

CODEx ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - E-mail: codex@fao.org - www.codexalimentarius.org

Agenda item 7

CX/FH 18/50/7-Add.2
Original Language Only

JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON FOOD HYGIENE

Fiftieth Session

Panama City, Panama, 12 - 16 November 2018

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

Comments of Australia, European Union, Nicaragua, African Union and FoodDrinkEurope

Australia

Paragraph	Comment
3	Australia suggest to broaden the role of Competent Authorities to provide guidance as well as oversight of complaint investigations. I.e. that Competent Authorities provide guidance , oversight and advice, where necessary, to FBOs on food allergen complaint investigations.
7	Australia suggest that the list of allergens aligns with the wording in CXS 1-1985. For example eggs, peanuts and soybeans should be plural.
9	Australia notes a missing in the sentence 'lupin_are'
11	Australia suggest that the word 'batch' is removed from the sentence I.e. 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 batch -threshold that would cause an adverse reaction in an allergic consumer.
12	Australia suggests that 'processing aids' be included I.e. It is important that FBOs are able to identify the allergenic nature of the foods, ingredients and processing aids they.....
13	Australia suggests that the 2 nd dot point be amended to 'inadvertent inclusion of foreign grains allergenic foods ' so it's less specific. Foreign grains may not be the only allergen, potential for peanut etc
20	Australia suggest that the list of allergens aligns with the wording in CXS 1-1985. For example eggs, peanuts and soybeans should be plural.
27 or 28	Australia suggests then inclusion of additional text, either in paragraph 27 or 28 as appropriate: Materials used for fertilising, whether as friable, dispersible material or spray, should not contribute an allergen risk.
35	Australia suggests that the working group may need to consider managing dust and airflow (where it is an issue) to minimise allergen cross-contact in this paragraph
44	Australia suggests that this paragraph include additional examples of particulate allergens to represent the particulate in different forms. I.e. To minimise the potential for allergen cross-contact, ideally, they should not contain areas where allergens, especially particulate allergens (e.g. peanuts, tree nuts, sesame seeds ,

	<i>crumbs from baked goods</i>) could get caught.....
65	Australia suggests replacing 'pull' with 'select' i.e. should be stored in a way that minimises the potential to pull <i>select</i> incorrect labels or containers during production.
68	Australia suggests that the paragraph be amended in the following ways: Suggest its split into two sections Add in additional text to show that all ingredients (not just multi-component ingredients) have potential for change Amend the typo in 'cross-contact' i.e. Manufacturers should regularly review suppliers to ensure that <i>all ingredients</i> , particularly multi-component ingredients (e.g. sauces, spice mixes), have not changed. <i>and verify that</i> Precautionary allergen labelling (such as "may contain" statements) <i>should only be</i> applied in instances where the manufacturer cannot reasonably prevent allergen cross-contact, when such <i>cross-contact</i> could present a risk to allergic consumers.
100	Australia suggest the following changes to simplify the paragraph. i.e. FBO managers and supervisors need to have enough knowledge and understanding of allergen control principles and practices to be able to judge <i>identify</i> potential risks and determine the need for <i>whether</i> new or revised procedures <i>are required</i> to prevent the presence of undeclared allergens or the need to take corrective action when allergen control procedures are not properly implemented.
111	Australia suggest the sentence be amended. I.e. "Cleaning should include the <i>The</i> ductwork in ventilation systems <i>should be considered when cleaning the processing environment</i> "....
113	Australia suggest the sentence be amended. I.e. For example, freshly prepared cleaning <i>and sanitising</i> solutions should be used.....
115	Australia prefer alternative text with proposed additional text i.e. Validation is the assessment of cleaning methods to ensure that they are adequate to minimise allergen cross-contact. <i>Where required the validation process should be specific to the allergen, process and matrix combination.</i>
116	Australia suggests to replace 'test kits' with 'allergen testing' or similar to be less specific. I.e. Where feasible, test kits <i>allergen testing</i> should be used to evaluate "push-through" material...
125	Australia suggests the text be amended i.e. Manufacturers should periodically conduct tests (e.g. rapid ATP (adenosine triphosphate) or protein or allergen swabs, or test kits) to detect food residues <i>on surfaces</i> that remain after cleaning.....
Alt text 144/145	Australia prefers text in paragraph 145 and suggest it would be useful to provide an explanation of what the "may contain" labelling statement means (or a reference) here.
153	Australia suggest that the third dot point be amended to replace 'detected' with 'may be present' I.e. the allergen detected <i>may be present</i> at levels that...
154	While the first part of the sentence identifies the intended outcome, it might be useful to simplify the sentence: 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...

