CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda item 7 **CX/FH 18/50/7-Add.1**

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

Fiftieth Session

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PROPOSED DRAFT CODE OF PRACTICE ON FOOD ALLERGEN MANAGEMENT FOR FOOD BUSINESS OPERATORS
Replies to comments at Step 3 to CL 2018/71-FH

Comments of Argentina, Brazil, Canada, Colombia, Costa Rica, Cuba, Ecuador, Egypt, Gambia, Guyana, India, Iraq, Japan, Kenya, Malaysia, Morocco, New Zealand, Norway, Panama, Peru, Philippines, Thailand, the United States of America, AOECS and IDF

Background

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2018/71-FH issued in August 2018. Under the OCS, comments are compiled in the following order: general comments are listed first, followed by comments on specific sections.

Explanatory notes on the appendix

2. The comments submitted through the OCS are hereby attached as **Annex I** and are presented in table format.

ANNEX I

GENERAL COMMENT	MEMBER/OBSERVER
Argentina appreciates the opportunity to be able to make these comments and congratulates the Electronic Working Group for the work done on this document. Argentina considers that the present draft is an appropriate and useful document which provides applicable guidelines for the prevention of cross-contact or contamination by allergens.	**Argentina**
Brazil would like to thank the outstanding work carried out by the United Kingdom and the opportunity to supplement the text with the specific comments that follow.	**Brazil**
Gloves are frequently used by FBOs, consider if information on changing gloves is necessary throughout the document. Canada noted that a few periods were missing in the document. There were also a few typographical errors.	**Canada**
Costa Rica believes it is important to clarify that when in the body of the document reference is made to cleaning, it should be clarified that it must be validated.	**Costa Rica**
Cuba appreciates the opportunity to present its comments on the document, which are as follows: - Cuba supports the document prepared by the Electronic Working Group chaired by Australia and co-chaired by the United Kingdom and the United States of America. - Cuba believes that in point 6.2.1 Manufacturing, the text contained in paragraph 115 should be maintained and the text included as alternative should also be included because it more fully clarifies the subject. -Cuba supports leaving the text of 144 as is and does not believe further clarification is necessary.	**Cuba**
(i) General Comments: Ecuador appreciates the work performed by the Electronic Working Group and considers supporting the document, taking into account the following comments: (ii) Specific Comments: -Improvement of the translation to the Spanish language is recommended. -Ecuador suggests changing the translation of the following terms: “comercio minorista” to “venta al por menor,” and “servicios de restauración” to “servicios de alimentación colectiva” in the entire document, in order to maintain the terminology used in the Spanish language. [Translator's Note: this change does not apply to the English version] - The country considers including the following text in paragraph 7: • crustaceans (by species); • egg; • fish (by species); • milk; • peanut; • soybean; • tree nuts (by species); and • wheat and other cereals containing gluten (and their derivatives). - In section I - Objectives, we recommend eliminating paragraphs 17 and 18, as we believe they should be included in section II – Scope, Use And Definition. -The country suggests including in numeral 2.1. Scope, the following paragraphs: The management tools and guidance in this Code are a proactive approach for effectively managing allergens in food production, preparation and service and reducing risk for consumers, rather than a reactive response once a food safety hazard has been detected in a food. Food allergen management also involves allergen labelling. While this Code addresses controls to ensure that the correct label is applied during manufacturing of a product or when labelled at retail for the customer, labelling requirements for food products are addressed by the General	**Ecuador**

Standard for the Labelling of Pre-packaged Foods (CXS 1-1985) and the Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten (CXS 118-1979). -The country recommends elimination of the following from paragraph 24: The document has been structured to outline the principles of food allergen management which apply broadly to food business operators, (...). 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, prepares and serves food for direct consumption. - Ecuador requests inclusion of the definition of “Retail Sales” and “Food Service” in numeral 2.3 Definitions: Retail sales.- means a food business primarily involved in selling pre-packaged or non-prepackaged food directly to consumers for off-site or future consumption. Food Service.- means a food business that produces, prepares and serves food for direct consumption. In section IV - ESTABLISHMENT: DESIGN AND FACILITIES, it is suggested that the term “Emplazamiento” be replaced with “Ubicación,” in order to facilitate better understanding of the document. [Translator's Note: this change does not apply to the English version] -The country believes that in numeral 4.2, the word “rooms” should be replaced with “areas,” in order to facilitate better understanding of the document. -In numeral 5.2.1.4 Monitoring and verification, elimination of the following from paragraph 67 is recommended: Regular internal audits of production systems should be conducted to verify that the product formulation matches the records of allergenic ingredient use, that the final product matches the ingredients specified on the label, (...). - In paragraph 106 of numeral 5.8.1. Consumer complaints, consider eliminating the following: (...) The action plan depends on the outcome of the investigation. Action should always be taken in a timely manner to ensure further incidents do not occur, and public health and safety are protected. -The country believes that the alternative text proposed in paragraph 113, numeral 6.2.1. Manufacturing, should be included in a footnote. -Ecuador supports inclusion of paragraph 114, in numeral 9.2.1. Manufacturing of Section IX-CONSUMER AWARENESS AND PRODUCT INFORMATION.	
Issue/Background: The text in Para. 38 is too long and complicated. Position: Gambia recommends rephrasing 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.” Rationale: The new sentence provides clarity and easy of reading Issue/Background: Para. 24: Inclusion of definitions for ‘retail’ in the text in this paragraph. Position: Gambia 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.” Rationale:Definitions of terms should be under the section for Definitions Issue/Background: Para. 21: Explanation to differentiate food allergens from food intolerants Position: Gambia recommends the modification of the sentence to read “This Code does not cover hypersensitivities with a non-immunological aetiology such as lactose intolerance and sulphite sensitivity.” Rationale:The scope is specific to allergens, it should not contain any examples of food intolerance. Issue/Background: Para. 20: Inclusion of details of eight food groups which are major sources of allergens Position:Gambia 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” Issue/Background: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. Rationale:For clarity of expression and stresses the need for implementation and provide consumer protection. Issue/Background	**Gambia**

Para. 13: Bullet 1: Use of the word 'bag' Position Gambia 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/Background: 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: Gambia 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 are part of the issues considered in the normal allergen management system Gambia 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	
The document is generally OK, but it includes too many details that are unnecessary and can be too prescriptive at times. As a guidance document, it should be explicit and provide a general framework for the implementation of an efficient allergen management system.	**Morocco**
New Zealand supports the development of this Code of Practice. General Comments: 1. New Zealand suggests that the eWG consider that work is being done on labelling, in the Codex Committee on Food Labelling document: 'Discussion Paper on labelling of non-retail containers', and that there is potential for overlap between the two documents. The discussion paper on non-retail containers is at http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-714-43%252FWD%252Ffl43_06e.pdf The discussion paper on 'non-retail containers' should also be cross-referenced in this document, when the former has been completed. 2. New Zealand recommends that the use of precautionary labelling should be limited to foods for which there is a real risk of allergen cross-contamination that cannot be controlled, and to achieve this, there should be tools available to assess the level of risk (including thresholds levels that need to be developed and used) to consumers with food allergies. • New Zealand also suggests that the text relating to precautionary labelling should be passed to CCFL for their input and expertise about this wording in the current document. 3. New Zealand suggests that Section III 'Primary Production' should include additional material on primary production controls including, the proximity of planted allergen-containing crops (like wheat, soy, sesame), cleaning of harvesters and equipment especially when stored and then used seasonally and the use of shared spaces, equipment and transport vehicles for post-harvest processing of crops. 4. The terms 'personnel' and 'staff' are used interchangeably through the document. We suggest the selection and use of one of these two terms throughout. 5. New Zealand suggests including the use of allergen reference doses/thresholds and cleaning validation to inform risk assessment and risk management decisions, in this Code of Practice. This can be done through the information provided by online tools that can be used as guidance. For example, a tool used in New Zealand is 'VITAL' at http://allergenbureau.net/vital/ 6. New Zealand acknowledges the concerns of the eWG that there are different principles applied currently to thresholds, and that this is an area of continuing scientific development, but considers that these concerns should not result in the omission of thresholds/dose responses	**New Zealand**

from the Code. It is preferable that the Code includes an acknowledgement that the use of scientifically based threshold levels are a tool to evaluate risk for consumers with food allergies. Use can be made of these thresholds to reduce the use of precautionary labelling where it is not warranted, in turn making precautionary labelling much more meaningful for consumers with food allergies.

7. New Zealand suggests the consideration that allergen labelling exemptions may be applied for derivatives of allergenic foods known to be low risk, for example, refined soy oil and substances derived from it. This would reduce the inclination to overuse allergen labelling, and the use of precautionary labelling frequently, the latter in ways that reduce food options for consumers with food allergies. Having these exemptions in place would also reduce the burden on FBOs to emphasize low-risk allergen derivatives in their allergen management procedures. International harmonisation of these exemptions would need to take place – currently, exemptions from allergen labelling of these derivatives are available in some countries, and not in others. Exemptions related to the derivatives of the top commonly listed allergens would be appropriate to be considered for mention within the Code. It is also recommended that CCFH requests the CCFL to review its labelling requirements to also include exemptions for the appropriate derivatives.

Specific comments on the draft text:

2, 16, 25 Consider: Alignment of the types of businesses covered in this Code of Practice, by defining FBOs.
Currently, there is lack of clarity as to what 'businesses' are captured – there are differences in various places throughout the document.

7, 20 For the list of allergens, align with the wording in CXS 1-1985. For example, eggs, peanuts and soybeans are plural in CXS 1-1985. For consistency with existing standards.

9 Replace 'lupinare' with 'lupin/s'. Lupin/s is the term used in the Australia New Zealand Food Standards Code, that includes lupins as allergens.

11 In the last sentence, replace ''that would cause an adverse reaction in an allergic consumer' with 'and take steps to manage any potential presence of undeclared allergens'. The 'No observed adverse effect level (NOAEL)' for the whole population (or population threshold) is not well-defined for food allergens (i.e. it is difficult to determine a dose that would not cause an allergic reaction in the most sensitive individuals). This makes it difficult to determine 'the amount of allergen present due to cross-contact is below a batch 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, such as a 'Bench Mark Dose' or 'Eliciting dose', which has been well characterised for several food allergens.

