CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 5 **CX/FH 19/51/5-Add.1**

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD HYGIENE

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DRAFT CODE OF PRACTICE ON FOOD ALLERGEN MANAGEMENT FOR FOOD BUSINESS OPERATORS

Comments at Step 6 in reply to CL 2019/69 -FH

Comments of European Union, India, New Zealand, Nigeria, Senegal, Tanzania, East African Community and Economic Community of West African States (ECOWAS)

European Union

The EUMS would like to make the following comments:

- Paragraph 9: The following change is propose to the first bullet:

  "cereals containing gluten (i.e. wheat, rye, barley, oats or their hybridized strains ~~and products of these~~)"

  Rationale: In order to avoid repetition, the EUMS propose the revision because "products of these" is already mentioned in the lines above with eight foods/food groups (and derived products).

- Paragraph 14: The following changes are proposed:

  "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 might be possible to minimise cross-contact to an extent that the amount of allergen present due to cross-contacts is below the threshold that would 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. **Such** threshold levels**, when endorsed by national authorities,** can be used to reduce precautionary allergen labelling, in turn making precautionary labelling much more meaningful for consumers with food allergies."

  Rationale: Clarity + FBOs should not base their risk assessment on any threshold level existing in literature. Pending the establishment of threshold levels by Codex, levels endorsed by national authorities should be used.

- Paragraph 28: The following changes are proposed to the definition of "precautionary allergen labelling":

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

  Rationale: clarity

- Paragraph 72:

  The following change is proposed in the last sentence of the paragraph:

  …~~Periodic~~ **In case of doubt, occasional** product testing for undeclared allergens may also be considered.

  Rationale: Manufacturers and suppliers must work hand in hand and allergen information provided by suppliers must be trusted and trustable.

- Paragraph 160:

- It is proposed to switch the order with paragraph 161.

  Rationale: clarity reasons.

- last sentence before bullet points: The following change is proposed: "Precautionary allergen labels that are **considered justified and** necessary following this process…"

  Rationale: The word "necessary" alone might be too strong and could be read as a mandatory requirement.

- Replace the last bullet point with the following text: **based on an assessment of risk, the allergen may be present above the threshold level referred to in paragraph 14.**

  Rationale: To make a link to the threshold levels foreseen in paragraph 14.

- Paragraph 161: The following changes are proposed:

  "[~~However~~ **In** order to not limit food choices to allergic consumers, the use of precautionary allergen labelling should be restricted to those situations in which cross-contact cannot be controlled to the extent that the product does not present a risk to ~~the~~ allergic consumer**s**.]"

  Rationale: On allergic consumers, we suggest the use of the same wording as in para 14.

India

1. Introduction,

Paragraph 9

Comment: It is proposed to delete 'Spelt' from the list of food groups within cereals containing gluten, as follows:

These are

- cereals containing gluten (i.e., wheat, rye, barley, ~~spelt~~ or their hybridized strains and ~~products of these~~)

Rationale: Spelt is a type of wheat only and need not be specifically listed. 'Products of these' is already mentioned in the above statement with '(eight foods/ food groups (and derived products).

Hence we propose to delete spelt to avoid repetition.

Paragraph 14

Comment: We propose to include "name of allergen" with the may contain statement to provide more clarity, as below:

[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 **name of allergen**" is substantiated…. consumers with food allergies.]

2. **Section 2.3 - Definitions**

Paragraph 28:

Comment: We propose to include "name of allergen" with the may contain statement to provide more clarity, as below:

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 **name of allergen")**

3. **Section 2.3 Definitions: visibly clean**

Editorial Comment: Separate 'Section III – Primary Production' from the definition. This should appear as a 'section heading style'.

• Also, delete the 'Section III – Primary Production' section header that appears after paragraph 29, since it is already present above.

4. **Section 5.2.1.1 Minimising cross-contact during processing**

Comment: Manufacturers should evaluate the potential for cross-contact due to cooking media, such as water or oil. It may be necessary to use an appropriate method to eliminate any allergen-containing particulate

material ***for example- dedicated cooking media,*** if it is likely that ***the allergen risk cannot be prevented or minimized ; e.g. in case where*** particles could end up in a food with a different allergen profile

Rationale: To bring more clarity.

5. **Section 5.2.1.4 Monitoring and verification**

Comment: 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.

Occasional ~~Periodic~~ product testing for undeclared allergens may also be considered **as and when required.**

Rationale: Periodic testing of 'undeclared' allergens in supplied materials will be difficult for manufacturers. Manufacturers and suppliers must work hand in hand and allergen information should be provided by suppliers.

6. **Section 5.3.1 Manufacturing, paragraph 91**

Comment: ~~The source of an allergen unintentionally presenting in a finished product may be an ingredient obtained directly from a supplier, or an ingredient manufactured by a third-party supplier.~~ Manufacturers should ~~establish specifications~~ **indicate requirements** for their suppliers that address allergen controls as appropriate to the supplier and the use of the ingredient by the manufacturer.

Rationale: To bring clarity.

7. Section 5.3.1 Manufacturing

Comment: Manufacturers should have programs in place to assess the allergen control programs of suppliers when necessary, e.g. a supplier questionnaire/survey and/or an audit to assess the allergen profile of foods produced at the supplier's site and the supplier's allergen management plan, including cross-contact controls and cleaning programs. A specification sheet, certificate of analysis, or vendor guarantee periodically or with each lot can also be useful in addressing a supplier's control of food allergens~~, as well as periodic testing for undeclared allergens~~.