European Union

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 effectiveness

It 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 Provision** 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 if 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

Nicaragua

Tema de agenda 7: Anteproyecto de Código de prácticas sobre la gestión de los alérgenos alimentarios por parte de los operadores de empresas de alimentos

Comentarios generales

Nicaragua agradece la elaboración del documento y por brindarnos la oportunidad de presentar observaciones.

Comentarios específicos

Introducción

Por lo antes expuesto, los alérgenos son una preocupación ~~constante en el ámbito de la inocuidad de los alimentos~~ para los consumidores alérgicos, para quienes son responsables del cuidado de personas con alergias alimentarias, para ~~los productores, los transportistas,~~ los operadores de empresas de alimentos (OEA) **transportistas** y para las autoridades competentes.

Justificación: Nicaragua propone ajustes con el objetivo de aportar a la comprensión. Se suprimió la categoría "productores", dado que de acuerdo a la definición, estos forman parte de los OEA.

Con la creciente carga para la salud que suponen los alérgenos alimentarios surge la expectativa de que los OEA tomen medidas para declarar con exactitud la presencia de ingredientes alérgenos y gestionar la presencia involuntaria de alérgenos, así como de que las autoridades competentes proporcionen a los OEA ~~asesoría y supervisión~~ en materia de investigación de ~~reclamaciones~~ **reclamos** sobre alérgenos alimentarios, cuando sea necesario. En un mercado mundial, es fundamental que exista un entendimiento **armonizado internacional** sobre esta cuestión y sobre las medidas necesarias para abordarla. Las prácticas de gestión de alérgenos deberían formar parte de las buenas prácticas de higiene (BPH) y, cuando proceda, de los sistemas de APPCC, en la **cadena alimentaria** ~~producción~~, la venta al por menor y los servicios de restauración.

Justificación

Se propone realizar las siguientes modificaciones:

- Suprimir el término **asesoría** dado que el rol de las autoridades competentes es de vigilancia y control.
- Sustituir el término internacional por armonizado.
- Sustituir el término producción por **cadena alimentaria**, para que sea congruente con el ámbito de

aplicación del documento.

Caracterización del peligro

Una mala gestión de los alérgenos (~~entre otros~~ por ejemplo: un etiquetado insuficiente o inexacto) puede dar lugar a la presencia de niveles variables de alérgenos no declarados en los alimentos, lo que podría suponer un riesgo si los consume una persona alérgica. La dosis que provoca una reacción puede variar de una persona a otra y depende, en parte, del tipo de alérgeno. El riesgo de que se produzcan reacciones alérgicas que afecten a una parte más amplia de la población alérgica aumenta cuando se produce una concentración creciente de alérgenos no declarados.

Justificación: Se sugiere sustituir “entre otros” por “por ejemplo”, para efectos de comprensión.

SECCIÓN I - OBJETIVOS

El presente código proporciona orientaciones a los OEA, ~~entre otros los productores primarios~~ para elaborar políticas y procedimientos destinados a identificar los alérgenos en todas las áreas de producción, preparación y servicio de alimentos, ~~para después y~~ aplicar prácticas de gestión de alérgenos, entre otros, controles ~~para~~ **con el propósito de:**

Justificación: Se propone realizar ajustes de redacción para efectos de comprensión. La eliminación de “entre otros los productores primarios” se debe a los productores primarios están incluidos en la definición de OEA.