11 In the last sentence, delete 'batch'. Thresholds may also be determined based on the amount of finished product consumed (Reference Amounts).

11 In the first sentence, add 'preparing and handling foods'….. after 'processing'. Addition of 'preparing and handling' lends the wider context of all steps considered, compared to just 'processing'.

13 In the section titled 'For harvesting, handling, storage and transportation', change the second bullet 'inadvertent inclusion of foreign grains' to 'Inadvertent inclusion of foreign particulates (e.g. grains, nuts or seeds).

This amendment clarifies that this is not limited to grains, as other particulates should also be considered.

13 In the section titled 'For packaged food manufacturing facilities', add 'incorrectly translated labels' to the first bullet point examples. Labels on imported foods could be incorrectly translated.

13 Under 'For retail and food service establishments', add another bullet point 'labelling errors for allergenic foods'.
Labelling errors can occur in food retail and food service situations.

24 Move the definitions of 'retail' and food service' to the 'Definitions' section in 2.3.
These definitions should be relocated to section 2.3 as they could be missed in the body of the text, here.

25 In the Definitions section 2.3,

• Include 'transporters' in the definition of 'Food business operator' (FBO): '…..includes producers, processors, wholesalers, distributors, importers, exporters, transporters, retailers, and food service operators'. Transporters should be inserted in the definition of a Food Business Operator as they have responsibilities under this Code of Practice.

25 In the Definitions section 2.3,

• Include the definition of Precautionary Allergen labelling • Include the definition of 'rework'. • Include the definition of 'cross-contact'. • Include the definition of 'batch threshold'. • Include the definition of 'SOPs', mentioned in paragraph 102 and 103. These terms have been used in the document, but are undefined in 2.3. 33 Add 'The use of one-time packaging may be a useful option for some transporters' as the fourth sentence in the paragraph. This may be an option if circumstances that allow thorough cleaning and separation of containers, do not occur. 37 Add to the end of the paragraph 'Separation by time should be considered as an option, especially for small businesses'. This addition ensures more substantive mention that allergen management procedures can include separation by time (not just separation by space, which is adequately covered), especially for smaller businesses. 39 Add the following at the end of this paragraph: Alternatively, equipment should be cleaned when switching between foods with different allergen profiles. It is likely that cleaning is the most practical solution for many retailers and food service providers, hence the suggestion for addition of this alternative. 42 Consider: Will partitions and curtains achieve the necessary barriers for containment of aerosolised allergens? Air currents and personnel traffic may negate the effect of partitions and curtains when used as containment barriers for aerosolised allergens. 44 Add the following at the end of this paragraph: And where elimination is not possible, these areas should be adequately cleaned. It may not be possible to eliminate all areas where food may accumulate, hence this suggested addition acknowledges this fact. 44 In sentence 2, consider replacing the examples of particulate allergens with ones that represent the food form. For example, 'seed', 'crumbs from baked goods'. Using more diverse examples would encourage readers to think more broadly about particulate allergens. 47 Add these two bullet points, as the second, and the last bullets in this section, respectively. • Allergens that share the same manufacturing line; • If known, the maximum potential cross-contact concentration of each allergen. These additional bullets cover minimum best practice as it encourages quantitative and qualitative risk assessment. This provides more detailed information for risk management decisions. The first additional bullet has been added as it would be useful to distinguish between those cross-contact allergens present in the same facility vs same manufacturing line, to be included in assessing the risk. The second additional bullet has been added, as it is useful to know the maximum potential cross-contact concentration (if known) to accurately assess the risk. 47 Add text after paragraph 47: To determine the cross contact concentration through testing, the lower limit of detection and/ or quantification could be quoted as the maximum potential cross-contact concentration. For dry processes, this could be determined by taking into account the allergen protein concentration in an allergenic food and its dilution factor into another food. This paragraph has been added to provide 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, a quotation of the limit of detection or limit of quantification as the cross contact concentration, is suggested. 60 Delete: Frying oil may need to be filtered to remove allergen-containing particulate material if it is likely that such particles could end up in a food with different allergen profile. Filtration may help reduce risk of allergens in the filtered food, but will not eliminate it. After filtration, there is a high risk of cross-contact during reuse and it would be likely that precautionary labelling would need to be used on subsequent products. It is not appropriate to advocate that filtration alone is an effective measure to remove allergen-containing particulate material from frying oil. 68 (also similar in 145, 147, 153) Delete 'may contain' which is used to explain the definition of 'Precautionary allergen labelling (PAL)' here. It has been suggested earlier, that PAL be included in the definitions section. Use of both 'precautionary allergen labelling' and 'may contain' is not necessary when a definition for 'precautionary allergen labelling' is included in the text. 68 Add to the end of the paragraph	

"Necessary allergen cross-contact information should be provided to the purchasing FBO, as detailed in section 5.1 (paragraph 47)." Additional text has been suggested as it is important to distinguish between ingredients and finished product, and precautionary allergen labelling is only relevant to finished product, but cross contact information should be provided with ingredients. In this instance it is assumed that the manufacturer is making the finished product, however, that may not always be the case. 68 Consider: that introducing a new single-component ingredient even though not an allergen itself, may change the allergen profile of the new product. Suggest adding 'Manufacturers should regularly review suppliers to ensure that single and multi-component ingredients……' A single component grain may be exposed to other allergenic grains or seeds due to agricultural co-mingling. This grain may be sourced from different suppliers from different geographical regions and therefore have different cross-contact allergen profiles at different times. 73 At the end of the first sentence, add 'and stored separately'. Dedicated storage is also good practice if equipment used for allergen-containing foods is marked, tagged or colour-coded. 75, 148 Sentence 1 states 'Retail and food service personnel should ask customers if they have any food allergies, even if they are not told by the customer'. New Zealand notes that asking all customers if they have any food allergies in retail and food service situations, is not always feasible or realistic. Replace 'should' with 'could ask customers'. Recommending this practice is not always logistically possible, or situationally feasible, particularly in high-volume retail and food service operations. Asking about allergies may be more practical in some situations, e.g. restaurants offering table service, where the transaction volumes are low, allergen information may not otherwise be available to the customer, and wait-staff have the time to ask the question. Paragraph 81 covers how staff fronting customers should be knowledgeable about the allergenic status on foods served. 75 Consider adding 'Use signage about allergen information either in-store or documented on menus' as sentence 2. This practise is cost-effective and reiterates information from food labels. It also Illustrates 'risk' in the final product at point-of-sale of goods to the consumer. 77 Retail and food service operators should consider, where feasible assigning one individual to prepare an allergenic food. The current wording offers an either/or approach. Whereas, even if it is feasible to have a dedicated individual to prepare an allergenic food, the assigned individual still needs to understand the allergen control procedures in place at the business for preparation of foods with different allergen profiles. 79 Delete: Frying oil may need to be filtered to remove allergen-containing particulate material if it is likely that such particles could end up in a food with different allergen profile. Filtration will reduce but not eliminate the risk of allergens and we ask that the sentence is removed. 84 Delete 'unpackaged foods'. Replace with 'foods not required to bear a label'. This provides clarity that the wording is relevant to foods that are not required to be packaged. 88 In the first sentence, delete 'when necessary'. Assessing the allergen control programs of suppliers should be a regular feature, with additional assessments when changes pre-empt a more frequent assessment. 90 Delete 'minor ingredients' in the second sentence. Replace it with 'ingredients added in small amounts' This more accurately describes the ingredient in the context of allergen management. An allergen-containing spice blend or flavour added in small amounts can still have a major allergenic impact. 103 Should include most of the bullet points in 102 (except label application, and line clearance procedures). Specifies additional records that need to be kept. Section VI –Establishment: Maintenance and Sanitation Delete 'Sanitation'; add 'Cleaning' Sanitation is more relevant to the removal and disinfection of microorganisms so we suggest this is amended to 'cleaning'. 115 Suggest the use of the 'alternate text' paragraph. Also, suggest inclusion of the following bolded and underlined additions in the 'Alternate Text' section: 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. The validation process should be specific to the allergen, process and matrix combination and should be performed more than once. The protocol must be documented and revalidated regularly (at least annually) or if any substantial change occurs. Where cross-contact allergens have been identified as a risk, cCleaning processes should be validated using the most robust and appropriate method available, 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 (or at an appropriate frequency) to ensure that the validated procedures are effective.being followed Testing should include a combination of swabbing, in-line samples and post-clean finished product where necessary, depending on whether the methods are applied to ingredients, surfaces, or finished products. The alternate text is more appropriate, providing guidance for the validation and verification of cleaning procedures, as this is what suppliers should be encouraged to do. In some instances where there is confidence that a cleaning procedure is standardised and consistently effective, a decreased verification frequency may be appropriate, such as once annually, which would avoid unnecessary testing costs. This provides much clearer expectations, and is useful guidance on "best practice". 115 Delete: 'where feasible' in sentence 3. Visual assessment is rarely sufficient for validation of cleaning as it only allows assessment of easily accessible areas and does not ensure that hang-up points and clean-in-place/difficult to clean areas have been assessed. 116 In the last sentence of this paragraph, add 'adequately' before 'removed by this process'. Since all analytical methods have a limit of detection where it cannot be proven that lower amounts are absent or present we suggest adding the word 'adequately' as it is text to make it clear that it is practically impossible to prove that a substance, such as an allergen, is completely removed. 127 In this sentence, replace 'encourage' with 'ensure that employees wash hands…..' It should be mandatory for hands to be washed between handling different allergens. 135 Delete this paragraph and replace with 'The FBO assigning the food to be transported should ensure that the transporter/haulier has clear instructions to follow, regarding potential allergen cross-contact situations. The transporter/haulier should have procedures in place to ensure the integrity of the items they are transporting.' It may not be feasible to expect (or demonstrable) that the transporter/haulier understands and identifies potential cross-contact situations. Clear and complete instructions from the supplier should be given to the transporter/haulier. 144, 145Food allergen information can either be in supporting documentation, or on the package. New Zealand's response to the discussion paper on labelling of non-retail containers supports this information being able to be provided in accompanying documentation. 144 and 145 Suggest the use of the 'alternate text' paragraph. Add: This includes any applicable information relevant to assess the cross-contact allergen risk, such as those outlined in section 5.1 (Paragraph 47), and may include precautionary allergen labelling as discussed in section 9.3. Delete: precautionary allergen labelling (e.g. "may contain"). The alternative text is our preference, as it is important to provide allergen information with food products and ingredients so purchaser can perform allergen cross-contact checks. We suggest that the allergen information (e.g. listed allergens, both intentional and cross-contact), their allergen protein concentrations, and amounts added/potentially present) should be provided but not necessarily accompanying every physical location of stored bags/packages in a manufacturing site. 144, 145Consider: Suggest that the Code recognizes alternatives to labels including allergen lists used for management of goods within FBO facilities, for example, electronic systems where label/barcode scanning reveals allergen information. Electronic scanning of label content and linked information also occurs at food businesses. 147 Add ' and that the allergens in any pre-packaged products are correctly labelled' to the end of the paragraph. Retailers also need to make sure that allergens in the pre-packaged manufactured products they sell are clearly labelled. 153 Bullet 3: Delete 'is detected at'. Replace with 'may be present at'. The sentence says 'based on an assessment of risk', which is wider than the allergen only being detected in the food.	

