraph 158: It is proposed to add an additional after the first one: "**Awareness of the different severe reactions associated with different food allergens**"

Rationale: Important to include in training programs