~~Las herramientas de gestión y orientación del presente código constituyen un enfoque proactivo para la gestión eficaz de alérgenos en la producción, la preparación y el servicio de alimentos y para la reducción del riesgo para los consumidores, más que una respuesta reactiva posterior a la detección de un peligro de inocuidad alimentaria en un alimento.~~

Justificación: Se considera que la redacción del párrafo es redundante, repite aspectos abordados en el párrafo 16, por lo cual se propone suprimirlo.

Ámbito de aplicación

El presente código abarca la gestión de los alérgenos a lo largo de toda la cadena **alimentaria de suministro**, desde la producción primaria hasta la fabricación, y en los puntos finales de la venta al por menor y el servicio de restauración. Complementa las buenas prácticas de higiene (BPH) en la fabricación y las prácticas de preparación de alimentos en los servicios de restauración.

Justificación: El término congruente con el ámbito de aplicación del documento es “cadena alimentaria” no cadena de suministro, por lo tanto se propone realizar la corrección.

El presente código comprende las alergias e hipersensibilidades alimentarias (p.ej., la enfermedad celíaca), tanto mediadas por inmunoglobulina E (IgE) como no mediadas por IgE, que pueden verse provocadas por pequeñas cantidades del alérgeno alimentario causante (por lo que es necesario prestar atención a las BPH además del al etiquetado). A escala mundial, la mayoría de las alergias alimentarias son provocadas por ocho alimentos o grupos de alimentos (y productos derivados): ~~a saber,~~ los crustáceos, los huevos, el pescado, la leche, el maní (cacahuete), la soja, las nueces de árbol, el trigo y otros cereales que contienen gluten

Justificación: Se propone realizar correcciones en la redacción del documento para efectos de comprensión.

Utilización

El documento se ha estructurado para exponer los principios de la gestión de alérgenos alimentarios aplicables en forma general a los operadores de empresas de alimentos, así como para señalar aquellos que se deberían aplicar específicamente al sector de la venta al por menor y de los servicios de restauración. ~~En el presente documento, por venta al por menor se entiende una empresa de alimentos dedicada principalmente a la venta de alimentos preenvasados o no preenvasados directamente a los consumidores, para su consumo en otro lugar o su consumo futuro, y servicios de restauración se refiere a aquellas empresas de alimentos que producen y sirven alimentos para su consumo directo.~~

Justificación: Nicaragua propone el texto e incorporar las definiciones de venta al por menor y servicios de restauración en el acápite de definiciones (2.3).

Definiciones

Nicaragua propone:

- Incorporar la definición de **gestión**, en este acápite.
- Que la definición de “Análisis de peligros y puntos críticos de control (APPCC), sea congruente con la definición incluida en el **CAC/RCP 1-1969**, una vez que finalice su revisión.

Sección V: Control de las Operaciones

Los OEA deberían controlar los alérgenos reduciendo al mínimo la posibilidad de contacto cruzado, al garantizar que la información de identificación de los alérgenos presentes en los alimentos sea clara, correcta y que, tanto los establecimientos dedicados a la venta al por menor como los de servicios de restauración sean capaces de informar de los alérgenos presentes en los alimentos que preparan. Los controles deberían estar basados en el riesgo. La información útil a la hora de evaluar el riesgo incluye lo siguiente:

- **Planificación de la producción**

Justificación: Nicaragua propone incluir la “planificación de la producción, dado que es información importante para definir el tiempo, orden de la producción y reducir la contaminación cruzada.

Programas de limpieza

Fabricación

Nicaragua apoya la inclusión del texto alternativo.

SECCIÓN VIII – TRANSPORTE

PRINCIPIO:

Los alimentos que **no** contienen alérgenos deberían manipularse durante el transporte de modo de evitar el contacto cruzado con alérgenos.

Justificación

La redacción del principio no tenía sentido, se propone ajustar la redacción para facilitar su comprensión.

SECCIÓN IX – INFORMACIÓN SOBRE LOS PRODUCTOS Y SENSIBILIZACIÓN DE LOS CONSUMIDORES

Fabricación

Nicaragua no apoya la inclusión del texto alternativo, el párrafo propuesto es más claro y conciso.

African Union

General Comment

The document is generally acceptable but gives a lot of unnecessary details and is in some cases too prescriptive. As a guidance document, it should be explicit and provide framework for establishing an effective allergen management system.