153 Delete 'may contain' from the first sentence. Precautionary labelling: any 'detection' should be labelled with an allergen declaration and not a "may contain" (precautionary labelling) statement. 153 Add 'including processing aids' after 'ingredients', at the end of the first sentence. Allergens also need to be declared when used as a processing aid. The current text does not make it clear that processing aids are included here. 154 For sentence 1, add '…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 amount/dose/concentration that would elicit an adverse reaction in a significant proportion of the population. Delete in which cross-contact cannot be controlled to the extent that the product does not present a risk to the allergic consumer.Replacement text has been suggested in alignment with the comments for paragraph 11. If there are areas that cannot be accessed for cleaning, or areas that cannot be cleaned in a manner where allergens can be adequately removed, this should be taken as a 'presence' and not a 'potential presence'. In these types of situations, precautionary labelling is not suitable. 156 Add 'handling' between 'preparation' and 'distribution' This is more inclusive for processes that may not be covered by 'preparation', including for example, packaging. 158 Add 'including clear between-process cleaning instructions and training' to bullet point 5, in this section. By including this, between-process cleaning is covered, along with end-of-day or start-up cleaning.	
We assess the structure of the document to be logic, the content to be important and thorough, and the practical approach in the code as essential and useful. Our understanding is that the "Proposed draft code of practice on food allergen management for food business operators" will improve consistency of allergen management, methods and practices. Consequently the health burden posed by food allergens will be reduced. We support that, in a global market, it is crucial there is international understanding about that allergens need to be managed throughout the supply chain and production process. Minimizing allergen cross-contact and the use of precautionary allergen labelling will also increase the choices available to allergic people. Control authorities in the Nordic countries have performed allergen control, including sampling, on companies producing and importing pre-packed chocolate/candy, bakery products, ready-made meals, and meat and fish products . These products were analyzed for the allergens milk protein (casein), egg-white protein, hazelnut, peanut and gluten when these were not declared as ingredients. Allergenic ingredients were incorrectly labelled on 10% of the controlled products. These results also showed that milk was commonly detected in products without any declaration of milk (12%), and hazelnut in 4% of the studied chocolate/bakery products that did not declare hazelnut as an ingredient. Further results showed that a total of 51% of products labelled with precautionary allergen labelling for milk contained casein. The range was quite wide (2.7–8,800 mg casein/kg). The range of allergen concentrations was also wide for products with precautionary labelling for nuts, - for hazelnuts the range was 3.1–18,500 ppm, and for peanuts 0.7–42,500 ppm.	**Norway**
The United States co-chaired the development of this document. We appreciate all the input received from the working group members and we look forward to country comments that can improve the text. Our comments are primarily for clarification of the text and to provide input on those areas where the working group provided alternate text from which to choose.	**USA**
IDF thinks the best way forward for allergen management in the food industry, is to determine allergen protein concentrations in food, and potential cross-contact concentrations in foods, so that cross-contact risk can be assessed quantitatively (rather than qualitatively). Also, IDF recommends comparing allergen protein doses (per serving) in foods to population threshold doses, such as the Eliciting Dose 05 or other systems, as a way of evaluating allergen cross-contact risk, and to appropriately use precautionary allergen labelling statements, such as 'may contains'. Of course, there will be some instances where allergen protein cross contact concentrations are not known, and only qualitative risk assessments can be done, however, if allergen protein cross contact concentrations are known, a quantitative risk assessment would be more informative and allow for better risk management decision making. Re: Work of the EWG, page 2, paragraph 11. It is appreciated that the Chairs sought feedback on the application of thresholds/dose responses. IDF supports the use of general text to introduce the idea, and that specified thresholds are excluded from this document, since consensus thresholds are yet to be ascertained, and may differ depending on the	**IDF**

data sets used and the geographical region. However, IDF would encourage including specific guidance on how to use a threshold dose when assessing an allergen cross-contact risk. Accordingly, we have included some comments in paragraphs 11, 47, 145, 153 and 154. The main point of guidance would be to encourage the use of a quantitative hazard analysis, which could be done by ascertaining allergen cross-contact concentrations in incoming ingredients, and in finished products that share the same line as allergens, and calculating the allergenic protein dose by taking into account the finished food serving size. The allergen dose per serving could be compared to the population threshold dose of the allergen, such as the Eliciting Dose 05 or Bench Mark Dose.	

SPECIFIC COMMENTS	MEMBER / OBSERVER AND RATIONALE
We are generally in agreement with the draft position and we would like to propose inclusion of the following points under General comments: • Hypersensitivities with a non-immunological aetiology such as lactose intolerance and sulphite sensitivity shall not be covered by the Code but would need to be declared in the label as present in the product even in miniscule quantity to protect the potentially affected consumers. • The Code shall not be specific on thresholds or allergen dose response since allergen thresholds are subject to a number of scientific studies and largely influenced byindividual differences on allergic reactions and sensitivities.	**Philippines**
SECTION IV - ESTABLISHMENT: DESIGN AND FACILITIES 11 **[TRANSLATOR'S NOTE: THIS CHANGE DOES NOT APPLY TO THE ENGLISH VERSION]**	**Colombia** Colombia proposes considering that the correct translation to Spanish is diseño. **[Translator's Note: this change does not apply to the English version]**
INTRODUCTION	
Food allergies are an increasing food safety issue globally and have emerged as a major public and personal health burden...	**Costa Rica** Costa Rica believes it is important to note from the outset that the subject is regarding allergens and Coeliac disease, since in the text as written, it appears as if Coeliac disease were an allergy.
Food ~~allergies~~ hypersensitivities, generally defined as "allergies" are an increasing food safety issue globally and have emerged as a major public and personal health burden…	**Association Of European Coeliac Societies** AOECS asks to be conform with the text of the "General Standard for the Labelling of Prepackaged Foods (CXS 1-1985), 4.2.1.4. Following foods and ingredients are known to cause hypersensitivity...
With the increasing health burden posed by food allergens, comes the expectation that FBOs take steps to accurately declare the presence of allergenic ingredients and manage unintended allergen presence... Allergen management practices should be part of good hygiene practices (GHPs), and, where appropriate, HACCP systems, in manufacturing, retail and food service. [**Translator's Note: this change does not apply to the English version]**	**Colombia** Colombia proposes considering that, throughout the entire text, the correct translation to Spanish is food service**. [Translator's Note: this change does not apply to the English version]**
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, ~~may be effective~~can minimize the allergenic risk, but ~~these treatments~~ should not be ~~validated for effectiveness in addressing an allergen hazard.~~relied upon to eliminate or completely destroy allergenic proteins	**IDF** The minimum protein size for an allergen to elicit an allergic reaction is ~30 amino acids in length (3 kDa) (Food Allergy and Intolerance: Current Issues and concerns edited by Victoria Emerton 2002; Chapter 2, Proteins as allergens: A toxicological perspective, Dr Rebecca J. Dearman and Professor Ian Kimber). It would be difficult to validate that an enzymatic or acid hydrolysis process would