Rationale: Periodic testing of 'undeclared' allergens in supplied materials will be difficult for manufacturers. Manufacturers and suppliers must work hand in hand and allergen information should be provided by suppliers.

8. Section 6.1.1. Manufacturing, paragraph 116

Comment: Equipment and preparation areas should be adequately cleaned between manufacturing foods with different allergen profiles to prevent or minimise the potential for allergen cross-contact. Cleaning procedures to remove allergen residues depend on the nature of the food residue, the equipment, the food contact surface, the nature of the cleaning (e.g. dry cleaning or wet cleaning) and the equipment, tools and materials used for cleaning. Equipment may need to be disassembled, where feasible, to adequately remove allergen residues***. H***owever ***if*** some equipment cannot be disassembled***, the allergen management program*** should take ***it*** into account in. Dust socks need to be removed and cleaned periodically.

Rationale: To bring clarity.

New Zealand

New Zealand would like to thank the Chair and Co-Chairs of the Working Group, and the participating member states, for preparing the draft documents.

Comments on the draft document:

General Comments:

1. New Zealand supports the development of this draft Code of Practice (COP). It is noted that the Code will need to incorporate the amendments adopted by the CCFL as per work agreed (*Proposal for new work on allergen labelling: Revision to the General Standard for the Labelling of Prepackaged Foods: allergen labelling, and guidance on precautionary allergen or advisory labelling*) [CAC July 2019]. Further consultation will be needed on of the Code of Practice, in relation to the adoption of the proposal for revised allergen labelling.
2. New Zealand notes that this draft COP does not align with the proposed labelling requirements under CCFL for non-retail containers. It is proposed that CCFH request that CCFL take another look at this, including allergens in Section 5: 'MANDATORY INFORMATION REQUIREMENTS ON LABEL' of the

draft guidance on the labelling of NRC in Appendix 2, REP19/FL Appendix II: PROPOSED DRAFT GUIDANCE FOR THE LABELLING OF NON-RETAIL CONTAINERS OF FOODS (at Step 5), section 5, in the context of requirements in 5.3.1 Manufacturing paragraph 97 of this draft COP.

We would like to note that GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS (CXS 1-1985) applies to the labelling of all pre-packaged foods to be offered as such to the consumer or for catering purposes and to certain aspects relating to the presentation thereof.

3. New Zealand would like to emphasize the use of precautionary labelling being reduced as far as practical, by reducing the risk of cross-contamination where feasible and by use of scientifically established threshold levels to evaluate the potential risk to allergic consumers. These steps will ensure that precautionary labelling, where used, will be more meaningful than is currently the case. If CCFL advise against use of precautionary labelling, the content of the paragraphs in square brackets should be considered carefully to check for content that should be retained within the draft Code, for example, information about use of scientifically established threshold levels for risk evaluation.
4. New Zealand supports the concept that all food businesses across the food chain have a hazard identification and analysis associated with their business food production or process. This should be appropriate to the nature (in terms of food safety risk) and size of the business and may be assisted by the competent authority providing technical information and/or guidance to a food business sector.
5. New Zealand suggests that the topic of 'derivatives of food allergens that pose very low risk to allergic consumers' be addressed in the draft Code. The Australia New Zealand Food Standards Code lists a number of **exceptions** in Standard 1.2.3-4 based on risk assessments for specific derivatives of allergenic foods. International harmonisation of these exemptions needs to be encouraged. FBOs having in place allergen management procedures for these derivatives yields no follow-through benefit to allergic consumers. We suggest that appropriate exceptions are detailed within the draft Code for the top eight foods/food groups responsible for the majority of food allergies globally.
   One way of doing this could be to amend paragraph 11 to note that risk assessments by competent authorities identify derivatives of allergenic foods that are considered not to warrant labelling or management as allergens. It is very important that a risk analysis approach is taken for both allergen labelling and to identify foods and ingredients that need to be managed as allergens.
6. New Zealand would like to note the importance of consistency between allergen labelling requirements detailed in CXS1-1985 and this draft Code. Currently this draft Code is not fully aligned with the labelling text in CXS1-1985. CXS1-1985 includes allergens within "foods and ingredients …known to cause hypersensitivities." By contrast the draft Code differentiates between allergens, substances that have the potential to cause hypersensitivities with an immune etiology (such as Coeliac disease) and substances that have the potential to cause hypersensitivities with a non-immunological etiology (such as sulphites and lactose with respect to lactose intolerance). It is suggested that the significance of lactose (from a milk allergy perspective) be considered, including a risk assessment.
7. New Zealand would like to note that there is ongoing interest in threshold levels and the application of scientifically based threshold levels for evaluation of risk (for example in relation to the principles for precautionary labelling detailed in paragraph 160) should be encouraged. Expert consultation will look at threshold levels in the future. The draft Code should therefore include wording that emphasizes that thresholds should be used for risk assessment once available. This would help future-proof this Code of Practice.
   The COP has a gap in not addressing how estimates of the level of cross-contact can be made such that a risk assessment for the consumer can be carried out. We believe that a new section on risk assessment of cross-contact should be considered.
8. New Zealand would like to suggest that parts of the draft Code that are repeated in different sectors, be aligned for consistency, throughout the draft Code. In the current layout of the document, it is sometimes hard to know whether information applies to everyone or to a particular sector. For example the header 5.3.2 'Retail and Food Services' is in bold, and then the header 5.4 'Packaging' is in italics, but is a higher level than 5.3.2.
9. New Zealand would like to note that while food-allergic individuals should always be encouraged to make their allergies known, consumer education on what they should expect of food services should be provided by regulators and is not only the responsibility of food service operators.
10. New Zealand suggests that the draft Code include information around potentially allergenic ingredients in a compound product, so that food business operators would be able to recognize the significance of this and address the issue when sourcing commodities.
11. New Zealand supports the definition of rework and suggest considering that rework is a standard term and not specific to allergens.
12. New Zealand would like to note that the phase-out of single-use plastic carrier bags does increase the risk of cross-contamination. Barrier bags may be offered to customers to reduce this risk however customers may refuse them. This points to a need for some consumer education in this COP about the risk, so the consumers make informed decisions.