Issue

Para. 144 & 145: Alternative statement to use for information to consumers in as far as allergen labelling is concerned.

Position

African Union recommends the use of the alternative statement in para. 145 which reads **“All food products and ingredients should be accompanied by or bear adequate information to ensure other food manufacturers or processors can be informed whether the food contains an allergen. This includes any applicable precautionary allergen labelling (e.g. “may contain”). Nevertheless, it’s desirable to avoid the systematic use of such statements, which can reduce the available food in the market for allergic consumers”** as opposed to use of the statement in par. 144 which reads **“All food products and ingredients 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 allergenic ingredient.”**

Rationale

Para. 145 gives more guidance on allergen labelling including the use of precautionary labelling where absence of allergens may not be guaranteed.

Issue

Para.10: Inclusion of the phrase **“including insufficient or inaccurate labelling”** to emphasise poor allergen management even though it is already part of poor allergen management

Position

African Union recommends to rephrase the 1st sentence to read “Poor allergen management **(including insufficient or inaccurate labelling)** can result in the presence of varying levels of undeclared allergens in food, which may pose a risk if consumed by an allergic individual.”

Rationale

Insufficient or inaccurate labelling is part of the issues considered in the normal allergen management system.

Issue

Para. 13: Bullet 1: Use of the word **‘bag’**

Position

African Union recommends the replacement of the word **‘bag’** with **‘container’** so that the sentence reads **“inadequate or ineffective cleaning of, bags containers and transport vehicles”.**

Rationale

Various type of containers can be used including bags.

Issue

Para. 15: Detail on results of an effective allergen management

Position

FBOs are encouraged to have documented **allergen management policies and procedure specific to their food businesses. Such policies should be fully implemented to demonstrate compliance to reducing the likelihood of cross contaminants in their operations.** and detailed allergen management policies and procedures specific to the food business. Having allergen management policies and procedures in place, and compliance with these, allows a business to demonstrate it is taking all necessary steps to reduce the likelihood of an allergen being unintentionally present in a food. It also provides an opportunity for businesses to demonstrate adequate skills and knowledge in allergen management and reduces the risk of an allergen incident occurring.

Rationale

For clarity of expression and to emphasize the need for implementation of allergen policies for consumer protection.

Issue

Para. 20: Inclusion of details of eight food groups which are major sources of allergens

Position

African Union recommends the deletion of the detail on the eight food groups associated with allergens so that the sentence reads, “This Code covers IgE-mediated, non Ig-E-mediated food allergies and hypersensitivities (e.g. Coeliac disease) that can be triggered by small amounts of the offending food allergen” **(thus requiring attention to GHPs in addition to labelling). There are eight foods/food groups (and derived products) that cause the majority of food allergies on a global basis and these include crustaceans, egg, fish, milk, peanut, soybean, tree nuts, wheat and other cereals containing gluten.**

Rationale

The information has already been well presented in the introduction section and thus constitute a repetition.

Issue

Para. 24: Inclusion of definitions for **‘retail’** in the text in this paragraph.

Position

AU recommends to relocate the sentence that defines 'retail' to the section on definitions so that the paragraph reads "This section of the document has been structured to outline the principles of food allergen management which apply broadly to food business operators, as well as identify those which should be specifically applied to retail and food service sectors." ~~In this document, retail means a food business primarily involved in selling pre-packaged or non-prepackaged food directly to consumers for off-site or future consumption and food service means a food business that produces and serves food for direct consumption.~~

Rationale

Definitions of terms should be moved to the section on "definitions"

Issue

The text in Para. 38 is too long and complicated.

Position: African Union recommends rephrasing the sentence to read "~~If where~~ separate production lines are used for foods with different allergen profiles, ~~(e.g. for foods that do not contain a particular allergen and for foods that do)~~, manufacturers should provide ~~sufficient~~ adequate separation to minimise the likelihood of cross contact." ~~potential for cross-contact from one line to another based on the food, the process, and the likelihood of cross-contact. Manufacturers should eliminate cross-over points or provide a means to contain or shield food (e.g. closed pipes, enclosed or covered conveyors) to prevent food spilling from one line to another.~~

Rationale

To enhance clarity and logical flow.