	decrease all allergenic proteins in a batch to <3 kDa? ‘
IgE-mediated symptoms typically develop within minutes to 1-2 hours of ingesting the food, Non–IgE-mediated and mixed IgE- and non–IgE-mediated food allergies present with their symptoms several hours after the ingestion of the food...	**USA** We suggest separating the paragraph into two paragraphs, beginning a new paragraph with “Coeliac disease.”
IgE-mediated symptoms typically develop within minutes to 1-2 hours of ingesting the food, Non–IgE-mediated and mixed IgE- and non–IgE-mediated food allergies present with their symptoms several hours after the ingestion of the food. Symptoms of IgE-mediated food allergy may include itching around the mouth, hives, swelling of lips and eyes, difficulties in breathing, drop in blood pressure, diarrhoea and, in its most severe form, anaphylaxis; and may result in death. ~~Coeliac~~ Although not a response of the immune system, people with coeliac disease is a serious lifelong illness where the body’s immune system attacks its own tissues when gluten is consumed, should have the same kind of attention with food, including attention with the risk of cross-contamination. ~~This~~ For the coeliac people the contact with gluten causes damage to the lining of the gut and results in the inability of the body to properly absorb nutrients from food.	**Brazil** Rationale: It seems relevant to clarify that they are distinct pathologies.
IgE-mediated symptoms typically develop within minutes to 1-2 hours of ingesting the food,...Symptoms of IgE-mediated food allergy may include itching around the mouth, hives, swelling of lips and eyes, difficulties in breathing, drop in blood pressure, diarrhoea and, in its most severe form, anaphylaxis; and may result in death. Include sentence break in the following sentence> Coeliac disease is a serious lifelong illness where the body’s immune system attacks its own tissues when gluten is consumed. This causes damage to the lining of the gut and results in the inability of the body to properly absorb nutrients from food. Rationale: the correction is one of form, since if it is left with no break, it can be interpreted as an allergy.	**Costa Rica** It is important to include the symptoms of the non–IgE-mediated allergy (such as gastrointestinal symptoms, vomiting, constipation, dermatitis, among others)
While many different foods can cause allergic reactions in susceptible individuals, the majority of food allergies on a global basis are caused by a variety of proteins ~~in eight~~ in nine foods/ food groups (and derived products). These are[1]	**Iraq** add banana to the food group
While many different foods can cause allergic reactions in susceptible individuals, the majority of food allergies on a global basis are caused by a variety of proteins in eight foods/ food groups (and derived products). These are[1]:	**Costa Rica** Indicate which products do not contain them, e.g. soy oil.
cereals containg gluten; i.e., wheat, rye, barley, oats, spelt or their hybridized strains and products of these~~wheat and other cereals containing gluten (and their derivatives).~~	**Association Of European Coeliac Societies** Because of consistancy with the General Standard for the Labelling of Prepackaged Foods (CX 1-1985), the text should be in accordance with 4.2.1.4 starting with cereals containg gluten and not at the end of the list starting with wheat...
wheat and other cereals containing gluten (and their derivatives).	**Costa Rica** Recommends specifying the cereals that contain gluten.
While these are the most common, other food allergens such as sesame seeds, buckwheat, celery, mustard, molluscs, kiwi fruit and lupin are recognised as important in many countries and there is the potential for additional major allergens to be identified in the future. The controls outlined in this Code of Practice (Code) would be similar for any other allergens, and FBOs should apply these as appropriate to their own business requirements and applicable legislation. This includes being aware of the food allergens recognised as important in countries they are	**Canada** This is an important consideration for food business operators to prevent non-compliance and recalls in foreign markets.

exporting their product to and ensuring the necessary allergen labels are applied.	
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. The doses that provoke reactions vary among ~~individuals~~ individuals, the presence of cofactors, such as non-steroidal anti-inflammatory drugs (NSAID), physical exercise, alcohol, fever, acute infection and mastocytosis, and depend in part on the type of allergen. The risk of allergic reactions among a larger proportion of the allergic population ~~increases with~~ is greater due to increasing concentration of undeclared allergen.	**Brazil** Rationale: The text was supplemented by other factors that interfere with the individual allergic reaction. Reference: EAACI food allergy and anaphylaxis guidelines: diagnosis and management of food allergy. Allergy. 2014 Aug;69(8):1008-25, p. 89 and 63. doi: 10.1111/all.12429. Epub 2014 Jun 9. http://www.eaaci.org/foodallergyandanaphylaxisguidelines/Food%20Allergy%20-%20web%20version.pdf / https://www.ncbi.nlm.nih.gov/pubmed/24909706)
Poor allergen management (including insufficient or inaccurate labelling) can result in the presence of varying levels of undeclared allergens in food,...	**Costa Rica** larger proportion of the allergic population"....of the population with this condition... Rationale> to avoid redundancy.
Allergen cross-contact can result from a number of factors in processing foods, some of which pose a greater potential for cross-contact than others…	**USA** In the last sentence, we recommend deleting “batch.” 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. Rationale: Editorial. It is not clear what “batch threshold” means.
Allergen cross-contact can result from a number of factors in processing foods, some of which pose a greater potential for cross-contact than others. The control measures implemented to minimise cross-contact should be based on risk. In some instances, it may not be possible to prevent cross-contact, despite the implementation of preventative measures and GHPs, and in such situations the application of a “may contain” statement is substantiated.. However, it may be possible to…	**Canada** We are not clear on the meaning of “batch threshold”. Suggest defining or alternatively, deleting the word batch.Suggest introducing this concept early on in the document.
Allergen cross-contact can result from a number of factors in processing foods, some of which pose a greater potential for cross-contact than others… However, it may be possible to minimise cross-contact to an extent that it is possible to guarantee the ~~amount~~ absence of ~~allergen present due to cross-contact is below a batch threshold that would cause an adverse reaction in an allergic consumer~~cross-contamination of food.	**Brazil** Rationale: For many allergens there is not a secure stablished level of tolerance, since it depends on age, cofactors, amount of food consumed, and also the risk of variation between lot References: “Insufficient threshold dose information within the food allergic population restricts the advice on safe levels of contamination allergenic foods” - EAACI food allergy and anaphylaxis guidelines: diagnosis and management of food allergy. Allergy. 2014 Aug;69(8):1008-25, p. 249. doi: 10.1111/all.12429. Epub 2014 Jun 9. http://www.eaaci.org/foodallergyandanaphylaxisguidelines/Food%20Allergy%20-%20web%20version.pdf / https://www.ncbi.nlm.nih.gov/pubmed/24909706 “The severity of an allergic reaction is affected by several factors that include genetic predisposition (atopy), age, type of food allergen, nature of any food processing, environment, and physiological conditions (Taylor and Hefle, 2001; Sampson, 2003; Maleki, 2004)”(…) Moreover, sensitivity and reactivity may change with age for individuals within a population. For example, unpublished challenge

	data described in Moneret-Vautrin and Kanny (2004) show that 83% of wheat allergic children reacted to less than 2 g of wheat flour compared to 18% of wheat allergic adults. Therefore, the inclusion or exclusion of data for highly sensitive individuals can greatly affect the NOAEL determination for the population. To add to this uncertainty, the most sensitive individuals also may have more severe reactions (Wensing et al., 2002b; Perry et al., 2004). The thresholds measured for populations that exclude these individuals may not apply to those with severe allergic disease. – FDA, Approaches to Establish Thresholds for Major Food Allergens and for Gluten in Food. https://www.fda.gov/downloads/Food/IngredientsPackagingLabeling/UCM192048.pdf
Allergen cross-contact can result from a number of factors in processing foods, some of which pose a greater potential for cross-contact than others...	**Costa Rica** Clarify for better interpretation what is meant by batch threshold. Or eliminate it if there is no defined threshold. Or replace it with the term "limit of detection." ....."...should be based on the risk of contamination..."
Allergen cross-contact can result from a number of factors in processing foods, some of which pose a greater potential for cross-contact than others... 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.~~(*)	**Peru** (*)Confusing writing that does not allow adequate interpretation to express an opinion.
Allergen cross-contact can result from a number of factors in processing foods, some of which pose a greater potential for cross-contact than others… 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~~ a significant proportion of the population of consumers allergic ~~consumer.~~to the specific allergen	**IDF** The 'No observed adverse effect level (NOAEL)' for the whole population (or population threshold) is not well defined for food allergens (i.e. it is difficult to determine a dose that would not cause an allergic reaction is the most sensitive individuals), which makes it difficult to determine or measure 'the amount of allergen present due to cross-contact is below a batch threshold that would cause an adverse reaction in an allergic consumer'. It would be more practical to use a threshold dose that is below what would elicit an adverse reaction in a significant proportion of the population, such as a 'Bench Mark Dose' or 'Eliciting dose 05', which has been well characterized for several food allergens. Also, a 'batch threshold' has not been defined.
A variety of situations may result in the exposure of allergic individuals to undeclared allergens. These include the following:	**USA** For the 3rd bullet under "For harvesting, handling, storage and transportation" we suggest the following addition: - inadequate physical separation of commodities with different allergen profiles; Rationale: Editorial. Clarify what is being separated.
inadequate or ineffective cleaning ~~of~~of containers, bags and transport vehicles;	**Canada** It seems that a word was missing, possibly "containers"?
inadequate or ineffective cleaning of, bags and transport vehicles;	**Costa Rica** inadequate or ineffective cleaning of, bags, baskets, boxes or other containers and.....

inadequate or ineffective cleaning of, bags and transport vehicles; - Cross-contact	**Colombia** Colombia believes that in the harvest, handling, storage and transportation, cross-contact of raw materials with allergens can be another factor that contributes to exposure.
inadvertent inclusion of ~~foreign~~ particulates (e.g. grains, nuts or seeds);	**IDF** We recommend replacing “grains” with “particulates (e.g. grains, nuts or seeds)” as this term will encompasses all types of relevant allergens, including grains.
inadequate physical ~~separation~~separation and /or storage segregation; and	**Philippines** We propose the addition of the text “or storage segregation” to provide clarity of the paragraph.
inadequate physical ~~separation; and~~separation of commodities with different allergen profiles;	**USA**
~~Inadequate~~ Inadequate physical separation **of the allergens ;**	**Costa Rica** inadequate physical separation;
inadequate or lack of employee training/education on managing food allergens.	**Philippines** We propose the addition of the text “or lack of” to be consistent on the training requirements
labelling errors (label misprints, outdated labels, wrong label ~~in a foreign language~~applied to package, product in the wrong package);	**USA** For the first bullet under “For packaged food manufacturing facilities” we suggest the following revision: labelling errors (label misprints, outdated labels, label in a foreign language, wrong label applied to package; product in the wrong package); Rationale: Substantive. A label in a foreign language would not meet a country’s labeling requirements and is unlikely to be purchased by allergic consumers if they cannot read the language. Putting the wrong label on a package is a common error resulting in undeclared allergens; it is different from product being placed in the wrong package (another common error).
labelling errors (label misprints, reduced legibility, outdated labels, label in a foreign language, product in the wrong ~~package)~~package or omissions (e.g., not declaring an allergenic component of an ingredient,not carrying over the declaration of an allergen onto new packaging during repackaging of imported products));	**Canada** These are other common examples of labelling issues that may occur
undeclared allergen in a supplier ingredient~~; and~~; and [Translator's Note: this change does not apply to the English version]	**Costa Rica**
For retail and food service establishments: [Translator's Note: this change does not apply to the English version]	**Costa Rica**
inappropriate flow of operations or improper ~~equipment~~ equipment and utensils lay-out;	**Peru**
absence of, or inadequate, food preparation and service procedures to avoid allergen cross-contact; [Translator's Note: this change does not apply to the English version]	**Costa Rica**
food delivery websites which fail to communicate ~~allergy requirements or~~ allergen presence; and	**USA** For the 8th (next to last) bullet under “For retail and food service