13. New Zealand would like to note that the size of food preparation areas in some retail stores does not allow for full separation of production and storage areas, equipment, ventilation systems and personnel. It may not be possible to have dedicated processing lines, processing equipment, or production areas. While best practice is followed, the draft Code would necessitate “may contain” labelling for virtually all products, which would not be useful.
    Due to the nature of retail food manufacture – a small team who multi-task to produce a variety of products in a short time-frame – it may not be feasible to have “one individual to prepare allergenic food”. In some cases, in some premises, there may only be one individual preparing all food.
    It may also not be feasible to have a specific “allergen clean-up procedure” due to the above. Accordingly small retail and foodservice premises must usually assume allergens are present in every spill.

Specific comments on the draft text:

Paragraph	Comment	Rationale
Introduction	It would improve document clarity if a paragraph on scope was inserted before hazard characterization as scope is covered in paragraphs 22-24 much later in the document.	The inclusion of this paragraph would outline what is being covered and also which allergens and allergenic reactions are included. For example, hypersensitivity is outlined in the hazard characterisation section but made clear only in the scope section that non-IgE mediated hypersensitivity is out of scope.
Paragraph 4	Add the new text as follows: Allergen management practices should be part of good hygiene practices (GHPs), and, where appropriate, HACCP systems, in manufacturing, **transporting**, retail and food service.	Risks need to be managed in bulk transportation in relation to cross-contact.
Paragraph 5	Add the following text to the start of the paragraph: **Allergens may be present in food due to; intentional addition, unintentional addition (through inadequate information about the presence of the allergen in an ingredient) or from cross contact at any stage of production**. Allergens need to be managed throughout the supply chain and production process. Treatments lethal for microbial pathogens, such as heating, high pressure processing, etc. generally do not destroy allergenic proteins. ~~Processes that degrade proteins, such as enzymatic or acid hydrolysis, can minimise the allergenicity, but should not be relied upon to eliminate or completely destroy allergenic proteins.~~	Suggest the addition of the initial sentence to provide more context. Suggest deletion of the final sentence as the allergenicity can be either increased or decreased with further processing. If this text was to be retained it could be amended from use of the word “minimise” to alter, as this would align with the principle that processing may not eradicate and is more scientifically correct. This would then read as follows: “Processes that degrade proteins, such as enzymatic or acid, can alter the allergenicity, but should not be relied upon to eliminate or completely destroy allergenic proteins.”
Paragraph 9	It is recommended that footnote 1 is reconsidered based on the different terminology used in CXS1-1985 (it does not mention allergens) and	This consideration would help align various Codex texts.

	the review of allergen labelling requirements by CCFL). Also, we query the rationale behind paragraph 9 in the COP listing different foods to those listed in the GSLPF as foods and ingredients known to cause hypersensitivity. The main differences between the lists are, that the list in the COP doesn't include sulphites and it also doesn't include products of each of the listed foods e.g. fish "and fish products". CCFL are reviewing this list as part of new work on allergen labelling and it would be appropriate that any updates were automatically picked up by the CCFH COP by cross referencing the GSLPF here.	
Paragraph 11	In reference to the last part of the paragraph 'ensuring necessary allergen labels are applied': The scope should be expanded to cover provision of information throughout the supply chain via labelling, documentation etc.	Allergens may not be always identified by labels only. This point should be addressed throughout the document.
Paragraph 11	Add new text to the end of the paragraph: **It is important to maintain the allergen list (and exceptions thereof) as up-to-date.**	Updating allergen lists in a food business should also be mentioned here.
12. Poor allergen management and 13. Allergen cross-contact and 17. Allergen cross-contact	13. Change the text as follows: Allergen cross-contact can result from a number of factors in processing, preparing and handling foods, ~~some of which pose a greater potential for cross-contact than others~~. The control measures implemented to prevent or minimise the likelihood of allergen cross-contact should be based on ~~risk~~ **a**	The definition of 'risk' in the Draft Code is not clear. For example, in paragraph 12 it refers to the risk to the consumer of varying levels of undeclared allergens in food. However, in para 13. It refers to the risk of cross-contact of an allergen. A process where there is a 'high' risk of cross-contact leading to an undeclared allergen in food may not necessarily be a high risk to the consumer, e.g. the risk may be high but the amount that is likely to get into the food, low (such as a dispersible allergen like milk). However, the risk of cross-contact for a particulate (e.g. peanut) may be low, but the risk to a consumer be high. All risks of cross-contact should therefore be managed.