Issue

Para. 46: The use of the term 'hand wash basin' and 'soap' is not appropriate by FBOs

Position

AU recommends the following text to replace para.46: "FBOs, including retail and food service, should place hand washing basins facility in appropriate areas to prevent allergen cross-contact via personnel. Having convenient hand washing basins facility will encourage employees to wash hands with liquid soap and water between handling foods that have different allergen profiles."

Rationale

Hand "washing facilities" is more appropriate than "*washing basin*" since it covers all the facilities required for effective hand washing.

Issue

Para. 94: contain too many repeated examples.

Position

African Union recommends the paragraph to be modified to read "Retail and food service operators should purchase ingredients for which the allergen profile is known, e.g. packaged foods that list all ingredients. ~~For example, if a bag of dried porcini mushroom and herb risotto mix does not list the contents, then the product should not be used.~~ Sourcing ingredients from the same supplier may minimise changes in the allergen profile of foods supplied."

Rationale

The statement is self-explanatory even without examples.

Issue

Para. 107 is a repetition of par. 106

Position: AU recommends to delete para.107 to avoid duplications.

Issue

Para. 111: Statement not easily readable and understood.

Position

AU recommends modifying the sentence to improve logical flow. The sentence should read as follows: **“If..... where compressed air is used, precaution should be taken to contain all food residues from spreading, because vacuums cannot remove such residues and it is not practical to disassemble equipment for cleaning food residue, manufacturers should take precautions to contain food residues that are removed by the compressed air.”**

Issue

Par. 114: The use of the expression **“at a minimum visually clean”** to describe adequate cleaning.

Position

AU recommends to modify the sentence to read as follows: “Equipment, utensils, containers and preparation areas should be adequately cleaned **(at a minimum visually clean)** immediately after the preparation, storage, and dispensing of foods to prevent allergen cross-contact.”

Rationale: The expression **“adequately cleaned”** is more appropriate

Issue

Choice between two statements in para. 115.

Position

African Union supports the 1st text which reads “Having assurance that cleaning has been effective is known as cleaning validation. Validation is the assessment of cleaning methods to ensure that they are adequate to minimise allergen cross-contact. Cleaning processes should be validated through visual assessment (checking that equipment is visibly clean) and, where feasible, through an analytical testing programme. The effectiveness of cleaning should be monitored (verified) after each cleaning event to ensure the validated procedures are being followed.”

Rationale

This requirements have been well articulated.

Issue

Par. 136: The use of the words **‘must’** and **‘best’** in the statement.

Position

African Union recommends modification of para.136 to read as follows: “Vehicles such as bulk tankers used to transport liquids (e.g. raw milk, dairy mixes, juices, liquid egg, oil, water) **must should** be adequately cleaned between loads to minimise allergen cross-contact. **In some instances, where feasible,** dedicated bulk tankers may be **best appropriate, for example, when transporting dry powders such as wheat flour.**

Rationale

For consistency with Codex format of writing standards.

Issue

Para. 144 & 145: Choice between par. 144 and 145.

Position

African Union recommends para. 145.

Rationale

Para. 145 provides additional information to consumers where there is even the least likelihood of allergenic contamination of food.

Issue

Para. 148. Use of the term “front of house”

Position

African Union recommends the statement to be modified to read “~~Front of house~~ employees that serve food to customers should be knowledgeable about the allergens in menu items and preparation practices of the business that may result in cross-contact, or know how to obtain this information”.

Rationale

All employee need to have knowledge about the relevant allergens.

FoodDrinkEurope

General Comments:

The document has significantly advanced and would like to support the progress of this document.

We would like to provide the below specific comments.