	establishments" we suggest the following deletion: - food delivery websites which fail to communicate allergy requirements or allergen presence; Rationale: Editorial. It is not clear what "allergy requirements" means.
FBOs are encouraged to have documented and detailed allergen management policies and procedures specific to the food business… It also provides an opportunity for businesses to demonstrate adequate skills and knowledge in allergen management and reduces the risk of an undeclared allergen ~~incident~~ occurring.	**USA** "Allergen incident" is unclear.
SECTION II – SCOPE, USE AND DEFINITION	
This Code covers allergen management throughout the supply chain including at primary production, during manufacturing, and at retail and food service end points~~. It complements Good Hygiene Practice (GHP) in manufacturing and food preparation practices in food service~~.	**Japan** Japan proposes to delete this sentence, because it is well covered by para 23 and 24.
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. However, the complete list of recognised food allergens may vary between countries and is important to consider when exporting food.	**Canada** Consider adding this statement to raise awareness amongst FBOs that different countries have different allergen concerns and requirements.
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)...	**Costa Rica** .....Coeliac disease Is Coeliac disease a hypersensitivity? In Costa Rica Coeliac disease is considered a genetic autoimmune disorder. The term hypersensitivity is used to refer to an allergy.
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)...[Translator's Note: this change does not apply to the English version]	**Colombia** Colombia suggests a change in form.
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 cereals containg gluten, crustaceans, egg, fish, milk, peanut, soybean, tree nuts~~, wheat and other cereals containing gluten~~.	**Association Of European Coeliac Societies** because of consistency with CXS 1-1985 4.2.1.4
This Code does not cover hypersensitivities with a non-immunological aetiology ~~such as~~ **such as, for example:** lactose intolerance and sulphite sensitivity...	**Costa Rica**
The provisions in this document should be applied as appropriate for the food business (e.g. manufacturing, retail, food service), with consideration of the diversity of ingredients, processes, and control measures of the products and various degrees of ~~risk involved in managing~~ public health risks associated with allergenic ingredients/foods.	**USA**
The document has been structured to outline the principles of food allergen management which apply broadly to food business operators,… and ***food service*** means a food business or institution that produces and serves food for direct consumption.	**Canada** Institutions such as hospitals, senior homes, and daycares should also use this code.
The document has been structured to outline the principles of food allergen management which	**Costa Rica**

apply broadly to food business operators,...	the definitions of: Retail and food service should be moved to section 2.3
2.3 Definitions Include definition: "**food intolerance": the body's reaction to a food that it is unable to properly digest or metabolize.**	**Costa Rica**
2.3 Definitions Include the definition **"sensitive person": exacerbated response of the body after consuming a food.**	**Costa Rica**
2.3 Definitions	**Costa Rica** Move this section to the beginning of the document. Rationale: the definitions should go at the beginning of the document, since acronyms such as FBO and GHPs are used from the beginning.
For the purpose of this Code, the following expressions have the meaning stated:	**Costa Rica** Include the definition "Coeliac disease"
Allergen means a usually harmless ~~sustancia~~ substance (protein) capable of triggering a response that starts in the immune system and results in an allergic reaction in certain individuals...	**Colombia** Colombia suggests including the word protein after substance given that throughout the document, allergens refer to protein.
Allergen ~~***Cross-contact***~~ ***cross-contact*** occurs when an allergenic food is unintentionally incorporated into another food that is not intended to contain that allergenic food.	**USA**
~~***Cross-contact***~~ ***Allergencross-contact*** occurs when an allergenic food is unintentionally incorporated into another food that is not intended to contain that allergenic food.	**Colombia** Colombia proposes eliminating the word the and replacing with the word with an with of and changing allergen to allergens. [Translator's Note: this change does not apply to the English version] The foregoing taking into account that it is more appropriate for the text in Spanish.
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.	**Philippines** We propose to include the manner by which allergens are introduced into the product.
Allergen ~~***Profile***~~ ***profile*** means the food allergens present (or the absence of any allergens) in a food.	**USA**
Allergen Profile means the food allergens present by intentional addition as well as those inadvertently present (or the absence of any allergens) in a food.	**Brazil** Rationale: Clarify that the allergen may be present naturally in the food as can be added.
Allergen profile means the food allergens intentionally present (or the absence of any allergens) in a food.	**Costa Rica**
Competent ~~***Authority***~~ ***authority*** means the official government agency responsible for implementing food law.	**USA**
~~***Competent Authority*** means the official government agency responsible for implementing food law.~~	**Japan** This definition of "Competent Authority" should be deleted from this document, because the word has been used in many Codex documents without a definition. In addition, we do not see a significant difference in the meaning in this document and other Codex

	documents.
Food business operator (FBO) means the persons responsible for ensuring that the requirements of food law are met within the food business under their control,…	**Brazil** Harmonize the definition with the revision of the document “Proposed Draft Revision of the General Principles of Food Hygiene” (CXC 1-1969).
~~***Food business operator (FBO)*** means the persons responsible for ensuring that the requirements of food law are met within the food business under their control, and includes producers, processors, wholesalers, distributors, importers, exporters, retailers, and food service operators.~~	**Japan** The definition of "Food business operator" should be deleted from this document, because the word has been used in many Codex documents without a definition.
Food business operator (FBO) means the persons responsible for ensuring that the requirements of food law are met within the food business under their control, and includes producers, processors **including repackers**, wholesalers, distributors, importers, exporters, retailers, and food service operators. [Translator's Note: the second change in this paragraph does not apply to the English version]	**Costa Rica**
Good Hygienic Practices (GHPs) means guidelines, procedures, or activities designed to promote and maintain sanitary conditions in food production.	**Brazil** Harmonize the definition with the revision of the document “Proposed Draft Revision of the General Principles of Food Hygiene” (CXC 1-1969).
Hazard Analysis and Critical Control Points (HACCP) means ~~an established set~~ a system which identifies, evaluates, and controls hazards which are significant for food safety through implementation of ~~principles~~control measures at identified critical control points. ~~which provides a systematic way of identifying food safety hazards and making sure that they are being controlled.~~	**Philippines** We propose to adopt the definition of HACCP as indicated in the Codex General Principles of Food Hygiene (CXC 1-1969) for alignment purposes.
Hazard Analysis and Critical Control Points (HACCP) means an established set of principles which provides a systematic way of identifying food safety hazards and making sure that they are being controlled.	**Brazil** Harmonize the definition with the revision of the document “Proposed Draft Revision of the General Principles of Food Hygiene” (CXC 1-1969).
Hazard Analysis and Critical Control Points (HACCP) means ~~an established set of principles~~a system that identifies, evaluates and controls hazards that are significant for food safety ~~which provides a systematic way of identifying food safety hazards and making sure that they are being controlled~~.	**Japan** We should use the definition of HACCP in the RCP 1 document.
Visibly clean means having no visible ~~food or~~ food, debris and other residues.	**Philippines** We propose to add the word “debris” and replace “or” with “and” for clarity of definition.
SECTION III – PRIMARY PRODUCTION	
Depending on the crop, growers should consider the potential for allergen cross-contact from the growing environment. In order to assess the risk, growers should know the history of the specific growing area ~~i~~(i.e. previous ~~crops~~crops), and what other crops are being grown in close proximity…	**USA**
Depending on the crop, growers should consider the potential for allergen cross-contact from the growing environment...	**Panama** Eliminate the word as follows: Depending on the crop, growers should consider the potential for allergen cross-contact from the growing environment.[Translator's Note: this change does not apply to the English version] In order to

	assess the risk, growers should know the history of the specific growing area i.e. previous crops, and what other crops are being grown in close proximity. Where the adventitious presence of an allergen needs to be managed to ensure the allergen profile of the final food (e.g. gluten free), particular crop measures may be required to remove, to the extent practicable, the physical remains of previous crops prior to re-planting.
Harvested commodities should be cleaned to the extent possible using various methods such as sifting via size, aeration, and mechanical cleaning to remove foreign allergenic matter where feasible and consistent with Codex standards, where applicable.	**Canada** For clarification that: “consistent with Codex standards” will only apply for certain commodities where it is indicated in their specific Standard.
Harvested commodities should be cleaned to the extent possible using various methods such as sifting via size,...	**Costa Rica** Take into account that the recommendation "harvested commodities...." should only be made if the effectiveness of cleaning for removal can be validated. Costa Rica recommends that if it is going to be considered a control measure, the effectiveness should be validated.
Where a commodity is bagged, bags should be clean. Bags that have been used for an allergenic commodity should not be reused for a different commodity...	**USA** Move the last sentence of paragraph 35 to a new 32 bis following paragraph 32. 32 bis. FBOs should ensure storage areas and storage materials designated for allergenic commodities are clearly labelled or colour coded to prevent unintentional mix of commodities. Rationale: Editorial. This section is “Handling, storage and transport;” the sentence relates to storage, not cleaning and maintenance.
Where a commodity is bagged, bags should be clean...For example, avoid the re-use of jute / canvas bags for non-allergenic commodities if they have already been used for allergenic commodities, **bags used for allergenic commodities should be identified (e.g. with different colors)**. Where grains or pulses are bagged and stored together,...	**Costa Rica**
Transportation of food stuff should be carried out using a clean transport vehicle that is dry and free of the previous load to 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~~ **use specific containers identified for allergens or validate the effectiveness of the cleaning process** to minimise the potential for allergen cross-contact of the next load. For more detail on transportation refer to Section 8.	**Costa Rica**
In addition, FBOs should ensure that the area where commodities are dried is clean and physical barriers are in place to prevent spillage and cross-contact. Materials or containers used to lay, hang or bag commodities should be cleaned to remove allergenic residue. ~~FBOs should ensure storage areas and storage materials designated for allergenic commodities are clearly labelled or colour coded to prevent unintentional mix of commodities.~~	**USA** Move the last sentence to section 3.3 Rationale: Editorial. The sentence relates to storage, and does not belong in the section on cleaning and maintenance.
In addition, FBOs should ensure that the area where commodities are dried is clean and physical barriers are in place to prevent spillage and cross-contact. Materials or containers used to lay, hang or bag commodities should be cleaned to remove allergenic residue **and the effectiveness of the cleaning process should be validated**. FBOs should ensure storage	**Costa Rica**