	risk assessment across the food chain.	
Paragraph 12, sentence one	Change text as follows: Poor allergen management **and allergen labelling information** ~~(including insufficient or inaccurate labelling)~~ can result in the presence of varying levels of undeclared and/or unintended allergens in food, which may pose a risk if consumed by an allergic individual. The doses that provoke reactions vary ~~among~~ **between** individuals and ~~depend in part~~ **are dependent** on the type of allergen. The risk of allergic reactions ~~among~~ **within** a larger proportion of the allergic population increases with increasing concentration of undeclared allergen.	The changes make for easier reading.
Paragraph 14, 72, 152, 160, 161 (in brackets)	We recommend that these paragraphs are retained.	We agree with the use of scientific thresholds for the purpose of determining whether a PAL statement for an allergen is needed or not.
Paragraph 16	Change text as follows: A variety of situations may result in the exposure of allergic individuals to undeclared allergens. These include **but are not limited to** the following:	The changes make the text more accurate.
Paragraph 16 **For packaged food manufacturing facilities** Third bullet	Change text as follows: • ~~Inappropriate~~ **Sub-optimal** design of the establishment **for addressing allergenic materials processing**, in terms of separation of areas, location of equipment, traffic patterns, and the ventilation system, among others;	The additions clarify that design may be ‘sub-optimal’ rather than ‘inappropriate’.

Factors contributing to exposure Paragraph 16. **For packaged food manufacturing facilities** (seventh bullet)	Improper use **<u>or handling</u>** of an allergen-containing ingredient;	Handling is also a key consideration.
Paragraph 16: **For retail and food service establishments**: First bullet	Change text as follows: • failure of the establishment to **<u>ask for or</u>** receive accurate information from supply chain or lack of allergen information with ingredients or foods received;	It is also the responsibility of the establishment to proactively ask for allergen information through the supply chain.
Paragraph 16: **For retail and food service establishments:** Second bullet	Change text as follows: • failure ~~to receive~~ **<u>of the supplier to provide</u>** timely notification of ingredient changes or order substitution;	The supplier should also have responsibility to provide information about changes.
Paragraph 16: **For retail and food service establishments:** Fifth bullet	Change text as follows: • inappropriate flow or separation of operations or improper equipment lay-out or **<u>use of</u>** utensils;	Clarifies the role of utensil use in allergen management procedures.
For retail and food service establishments (eighth and ninth bullets)	• **<u>Failure</u>** ~~Inability~~ of FBOs to clearly communicate allergen information to customers, • food delivery websites which fail to communicate allergen presence in food items to the consumer, as well **<u>as</u>** failure of a **<u>meal</u>** delivery service to communicate a consumer's dietary requirements, with	Eighth - The bullet list is intended to convey situations that would result in exposure via undeclared allergens, therefore it would be the 'failure to declare' that resulted in exposure. Ninth – There is currently no Codex requirement to provide allergen information via websites. However this may be addressed by the CCFL review of allergen labelling and the possible new CCFL work on e-commerce. The work on non-retail containers is also relevant because food for catering will be captured by that proposed new standard, rather than by the GCSLPF. Progression of this document should take account of concurrent developments at CCFL in these areas.

	respect to allergens, to the FGO preparing the food; and	
Paragraph 18	Add this text to the start of this paragraph: **FBO Responsibilities**	Suggest that the heading FBO is inserted prior to this para as it is currently under "Factors contributing to exposure"
Paragraph 18, bullet 1	Replace with '**demonstrates a business is taking all necessary steps to reduce the likelihood of an allergen being unintentionally present in a food**'	The changes provide better readability of this paragraph
SECTION I - OBJECTIVES Paragraph 19.	Include as second bullet point • **prevent or minimise the potential for undeclared allergens being present in a food due to errors arising in the supply chain;**	Insertion covers the possibility that inaccurate information is supplied and allergens are present in an input without the knowledge of the manufacturer etc. This document includes management practices to reduce this risk.
Paragraph 22	Add the following text to the end of the paragraph '**and through the supply chain'**	GHP is important throughout the supply chain.
Paragraph 28	Add the definition of 'adventitious presence'. Add the definition of 'Processing Aid'	'Adventitious presence' is stated in paragraph 29, without prior definition.
Paragraph 28, definition of allergen	If it is intended that the definition of allergen includes hypersensitivities with immunological aetiology, then consider clarifying this within the definition. Consider adding definitions for 'Food hypersensitivities with immunological etiology' and 'Food hypersensitivities with non-immunological aetiology.'	Clarification and addition of these definitions would help better understanding of the draft Code content.
Section III - Primary Production	Relocate this heading to between the definition of "visibly clean" and the boxed text following it.	Adds clarity to this section, editorial.
Paragraph 30	The final sentence could be interpreted that adventitious presence of allergens in crops only need to be controlled if the crop is	Consider changing the text and example for better clarity in this paragraph.

	intended to be used in a food that is 'free' of that allergen. But the crop should be clean so that it can be used with confidence in many foods not only foods with claims. Suggest a different example because 'gluten free' can mean less than 20ppm in some countries, but not in others;	
Paragraph 37	Change text as follows: Transportation of food should be carried out using a clean transport vehicle that is dry and free of the previous load to prevent or minimise the potential for allergen cross-contact. As necessary, transport containers should be cleaned before use. At unloading, transport containers containing allergenic commodities should be emptied of all cargo and cleaned as appropriate to prevent or minimise the potential for allergen cross-contact of the next load. ~~The use of~~ **Single-use** ~~one-time~~ packaging may be a useful option for some transporters. For more detail on transportation refer to Section 8.	We suggest this amendment to further clarify 'one-time packaging'.
Paragraph 41, First sentence, last sentence	Change text in the first sentence as follows: When necessary, based on an assessment of risk to the allergic consumer, manufacturers should consider designing premises and rooms to ensure ~~appropriate~~ **effective** allergen dust removal or hood systems to mitigate the likelihood of airborne allergen cross-contact throughout the processing area, especially when powdered allergens such as wheat	Dedicated processing lines may not be feasible for all FBOs.