Specific comments:

Introduction

- Paragraph 7: Derived products are mentioned in the first sentence of the paragraph, but it is not clear why it is mentioned for the wheat and other cereals containing gluten, but not for the other allergens of the list.
- Paragraph 11: Suggestion to remove the word “batch” in the final sentence
- Paragraph 13: Under “For packaged food manufacturing facilities”:
 - to add “mistakes during label development”
 - the penultimate bullet needs rewording to clarify where the failure to communicate occurs and between whom
- Paragraph 15: It is suggested to add “... and ensure accurate allergenic ingredient declaration.” to the second sentence.

Section II – Scope, Use and Definition

- Paragraph 20: It is suggested replacing the word “include” with “are” in the final sentence.
- Paragraph 25:
 - It is proposed revising the definition of “Allergen profile” as below in order to clarify that it includes both intentionally plus unintentionally:
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.

Section IV – Establishment: Design and Facilities

- Paragraph 37: “An analysis of the process, including the equipment design, should be conducted to determine the risk to the allergic consumer and whether dedicated processing lines, equipment redesign, or other control measures are needed to ensure appropriate consumer protection.”

This is about equipment design and the equipment shall be validated to allergen cleanable. It is suggested changing “risk to the allergic consumer” to “risk to allergen cross-contact” and “ensure appropriate consumer protection” to “ensure the equipment is capable for allergen clean”.

- Paragraph 41: “FBOs should store allergens separately from other allergens as well as separate them from non-allergenic ingredients.”

It is suggested revising the sentence by adding “allergenic ingredients can’t be stored above a non-allergenic ingredient” and by adding “while ensuring potential spillage management” in order to address a potential spillage.

Section V – Control of Operation

- 5.2.1.3 Application of product labels: It is suggesting adding “outdated labels from inventory should be destroyed or archived in a manner that prevents accidental use”.

- Paragraph 68: Is additional text needed in paragraph 68 under Monitoring and verification to cover incoming ingredients which may have low level presence of allergen/s and how precautionary allergen labelling should only reflect actual risk in the finished product.

FoodDrinkEurope response: We believe that the current wording is very clear.

- 5.2.1.5 Product development and change: It should be added that if an allergen is added to a formulation, it might be useful to indicate this on pack to alert allergic consumer who may have previously eaten the product and as such not check the ingredient label without such an alert.
- 5.7 Documentation and records: records should also include positive release of product or product quarantine, root cause, and corrective action.

Section VI – Establishment: Maintenance and Sanitation

- Paragraph 115: We think that both pieces of text should be included, with the latter providing more detail and introducing the correct language. We do however question whether the location of the text is currently optimum and request that further consideration is given to this e.g. would this be better placed in section 6.5?
- For the cleaning validation procedures should also specify product type and run time.

Section VIII – Transportation

- Paragraph 125: ATP testing is not able to detect systematically commodities containing allergens, e.g. heat processed milk is very poorly detected and thereby propose to be deleted as an example for the above paragraph. Therefore we suggest deleting the ATP from the paragraph: “Manufacturers should periodically conduct tests (e.g. rapid ATP (adenosine triphosphate) or protein or allergen swabs, or test kits) to detect food residues that remain after cleaning as verification that the cleaning procedures have been appropriately implemented and are effective. Where feasible, these tests should include using..... the FBO should obtain expert advice on interpretation of results (e.g. from test kit supplier or an accredited testing laboratory).”

Section IX – Consumer awareness and product information

- 9.2.1 Manufacturing: Members have a preference on the alternate text as it is clearer. They also feel that the last sentence is not required as this is covered in the following paragraph 154:

“All food products and ingredients should be accompanied by or bear adequate information to ensure other food manufacturers or processors can be informed whether the food contains an allergen. This includes any applicable precautionary allergen labelling (e.g. “may contain”). Nevertheless, it’s desirable to avoid the systematic use of such statements, which can reduce the available food in the market for allergic consumers.”

- Paragraph 153: In order to provide more clarity it is suggested revising the text as follows: “Precautionary allergen labelling (e.g. “may contain [allergen]---”) should 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:...”

Section X - Training

In the Principle ‘box’: “PRINCIPLE: Personnel engaged in food operations should have sufficient training in food allergen management to ensure measures to minimise allergen cross-contact are implemented.” It is suggested adding the following between cross contact and are implemented “... and ensure accurate ingredient labelling”.