areas and storage materials designated for allergenic commodities are clearly labelled or colour coded to prevent unintentional mix of commodities.	
SECTION IV – ESTABLISHMENT: DESIGN AND FACILITIES	
Revise as follows: Establishment design should minimise the potential for allergen cross-contact with allergens with respect to delimitation and isolation of areas, location of equipment, process flow, personnel movement and ventilation systems.	**USA**
FBOs producing food at more than one site should consider whether it is feasible to consolidate production, processing and storage of products containing specific allergens at one location. Although this may not always be feasible, particularly for small businesses, it could be used to limit allergen cross-contact. If ~~this~~ dedication of production facilities is not possible,…	**USA**
Where feasible, FBOs (manufacturers, as well as retail and food service operators) should consider the need, based on ~~risk~~ risk, to provide a dedicated production area within the establishment for the preparation of foods that do not contain allergens, or provide dedicated production areas,…	**USA**
Where feasible, FBOs (manufacturers, as well as retail and food service operators) should consider the need, based on risk to provide a dedicated production area within the establishment for the preparation of foods that do not contain allergens, or provide dedicated production areas, or use screens to set up temporary segregated areas, for foods with different allergen profiles. ~~For example, an establishment that handles different types of tree nuts could dedicate separate rooms or other areas for handling each type of nut.~~ One that handles different types of protein powders such as soy protein and milk powder could dedicate separate areas for handling these powders. Where applicable, the rooms should be appropriately designed such that effective cleaning could be administered to reduce cross-contact.	**Brazil** Rationale: As the labeling declaration is generally the same for all nuts, it does not justify separate processing areas for different nuts.
Where feasible, FBOs (manufacturers, as well as retail and food service operators) should consider the need, based on risk to provide a dedicated production area within the establishment for the preparation of foods that do not contain allergens,… Where applicable, the rooms should be appropriately designed such that effective cleaning could be administered to reduce cross-contact to avoid cross-contact.	**India** To address cross-contact
Where feasible, FBOs (manufacturers, as well as retail and food service operators) should consider the need, based on risk to provide a dedicated production area within the establishment for the preparation of foods that do not contain allergens,…	**IDF** It is likely that cleaning is the most practical solution for many retailers and food service providers, so we suggest to also mention cleaning. Alternatively, equipment should be thoroughly cleaned when switching between different food allergens.
Where feasible, FBOs (manufacturers, as well as retail and food service operators) should consider the need, based on risk to provide a dedicated production area within the establishment for the preparation of foods that do not contain allergens,...[Translator's Note: this change does not apply to the English version] Where applicable, the rooms should be appropriately designed such that ~~effective~~ validated cleaning could be administered to reduce cross-contact.	**Costa Rica**
FBOs should have areas to store allergens separately from other ~~allergens~~ allergens, as well as separate them from non-allergenic ingredients.	**USA** Section 4.2 is about “Premises and rooms” and having appropriate storage rooms; paragraph 94 addresses storage.
FBOs should store allergens separately from other allergens as well as separate them from non-	**Costa Rica**

allergenic ingredients **with physical barriers and by placing foods with allergens on lower shelves or in lower areas**.	
FBOs should store allergenic ingredients separately from other allergens as well as separate them from non-allergenic ingredients or foods.	**Colombia** Colombia suggests mentioning ingredients and not just the term allergen.
When necessary, based on an assessment of risk to the allergic consumer, manufacturers should consider designing premises and rooms to ensure appropriate allergen dust removal or hood systems…	**USA** Add a cross-reference to section 5.2.1 at the end: Where dust removal systems are not in place, other controls such as cleaning surrounding areas following dumping could be used to mitigate the risk of allergenic proteins in powders being transferred to other foods (See 5.2.1).
When necessary, based on an assessment of risk to the allergic consumer, manufacturers should consider designing premises and rooms to ensure appropriate allergen dust removal...Where dust removal systems are not in place, other controls such as **validated** cleaning of the surrounding areas following dumping could be used to mitigate the risk of allergenic proteins in powders being transferred to other foods.	**Costa Rica**
Equipment, tools, utensils and containers (other than single-use containers and packaging) contacting foods that contain allergens should be designed and constructed to provide for effective removal of allergens during cleaning. To minimise the potential for allergen cross-contact, ideally, ~~they~~ equipment, tools and utensils should not contain areas where allergens, especially particulate allergens (e.g. peanuts, tree nuts), could get caught in crevices such that ~~they~~ allergens are ~~not removed~~ difficult to remove by the cleaning procedures applied. Welds should be smooth, seals and hoses should not contain cracks, and “dead ends” or other areas where pockets of foods containing allergens can accumulate should be eliminated.	**USA**
Equipment, tools, utensils and containers (other than single-use containers and packaging) contacting foods that contain allergens should be designed and constructed to provide for effective removal of allergens during cleaning… Welds should be smooth, seals and hoses should not contain cracks, and “dead ends” or other areas where pockets of foods containing allergens can accumulate should be ~~eliminated~~avoided.	**IDF** In the last sentence (“Welds should…..”) we find that ‘avoided’ is a more appropriate term than ‘eliminated’, particularly when the cleaning process has been validated to adequately remove an allergen to below a threshold dose. It may not be cost-effective or cost-beneficial for a FBO to eliminate all imperfections in a process, such as small cracks.
Equipment, tools, utensils and containers (other than single-use containers and packaging) contacting foods that contain allergens should be designed and constructed to provide for effective removal of allergens during cleaning. To minimise the potential for allergen cross-contact, ideally, they should not contain areas where allergens, especially particulate allergens (e.g. peanuts, tree nuts), could get caught in crevices such that they are not removed by the cleaning procedures applied.[Translator's Note: this change does not apply to the English version] Welds should be smooth, seals and hoses should not contain cracks, and “dead ends” or other areas where pockets of foods containing allergens can accumulate should be eliminated.	**Colombia** Colombia proposes considering that the correct translation to Spanish is “grietas.” [Translator's Note: this change does not apply to the English version]
4.3.2 Retail and Food Service [Translator's Note: this change does not apply to the English version]	**Costa Rica**
Retail and food service operators should use equipment, tools, utensils and containers (other than single-use containers and packaging) that have been designed and constructed to ensure	**Costa Rica**

that allergens can be easily and effectively removed during cleaning. [Translator's Note: this change does not apply to the English version]	
SECTION V – CONTROL OF OPERATION	
5.1 Control of food hazards **Quantitative hazard analysis for cross-contact allergens in finished goods** **If the maximum potential allergen protein cross contact concentration is determined, the allergen dose per serving could be determined by taking into account the serving size of the finished food. The allergen dose per serving could be compared to a population threshold dose, such as the Eliciting dose, VITAL or Bench Mark Dose, to quantify the cross-contact risk, and evaluate the need for precautionary allergen labels such as a 'may contains' statement**	**IDF** we recommend providing a new paragraph on guidance on quantitative hazard analysis
FBOs should control allergens by minimising the potential for allergen cross-contact~~, by ensuring~~ . It should be ensured that information identifying the allergens present in foods are clear, correct, and that retail and food service establishments are able to communicate the allergens present in the foods they prepare. Controls should be risk-based. If it is possible to quantify the allergen dose in a finished food, this could be compared to the threshold dose for the specific allergen (e.g. Eliciting Dose 05 or Bench Mark Dose), in order to assess the risk… Information helpful in assessing risk include~~: :~~: • allergens that share the same manufacturing line: • If known, the maximum potential cross-contact concentration of each allergen (allergen protein). For instance, if testing was done, the lower limit of detection/quantification could be quoted as the maximum potential cross-contact concentration. For dry processes, this could be determined by taking into account the allergen protein concentration in an allergenic food and its dilution factor into another food.	**IDF** Suggest to make the first sentence into two separate sentences as they are covering two separate objectives. Further, we suggest addressing quantification of the risk by adding an additional sentence to this paragraph. When assessing the risk, it is also useful to distinguish between those cross-contact allergens present in the same facility vs. those that are present in the same manufacturing line. We recommend adding an inden
the nature of the allergen (i.e. whether the food itself is an allergen, derived from an allergen, or the allergen is a component in an ingredient), and, if known, the protein/allergen concentration of the allergen component or food);	**IDF** It is useful to add to the 2nd indent wording that address known maximum potential allergen cross-contact concentration, to quantitatively assess the risk, and compare to threshold doses, in order to make well informed decisions, particularly when deciding whether to use 'may contains' statements. This could be determined through testing, or for dry processes where it can be assumed that the allergen would be evenly dispersed, could be determined by taking into account the allergen protein concentration and its dilution factor into another food.
whether the allergen is a particle, powder, liquid or paste; -ease of preventing allergen cross-contact between processing line -ease of cleaning equipment used to process foods with different allergen profiles; and	**USA** Add two additional bullets as follows: Information helpful in assessing risk include: - allergens present in the facility; -the nature of the allergen (i.e. whether the food itself is an allergen, derived from an allergen, or the allergen is a component in an ingredient); - whether the allergen is a particle, powder, liquid or paste; - the processing steps where the allergen is used; - ease of preventing allergen cross-contact between processing line; - ease of cleaning equipment used to process foods with different allergen profiles; and