	flour, dried milk powder, soy protein, etc. are used. Change text in the last sentence as follows: An analysis of the process, including the equipment design, should be conducted to determine the likelihood of allergen cross-contact and whether dedicated processing lines, equipment redesign, or other control measures ~~are needed to prevent or minimise~~ **are feasible to assist in preventing or minimising** such cross-contact.	
Paragraph 47	Replace '~~dumped~~' with '**tipped**' in the second sentence. Replace the last sentence with 'Where dust removal systems are not in place, other controls such as cleaning surrounding areas **and equipment** following dumping could be used to mitigate the likelihood of allergenic proteins in powders being transferred to other foods (see section 5.2.1)'.	Consider that equipment in the area may also need cleaning.
Paragraph 48	Add to the end of the paragraph **'And where elimination is not possible, should be adequately cleaned'**	It may not be possible to eliminate all areas where food may accumulate. This suggested addition acknowledges this. Additional focus could be put on these areas where they exist, in the validation of cleaning.
Paragraph 50	Add the new text to the first sentence: 'FBOs, including retail and food service, should place hand wash basins in appropriate areas to prevent **or minimise** allergen cross-contact via personnel'.	These words are added since it may not be possible to completely prevent allergen cross-contact.
Paragraph 51	Add the new text to bullets eight and nine • ease of cleaning the equipment used to process foods with different allergen profiles **and**	Addition to the 8th Bullet is suggested to ensure that cleaning is checked to be adequate. Addition to the ninth bullet is suggested to provide clear direction to the food industry on how to calculate and use allergen cross-contact amounts/concentrations in combination with threshold level, to evaluate risk and dictate the use of precautionary labelling. This would encourage consistent use of allergen cross-contact risk assessment, and

	verification of the effectiveness of cleaning, after processing allergenic ingredients or foods; and • If the information is available, the maximum amount of an allergen due to cross-contact **can be calculated by the following and then compared to a threshold level (Refer to section 9.3)**: ○ **the addition rate of the ingredient/component with the allergen cross-contact risk to the final product,** ○ **the serving size of the final product, to determine the dose of cross-contact allergen.**	precautionary labelling which would help restore the confidence of consumers with food allergy.
New paragraph to be inserted after paragraph 51	**To determine the cross contact concentration through testing, the maximum potential cross-contact concentration could be deemed to be the lower limit of detection and/ or quantification. A risk assessment can be done to determine the risk of cross-contact contamination taking into account the level in the food, the limit of detection of the analytical method, the extent the food may be diluted and a threshold level agreed by allergen experts. (refer to Section 9.3)**	The addition of this paragraph provides more definitive guidance on how to determine cross contact concentrations through testing methods or mass-balance, as appropriate to the process. Since all analytical methods have a limit of detection where it cannot be proven that lower amounts are absent or present, we suggest the limit of detection or limit of quantification be considered the cross-contact concentration.

Paragraph 53	Add the new text to bullet 3 as follows: • monitor, and when appropriate document, **allergen management** control procedures to ensure their continuing effectiveness; Add a new bullet below bullet 3, as follows: • **ensure an appropriate change control procedure is in place to assess the allergen risk if there are operational or input changes;**	Addition to 3rd bullet is to provide context. Addition of a new bullet following the 3rd is to reflect that change control is a large part of ensuring that any changes are introduced in a controlled and coordinated manner and should be included in the responsibility of the FBO.
Paragraph 55	Change the text as follows: Retail and food service operators should also manage **allergen information**, ~~menus,~~ including in-store, ~~and~~ on websites **and on menus**, ~~if they contain allergen information~~, to assure content is current and matches the food product.	The paragraph has been reworded to relate to activities of retail operators.
Paragraph 59	This proposes restricting personnel working on lines that contain allergens from working on lines that do not contain those allergens. This is an unrealistic expectation in many, especially smaller, manufacturing facilities. Consider deleting this sentence.	An alternative might be for the manufacturer to provide 2 or more sets of overalls for different lines or production processes but even this requires storage, change rooms and time for personnel to change and may be unrealistic in all but the largest manufacturing facility.
Paragraph 60	Add new text to the end of the paragraph as follows: Disposable liners can also be an effective strategy. **These should be checked for liner integrity on removal or change.**	The liners should be suitably strong; and should not have been punctured or leaked during use.
Paragraph 60	Add new text to the second sentence ‘Where such dedication is	Cleaning should cover both containers and utensils.

	not possible, effective cleaning procedures should be in place to clean containers **and utensils** before use for a food with a different allergen profile'.	
Paragraph 61	Add the following to the end of the paragraph: **Allergen-containing ingredients should, if feasible and necessary to prevent or minimise the potential for cross-contact, be opened and weighed in designated areas before being transferred in covered or closed containers to the processing line.**	The suggested changes fit better for the understanding of this paragraph.
Paragraph 62	Delete the last sentence as follows: ~~Allergen-containing ingredients should, if feasible and necessary to prevent or minimise the potential for cross-contact, be opened and weighed in designated areas before being transferred in covered or closed containers to the processing line.~~	Deleted text fits better in paragraph 61
Paragraph 64	Change text as follows: Manufacturers should evaluate the potential for cross-contact due to cooking media, such as water or oil. It may be necessary to use **dedicated cooking media** if it is likely that **the allergen risk cannot be prevented or minimized to a safe level; e.g. in case** particles could end up in a food with a different allergen profile.	It is not only particulate allergens that are being discussed here.
Paragraph 66	Add in new text to sentence two as follows: The rework or WIP should be appropriately labelled, **tagged or colour-coded** with all food allergens specifically highlighted, and properly inventoried and	The additions provide other options for identifying rework.

	accounted for during storage and when used, to prevent or minimise the potential for incorporation into the wrong product.	
Paragraph 67	Add new text as follows 'Manufacturers should implement a policy for rework to be added back to the same product whenever feasible **and ensure that traceability is maintained (refer to paragraph 111)**	This addition is to make it clear that traceability is applicable to rework as it is something that can often be overlooked.
Paragraph 70, last sentence	Change text as follows: If it is not possible to re-label such food, they should have a procedure**s for diversion or disposal** ~~to destroy the food.~~	In the current environment of trying to reduce food waste, the last sentence which refers to manufactures having "a procedure to destroy the food" is problematic. Destruction might be one of several options.
Paragraph 83	Add the new text to the first sentence 'Food preparation operators should only use ingredients listed in the recipe, and not replace one ingredient with another unless the ingredient is known not to contain **a new or different** ~~an~~ allergen'. Add to the end of the paragraph **'Any change of ingredients should be pre-approved in the product specification or managed via a change control system'.**	Where the replacement ingredient contains the same allergen this should not be prevented. Change control is a large part of ensuring that any changes are introduced in a controlled and coordinated manner and should be included in the responsibility of the FBO.
Paragraph 84	Delete the last sentence: ~~'It may be necessary to use an appropriate method to eliminate any allergen-containing particulate material present in frying oil if it is likely that such particles could end up in food with a different allergen profile'.~~	We suggest that the final sentence be deleted or further guidance given on what processing could be done to assure the removal of the allergen. The feasibility and safety of this recommendation needs evaluation.
Paragraph 87	Suggest deleting this paragraph	Rework is defined to be "clean unadulterated food that has been removed from processing at any point up to and including final packaging". On this basis it is not applicable to food service or retail and we suggest that the paragraph is deleted.

Paragraph 92, first sentence	Change text as follows: Manufacturers ~~should ensure that their suppliers have good allergen management practices~~ **request assurances from their suppliers that the suppliers have good allergen management practices** to prevent or minimise the likelihood of cross-contact between foods with different allergen profiles	The addition clarifies that both manufacturers and their suppliers have responsibility here.
Paragraph 93	Delete from the end of the sentence: ~~as well as periodic testing for undeclared allergens~~.	Manufacturers and suppliers must work hand in hand and allergen information provided by suppliers must be trusted and trustworthy.
Paragraph 95	Change text as follows: Incoming foods that are, or that contain, allergens should be labelled to identify the allergens that are present using common terms (e.g. 'milk' when casein is an ingredient). Manufacturers should review labels on **the products**~~,~~ and documents accompanying~~,~~ shipments of ingredients (including ~~minor~~ ingredients **used in small amounts** such as spice blends and flavours) to confirm that the ingredient contains only the expected food allergen(s). Particular attention should be given to multi-component pre-mixed ingredient packages **where allergen information may be difficult to locate**. Manufacturers should have policies in place to address ingredients that contain advisory statements on the label with respect to the labelling of finished food containing that ingredient and controls to prevent or minimise allergen cross-contact	'Minor ingredients' is not appropriate. Replace with 'ingredients used in small amounts'. Spices might be used in a small amount but in terms of allergen controls it is a major issue.

	based on the risk to the allergic consumer.	
Paragraph 101	Add the following to the start of the paragraph**. Incoming packaged ingredients should be checked to ensure that the product received is an approved ingredient.**	Should be an inclusion that staff need to check the product that is received against the "approved" ingredients. This would help to reduce the acceptance of substituted ingredients by distributors.
Paragraph 104	Change text as follows: ~~Re-use of clean-in-place (CIP) solutions, including rinse water, from washing equipment containing an allergen should be avoided if this could result in allergen cross-contact that could present a risk to allergic consumers.~~ **Where clean-in-place (CIP) reclaim systems exist, fresh water should be used for final rinsing after the cleaning step. The CIP system should be validated to ensure that it effectively controls allergen cross contact and have procedures in place to reduce or mitigate contributing to cross contact. For example - detergent / caustic chemical are dumped after cleaning products which contain an allergen, and fresh solution prior to running non allergen containing products.**	Changes provide a better understanding of the text.
Paragraph 107	Add these 3 bullet points to the bottom of the list • **HACCP** • **Cross-contact risk assessment** • **Allergen map**	These additional items should be part of records kept.

Paragraph 108	Include the following as a bullet point: • **Equipment scheduling and use**	Equipment scheduling and use is an important aspect of allergen management.
Paragraph 112	Change the first sentence as follows 'FBOs should have procedures in place for handling consumer complaints with regard to undeclared allergens ~~in foods~~ **and food allergen incidents**'.	Suggest that procedures should cover incidents as well as undeclared allergens.
Section VI – Establishment: Maintenance and Sanitation	Change text as follows: Section VI – Establishment: Maintenance and **Cleaning** ~~Sanitation~~	We suggest that the section title is amended from 'Sanitation' to 'Cleaning'. Sanitation is more relevant to the removal and disinfection of microorganisms so we suggest this is amended to cleaning. This also aligns with the sub-headings below this that also refer to cleaning and not sanitation.
Paragraph 116	Delete the last sentence~~: Dust socks need to be removed and cleaned periodically.~~	It is not clear why dust socks are mentioned specifically.
Paragraph 129	Add new text as follows: FBOs should place waste materials that contain food allergens in covered **receptacles (e.g.** bins, totes, or containers**)** that are identified as holding waste and handled in a manner to prevent or minimise the potential for allergen cross-contact.	This suggested change makes it clear that all receptacles are to be covered, with bins, totes and containers being types of receptacles.
New Paragraph 132 a	Add new paragraph as follows: **Where FBO make a specific claim on the product, for example: dairy free, manufacturers should review the risk associated with the manufacture of this product, together with the cleaning efficacy of the facility. It may be necessary to perform allergen specific testing after each clean of a product which contains an allergen (in this case, a dairy containing allergen) to ensure that cross contact has been**	Provides better clarity to the content of this section.

	eliminate or reduce prior to the production of the dairy free product.	
Paragraph 134	Change text as follows: FBOs should **ensure** ~~encourage~~ personnel to wash hands between handling foods that have different allergen profiles, or after having been in contact with other sources of potential allergens. Where gloves are used, consider changing regularly to reduce the likelihood of allergen cross-contact.	It should be mandatory that hands be washed between handling different allergens.
Paragraph 150	Insert footnote: **Footnote: Reference to this standard may to be replaced with "Guidelines for the Labelling of non-retail containers for foods" once adopted.**	This will require amending once guidelines for labelling of non-retail containers for foods is adopted by CAC. CCFL45 agreed to include food for catering purposes in the proposed guidelines.
Paragraph 159	Consider deletion as it is covered by paragraph 158.	Repeated content.
Paragraph 160	Change the third bullet as follows: the allergen may be present at levels that, based on an assessment of risk, could result in adverse health consequences to **a significant proportion of the population** ~~the majority of~~ allergic consumers.]	It is difficult to determine a dose that would not cause an allergic reaction in the most sensitive individuals, which makes it difficult to determine the amount of allergen present due to cross-contact is below a threshold that would cause an adverse reaction in an allergic consumer. It would be more practical to use a threshold amount/dose/concentration that is below what would elicit an adverse reaction in a significant proportion of the population, which has been characterised for several food allergens.
New paragraph after 160	**The risk assessment that will determine if precautionary labelling is required should include the following considerations as a minimum:** • **If ingredients carry a potential cross contamination risk** • **threshold doses** • **If the allergen risk is particulate or dispersible**	Suggest that a paragraph is added to provide minimum considerations of the risk assessment that will inform whether precautionary labelling is required or not.

	• **Validation of different cleaning methods** • **Verification measurement of cleaning methods**	
Insert new paragraph before 161	**In those instances where testing is required to prove an adequate level of cleaning and allergen removal, a threshold level can be referred to in order to prove that an adequate level of cleaning has been achieved (given that test methods cannot prove allergen elimination since they have a Limit Of Detection (LOD) that is greater than zero. For example, if a test method is used to measure the amount of allergen in a rinse water or on a surface, the method has a LOD of 5 mg/kg, the serve size of the subsequent batch is 50 grams, and a not detected (< 5 mg/kg) result is obtained, it could be assumed that the allergen cross-contact amount is 5 mg/kg x 50/1000 kg = 0.25 mg. If the threshold level is >0.25 mg, then precautionary labelling could be omitted, and if the threshold level is <0.25 mg the precautionary labelling could be included.**	This would provide defined direction to the food industry for how to use testing in combination with a threshold level and subsequent batch size, in order to evaluate risk and dictate the use of precautionary labelling. This would encourage consistent use of allergen cross-contact risk assessment, and precautionary labelling, which would help restore the confidence of consumers with food allergy.
Paragraph 161	Change this paragraph as follows: [However, in order to not limit food choices to allergic consumers, the use of precautionary allergen labelling should be restricted to those situations **where there is potential for the cross-contact amount to be greater than a threshold**	Suggested replacement text for the paragraph in alignment with comments in paragraph 160.

	amount/does/concentration that would elicit an adverse reaction in a significant proportion of the population ~~in which cross-contact cannot be controlled to the extent that the product does not present a risk to the allergic consumer.]~~	

Nigeria

Issue: The Role of Competent Authority in the identification of common national allergens. According to the draft, the role of identifying allergens is left to the FBOs.

Position: Nigeria suggests that the role of Competent Authorities is not required to be included in the Code of Practice on Food Allergen Management for Food Business Operators.

Rationale: The Code of Practice is directed to FBOs and is advisory. The regulatory role of Competent Authorities is already covered in national regulations, which carry the force of law and identifies the list of recognized food allergens and criteria for food allergen.

Issue: Hazard Characterization para 14 text in square brackets:

[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 would 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.]

Position: Nigeria proposes that the square brackets be removed and supports precautionary allergen labelling while JEMRA continues work on determination of allergen threshold limits.

Rationale: The work undertaken by JEMRA for determination of food allergen threshold limits is ongoing.

Senegal

Contexte : Les informations fournies dans le projet de code de pratique sont acceptables. Le document contient des directives adéquates pour la gestion des allergènes tout au long de la chaîne alimentaire. Le sénégal soutient donc l'avancement de Projet à l’étape suivante

Question : Le rôle de l'autorité compétente dans l'identification des allergènes. Selon le projet, le rôle d'identifier les allergènes est laissé aux Exploitants du Secteur Alimentaire
Position : Le Sénégal propose d'inclure le rôle de l'autorité compétente dans l'identification des allergènes importants dans leurs pays. En outre, le Sénégal propose d'ajouter la phrase suivante: "Les autorités compétentes identifieront la liste des allergènes alimentaires reconnus et les critères d'allergène alimentaire". Soit sous la section 2.1 "Champ d'application" ou la section 2.2 "Utilisation".
Justification : Même si les lignes directrices provisoires s'adressent aux Exploitants du Secteur Alimentaire le rôle d'autorité compétente est important pour l'établissement de critères et l'élaboration de la liste des allergènes alimentaires.
Question : Caractérisation des dangers, paragraphe 14, texte entre crochets:
[Dans certains cas, il peut ne pas être possible d'empêcher les contacts croisés malgré la mise en œuvre de mesures préventives et de BPH, et dans de telles situations, l'application d'une déclaration d'allergie de précaution telle que «peut contenir» est justifiée. Toutefois, il peut être possible de minimiser les contacts croisés dans une mesure telle que la quantité d'allergène présente du fait des contacts croisés soit inférieure à un seuil qui provoquerait une réaction indésirable chez la majorité des consommateurs allergiques à l'allergène spécifique. Dans ces cas, l'utilisation de seuils scientifiquement fondés est un outil d'évaluation du risque pour les consommateurs souffrant d'allergies alimentaires. Des seuils peuvent être utilisés pour réduire l'étiquetage préventif des allergènes, ce qui rendra l'étiquetage de précaution beaucoup plus significatif pour les consommateurs souffrant d'allergies alimentaires.]
Position : Le Sénégal est d’avis qu’il est nécessaire d’établir un étiquetage de précaution pour les aliments soupçonnés de contenir des allergènes dans l’attente des travaux sur l’élaboration des critères de détermination des limites de seuil pour les allergènes entrepris par le JEMRA.
Justification : Aucune évaluation des risques n'a été réalisée pour soutenir la mise au point de seuils d'allergène

Tanzania

The members reviewed the proposed draft and commented as below:-

- Para 9/14/72/160: The United republic of Tanzania proposes to maintain the current status on precautionary labelling and review of list of allergens in the General Standards of Labeling of Pre-packaged foods (GSLPF) until such labeling provisons are endorsed by the CCFL.

- Para 152 The United republic of Tanzania accepts the para 152 with amendements to read as follows;

~~All~~ Food products and ingredients of which are likely to contain allergens should be accompanied by, or bear adequate information, to ensure other food manufacturers or processors and consumers can be informed whether the food is, or contains, an allergen. This includes any applicable information relevant to assess the likelihood of allergen cross-contact, such as that outlined in section 5.1, and may include precautionary allergen labelling as discussed in section 9.3. Such statements should be truthful, not misleading and not used in lieu of GHPs (see section 9.3).

Justification

Amendement is based on the fact not all food products or some ingredients contain allergens.

East African Community

Para 9/14/72/160: The East Africa Community (EAC) proposes to maintain the current status on precautionary labelling and review of list of allergens in the General Standard for Labelling of Pre-packaged foods (GSLPF) until such labelling provisions are endorsed by the CCFL.

Para 152: The East African Community (EAC) accepts the para 152 with amendments to read as follows;

~~All~~ Food products and ingredients of *which are likely to contain allergens* should be accompanied by, or bear adequate information, to ensure other food manufacturers or processors and consumers can be informed whether the food is, or contains, an allergen. This includes any applicable information relevant to assess the likelihood of allergen cross-contact, such as that outlined in section 5.1, and may include precautionary allergen labelling as discussed in section 9.3. Such statements should be truthful, not misleading and not used in lieu of GHPs (see section 9.3).

JUSTIFICATION

Amendment is based on the fact that not '*all food products'* or some ingredients contain allergens.

Economic Community of West African States (ECOWAS)

General Comment

The information provided in the draft Code of Practice (CoP) is acceptable. The document contains adequate guidance for the management of allergens along the food chain. ECOWAS therefore support the advancement of the CoP in the stepwise process.

Issue: The Role of Competent Authority in the identification of allergens. According to the draft the role of identifying allergens is left to the FBOs.

Position: ECOWAS propose to include the role of Competent Authority in identifying allergens that are important in their countries. Further ECOWAS proposes to add the sentence of as follows: **"competent authorities to identify list of recognized food allergens and criteria for food allergen."** Either under section 2.1 "Scope" or section 2.2 "Use"

Rationale: Even though the draft guidelines are meant for FBOs the role of Competent Authority is important in establishing criteria and the development of the list for food allergens.

Issue: Hazard Characterization para 14 text in square bracket:

[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 minimise cross-contact to an extent that the amount of allergen present due to cross-contact is below a threshold that would 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.]

Position: ECOWAS is of the opinion that there is need for precautionary labelling for food suspected to contain allergens pending the work on the development of the criteria for determination of allergen threshold limits being undertaken by JEMRA.

Rationale: No risk assessment has been conducted to support the development of thresholds for allergen.