	- the amount of allergen used in products. Rationale: Substantive. Add some important factors.
the amount of allergen used in products.	**Canada** Suggest to modify or delete the last bullet because it is not clear how "the amount of allergen used in products" would be helpful in assessing risk when there doesn't seem to be any known thresholds for allergens.
~~It is important~~ It is **necessary** that FBOs educate and train personnel to have awareness of food allergens and their health impact in order to ensure they implement the necessary allergen controls.	**Costa Rica**
FBOs ~~should~~ must:	**Costa Rica**
Manufacturers should also identify steps in the operation that are critical to ensuring allergens are properly labelled including reviewing recipes and labels on compound ingredients, and ensuring that the correct product is packed in the correct ~~package~~package (i.e., with the correct label).	**USA**
Manufacturers should also identify steps in the operation that are critical to ensuring allergens are properly labelled including reviewing recipes and labels on compound ingredients, and ensuring that the correct product is packed in the correct package~~.~~. When reviewing recipes, product enhancement processes, such as egg washes on baked products for glossy finish, should also be included.	**Canada** It's been observed that this type of processes can be omitted from the recipes, which has led to undeclared eggs in products.
Retail and food service operators should also manage menus, including in-store and on websites, if they contain allergen information, to assure content is current and matches the food product. There should be an advice in menus and/or at the counter stating that customers should notify the server of any food allergies and documentation about allergens was available in the kitchen area.	**Brazil** Rationale: To be more specific about food service. Reference: Food Allergy Knowledge and Attitudes of Restaurant Managers and Staff: An EHS-Net Study. J Food Prot. Author manuscript; available in PMC 2017 Feb 23. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5321626/
Manufacturers ~~should develop~~ should **design** traffic flow of allergen-containing ingredients, packaging supplies and employees during the manufacture of foods to minimise the potential for allergen cross-contact. This should include consideration for managing the movement for transient people such as managers, quality assurance personnel, inspectors, maintenance personnel, and visitors.	**Costa Rica**
Where there is a risk of ~~contamination~~ allergen cross-contact by personnel, personnel working on processing lines that contain an allergen should be restricted from working on lines that do not contain that allergen. Manufacturers should consider a system to clearly identify employees working on lines manufacturing foods containing different allergen profiles, e.g. different coloured uniform or hair net.	**USA**
Manufacturers ~~should~~ **must** provide shielding, permanent and/or temporary partitions, covers, and catch pans to protect exposed unpackaged product from allergen cross-contact. Dry ingredients should be physically contained by covering specific equipment, such as conveying equipment, hoppers, storage silos, shakers, and size graders. Where feasible, manufacturers ~~deberían~~ must dedicate utensils and tools for processing lines with different food allergen profiles;...	**Costa Rica**
Dry ingredients that are, or contain, a food allergen should be added in a manner that minimises	**Philippines**

the potential for unintentional dispersion by dust… The use of dry allergens with a propensity for dust formation should, where feasible, be scheduled at the end of a production/processing day to allow sufficient time for the air handling system to evacuate any residual allergenic dust from the establishment ~~environment overnight~~environment.	We propose deletion of "overnight" so as not to be too prescriptive.
Manufacturers should evaluate the potential for cross-contact due to cooking media,…	**Philippines** For Clarification on the basis of the statement "Frying oil may need to be filtered to remove allergen-containing particulate material if it is likely that such particles could end up in a food with a different allergen profile."
Manufacturers ~~should~~ **must** evaluate the potential for cross-contact due to cooking media, such as water or oil... Frying oil may need to be filtered to remove allergen-containing particulate material if it is likely that such particles could end up in a food with a different allergen profile.	**Costa Rica** ....Frying oil may need to be filtered. Costa Rica believes it is important to evaluate whether filtration is effective for completely removing allergens.
Spills that contain food allergens should be cleaned up immediately, avoiding further dispersion (e.g. care should be taken not to generate aerosols with high pressure washers, or to re-suspend dust using compressed air hoses).	**USA**
Spills that contain food allergens ~~should~~ **must** be cleaned up immediately, avoiding further dispersion (e.g. care not to generate aerosols with high pressure washers, or to re-suspend dust using compressed air hoses)~~.~~. Recommendations can be made for using, for example for liquids, spill kits or vacuums for dust.	**Costa Rica**
Rework and Work-in-Process (WIP) that contains allergens should be stored in sturdy containers with secure covers in designated, clearly marked areas. [Translator's Note: this change does not apply to the English version] The **rework** or WIP ~~should~~ **must** be appropriately labelled with all food allergens specifically highlighted, and ~~properly inventoried and accounted for~~ must be properly **traced** and during storage and when used, to minimise the potential for incorporation into the wrong product.	**Costa Rica**
Manufacturers should implement a policy for rework to be added back to same finished product whenever feasible. Alternatively, rework can be added to another product with the same food allergen profile.	**USA** Rework is added back to a product before it is "finished."
Manufacturers should implement a policy for rework to be added back to the same ~~finished~~ product whenever feasible. Alternatively, rework can be added to another product with the same food allergen profile.	**USA**
Manufacturers should implement procedures to ensure that allergen information and labels are accurate (see 5.3 Incoming Material Requirements) and verify that the correct product labels are used on the production line when packaging/labelling products. This could involve manual checks and/or automated checks such as bar code recognition or vision inspection systems to ensure the correct packaging is used.	**Canada** Suggestion to add an additional example of an automated check.
Manufacturers ~~should~~ **must** implement procedures to ensure that allergen information and labels are accurate (see 5.3 Incoming Material Requirements) and verify that the correct product labels are used on the production line when packaging/labelling products...	**Costa Rica**
5.2.1.4 Monitoring and verification	**IDF** It is important to distinguish between ingredients and finished product, since precautionary allergen labelling is only relevant to finished foods.

	Cross contact information should be provided with ingredients, so that risk assessments can be done in the finished goods that contain the ingredients or share the same line as products that contain the ingredients. In this instance it is assumed that the manufacturer is making the finished product, however, it may not always be the case as often FBOs manufacture foods to be used as ingredients in other foods. Additional text/guidance should be considered that addresses low level presence of allergens and how precautionary labelling should be determined in finished product would add value to the document. Such additional information should detail how/on what basis this is to be determined (e.g. thresholds).
Manufacturers should regularly review suppliers to ensure that multi-component ingredients (e.g. sauces, spice mixes) have not changed and verify that precautionary allergen labelling (such as "may contain" statements) are only applied in instances where the manufacturer cannot reasonably prevent allergen cross-contact when such cross-contract could present a risk to allergic consumers~~.~~. Periodic product testing of ingredients for undeclared allergens may also be considered.	**Canada** Testing foods for allergens could be included as an additional example of verification options.
Manufacturers should regularly review suppliers to ensure that multi-component ingredients (e.g. sauces, spice mixes) have not ~~changed and verify~~ changed. The verification should be carried out that precautionary allergen labelling (such as "may contain" statements) are only applied in instances where the manufacturer cannot reasonably prevent allergen cross-contact when such cross-contract could present a risk to allergic consumers.	**Japan** The allergen labelling should be separately stated from ingredients (1st sentence).
Manufacturers should regularly review suppliers to ensure that multi-component ingredients (e.g. sauces, spice mixes) have not changed and verify ~~that~~ that, , if manufacturing a finished food, precautionary allergen labelling (such as "may contain" statements) are only applied in instances where the manufacturer cannot reasonably prevent allergen cross-contact when such cross-contract could present a risk to allergic ~~consumers~~consumers or in the case of manufacturing an ingredient, necessary allergen cross-contact information is provided to the purchasing FBO, as detailed in paragraph 48.	**IDF**
When developing new products, or changing formulations or ingredient suppliers, manufacturers should consider whether it is feasible to use a non-allergenic ingredient to provide the same functionality as an allergenic ingredient to avoid introducing a new allergen into the establishment or a processing line. Manufacturer's allergen monitoring and verification process should include any or all ingredients which may have low level presence of allergens and that precautionary allergen labelling ('may contain"…) should only reflect actual risk in the finished product based on risk assessment.	**Philippines** Raw materials from primary production to harvesting and conversion to finished products would have been subjected to potential risks of cross-contact with allergens. It is imperative for the manufacturer to conduct its own risk assessment even at the developmental stage on new products, formula revisions and new suppliers.
When developing new products, or changing formulations or ingredient suppliers,…	**Association Of European Coeliac Societies** to respond to the question in the document CX/FH18/50/7: AOECS is very happy with this text as it is, it would contribute to more products for gluten intolerant consumers.
Product labels should be developed and verified to match the formulation before the new product or changed formulation is produced, and product and label specifications that are no longer used should be destroyed or archived in a manner that prevents accidental use~~.~~.	**Brazil** Rationale: The rational is the same of the one in the item in which is stated manufacturer should communicate "any changes in the supplier's operation that could impact the allergen profile of the

Paragraph 72 bis: In case of a change in the formulation in which there is an addition of allergenic information, manufacturers should promote campaign informing the change, with indication on the packaging - "new formulation" - and on their websites.	ingredient".
Product labels ~~should~~ **must** be developed and verified to match the formulation before the new product or changed formulation is produced, and product and label specifications that are no longer used should be destroyed or archived in a manner that prevents accidental use.	**Costa Rica**
5.2.2 Retail and Food Service [Translator's Note: this change does not apply to the English version]	**Costa Rica**
Food that contains allergens should also be stored separate from food that does not contain allergens, or from food with a different allergen ~~profile~~profile (e.g., separation that prevents physical contact).	**USA**
Retail and food service personnel should ~~ask~~ be aware of allergens in the foods provided to customers ~~if~~ in order to provide appropriate information when a customer indicates they ~~have any~~ have a food ~~allergies, even if they are not told by the customer~~allergy. They should also know and understand the risks of allergen cross-contact from the processes followed in the preparation of food items. Cross-contact during preparation primarily occurs in the following ways:	**USA** Rationale: Substantive. It is up to the customer to indicate they have a food allergy, rather than putting the burden on retail and food service to ask each customer about food allergies.
Retail and food service personnel should ask customers if they have any food allergies, even if they are not told by the customer...[Translator's Note: this change does not apply to the English version]	**Costa Rica**
Retail and food service personnel should ask customers if they have any food allergies,...	**Panama** For these precautions at retail and food service, one option would be to place warning signs on site and on the menu.
Retail and food service operators should consider, where feasible, assigning one individual to prepare an allergenic food (e.g. deveining prawns/shrimp). Where this is not possible, allergen control procedures should be in place between preparation of foods with different allergen ~~profiles~~profiles (e.g., washing hands, changing disposable gloves). .	**USA**
Containers and tools used to hold or transfer foods that contain allergens should, where possible, be dedicated to holding a specific allergen and be marked, tagged, or colour-coded to identify the allergen. Where such dedication is not possible, effective cleaning procedures should be in place to clean containers and tools before use for a food with a different allergen profile.	**USA**
~~Food~~ There should be a list of allergens available in the kitchen area. Food preparation staff should only use ingredients listed in the recipe, and not replace one ingredient with another unless the ingredient is known not to contain an allergen…	**Brazil** Rationale: In order for operators to consult a list of allergenic foods in case of recipe changes. Reference: Food Allergy Knowledge and Attitudes of Restaurant Managers and Staff: An EHS-Net Study. J Food Prot. Author manuscript; available in PMC 2017 Feb 23. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5321626/
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 an allergen...	**Costa Rica** .... Frying oil may need to be filtered... Costa Rica would like to ask if there is evidence that this procedure
Food preparation operators should only use ingredients listed in the recipe, and not replace one ingredient with another...	**Panama** Panama does not agree with the current text and proposes:

	...It may be necessary to use an appropriate method to eliminate any trace of allergens present in frying oil, when it is likely that they may end up in a food with a different allergen profile...
Personnel handling product at display and consumer purchase, as well as servers in restaurants and other food service operations, ~~should~~ must be knowledgeable about the allergens in products; ... [Translator's Note: the first change in this paragraph does not apply to the English version]	**Costa Rica**
Rework and WIP should be stored in sturdy containers with secure covers in designated, clearly marked areas. The rework or WIP should be appropriately labelled to minimise the potential for incorporation into the wrong product. Food handlers should implement a policy for rework to be added back to the ~~same finished~~ same product) whenever feasible. Alternatively, rework can be added into another product with the same food allergen profile.	**USA** Rationale: Editorial. Rework is added back to a product before it is "finished."
Rework and WIP should be stored in sturdy containers with secure covers in designated, clearly marked areas... [Translator's Note: this change does not apply to the English version]	**Costa Rica**
Supervisors of food preparation and service staff in retail and food service operations should periodically verify that employees are following the procedures established to minimise the potential for allergen cross-contact and inform the consumer about allergens in foods,...[Translator's Note: this change does not apply to the English version]	**Costa Rica**
When introducing a new product or recipe with a different allergen profile, procedures for minimising cross-contact should to be reviewed and possibly revised. Employees that handle these foods, in particular those who have direct interaction with customers should be made aware of the changes in a timely manner. Allergen information on menus and on websites should also be updated.	**USA** Allergen information is often provided via websites, which need to be updated when changes are made.
Manufacturers should have programs in place to assess the allergen control programs of suppliers when necessary, e.g… 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.	**USA** Rationale: Editorial. "With each lot" is inconsistent with "periodically."
Manufacturers should have programs in place to assess the allergen control programs of suppliers when necessary,… A specification sheet, certificate of analysis, or vendor guarantee periodically with each lot can also be useful in addressing a supplier's control of food allergens, as well as periodic testing for undeclared allergens.	**Canada** Testing foods for allergens could be included as an additional example of verification options.
Manufacturers should have procedures/policies in place for suppliers to notify, in a timely manner, the manufacturer of any changes in the supplier's operation as necessary that could impact the allergen profile of the ingredient from the supplier…	**Japan**
5.3.2 Retail and Food Service [Translator's Note: this change does not apply to the English version]	**Costa Rica**
Retail and food service operators should purchase ingredients for which the allergen profile is known, e.g. packaged foods that list all ingredients....[Translator's Note: this change does not apply to the English version]	**Costa Rica**
Retail and food service operators ~~should inspect ingredients~~should: • Inspect all raw materials, especially allergen-containing ingredients, upon receipt to ensure that the containers are intact and that the contents have not leaked or spread. If containers have leaks, tears, or other defects, operators should inspect nearby containers for evidence of	**Philippines** We propose to itemize the guidance procedure in handling allergen leaks and issuance of disposition for ease in understanding the requirements.

allergen cross-contact~~. Retail and food service operators should~~ . • reject (or properly dispose of) ingredients when a container is not intact or there is evidence of allergen cross-contact~~, or~~ • handle damaged containers in a manner that minimises the potential for allergen cross-contact (e.g. place a damaged container inside another container, or move the contents of the damaged container to a different container)~~.~~.	
The labels of incoming packaged ingredients used in the preparation of foods should be reviewed for allergens to ensure knowledge about the allergens present in the final prepared food. Retail and food service operators should store allergen-containing ingredients in a manner to minimise the potential for allergen ~~cross-contact~~ cross-contact, e.g. store allergen-containing ingredients below those that do not contain allergens.	**USA**
FBOs should have procedures in place to review and approve all proposed product labels of all foods to ensure they are accurate with respect to ~~allergens~~allergens and updated in case of any change in the formulation of the product. …	**Brazil** Rationale: The rational is the same of the one in the item in which is stated manufacturer should communicate “any changes in the supplier’s operation that could impact the allergen profile of the ingredient”.
FBOs should have procedures in place to review and approve all proposed product labels of all foods to ensure they are accurate with respect to allergens...[Translator's Note: this change does not apply to the English version]	**Colombia** Colombia proposes considering that the correct translation to Spanish and to improve the wording of the text.
Rework [Translator's Note: this change does not apply to the English version]	**Costa Rica**
verification activities (including any analytical test results for allergens); and	**USA** Add “corrective actions taken” to the list of manufacturing records as the next to the last bullet (after “verification” and before “training”). Rationale: Substantive. Corrective action records are important records to maintain.
verification activities (including any analytical test results for allergens); -corrective actions taken; and	**USA**
5.7.2 Retail and Food Service [Translator's Note: this change does not apply to the English version]	**Costa Rica**
allergenic ingredients associated with each menu ~~item~~item (where possible, retailers and food services operators should keep a copy of the label) ; • register of any information regarding risk of cross-contact, such as oil in fryer or cutting boards;	**Brazil** Rationale: To be more specific and effective in food service.
cleaning (SOPs); and	**Costa Rica** It is important to include validation
training (personnel trained, type of training, and date of training). - label printing and application	**Canada** Label application could also be included for the retail sector under records of the Retail and Food Service (section 5.7.2).
A traceability/product tracing system should be designed and implemented according to the *Principles for Traceability/Products tracing* as a tool within a *Food Inspection and Certification System* (CXG 60-2006) to enable the withdrawal of products where necessary…	**USA** Rationale: Editorial. To explain what is meant by a “food allergen incident.”
A traceability/product tracing system should be designed and implemented according to the	**USA**

Principles for Traceability/Products tracing as a tool within a *Food Inspection and Certification System* (CXG 60-2006) to enable the withdrawal of products where necessary. Procedures and processes should be in place that facilitate a one-step back and one-step-forward traceability review in the case of a food allergen ~~incident~~incident(e.g., an allergic reaction to an undeclared allergen).	
FBOs should have procedures in place for handling consumer complaints with regard to undeclared allergens in foods. The procedures should define the steps to be followed in handling complaints and include complaint collection, investigation, analysis, record keeping and reporting to relevant competent authorities where appropriate.	**Philippines** We propose to add the word "relevant" to describe competent authorities to be aligned with Paragraph 107.
The complaint particulars should be evaluated and a decision made as to what action to take, e.g. recall of product, publicity in websites and newspapers, changes in manufacturing or preparation procedures…	**Brazil** Rationale: To emphasize the need for information publicity.
The complaint particulars should be evaluated and a decision made as to what action to take, e.g. recall of product, changes in manufacturing or preparation procedures...	**Panama** Panama proposes: FBOs must develop a recall plan that includes Allergens
SECTION VI – ESTABLISHMENT: MAINTENANCE AND SANITATION	
SECTION VI – ESTABLISHMENT: MAINTENANCE AND ~~SANITATION~~CLEANING	**IDF** Cleaning is a more appropriate term for allergens, as sanitation is more relevant to removal and disinfection of micro-organisms
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. Where feasible, cleaning equipment, tools, cloths, sponges, and cleaning solution should be designated for foods with specific allergen profiles and used in a manner that does not result in cross-contact. For example, freshly prepared cleaning solutions should be used rather than reusing cleaning solutions that have been used for foods with different allergen profiles to prevent the recontamination of surfaces with allergenic food residues.	**Canada** Suggest adding information from paragraph 113 (or similar wording) to paragraph 114 since the recommendation could apply to Retail and Food Service as well.
Equipment, utensils, containers and preparation areas should be adequately cleaned (~~at a minimum visually clean)~~ (properly cleaned) immediately after the preparation, storage, and dispensing of foods to prevent allergen cross-contact.	**Morocco**
~~Manufacturers should develop cleaning procedures designed to remove food allergens to the extent possible.~~ Manufacturers should implement validated allergen cleaning process designed to adequately remove food allergens to the extent possible and minimize cross-contact. Cleaning processes are 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.115. Manufacturers should implement validated allergen cleaning process designed to adequately remove food allergens to the extent possible and minimize cross-contact. Cleaning processes are 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	**Philippines** The cleaning process has to be validated to evaluate effectiveness. Incomplete data on cleaning validation can result to undeclared allergens and put lives at risk due to a potentially life-threatening contaminant.

procedures are being followed.	
Manufacturers should develop cleaning procedures designed to remove food allergens to the extent possible.	**USA** Recommendation: We recommend combining the alternate text with the sentence in paragraph 116 as follows: Manufacturers should develop cleaning procedures designed to remove food allergens to the extent possible. Having assurance that cleaning has been effective is known as cleaning validation. Validation is the assessment of cleaning methods to ensure that they Validation of the cleaning process provides a means of assuring that cleaning processes are adequate to reduce or eliminate allergens and thereby 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: Substantive. The alternate text provides additional information to explain the first sentence. The last sentence is deleted because it is covered in paragraph 124.
~~Manufacturers should develop cleaning procedures designed to remove food allergens to the extent possible.~~	**Japan**
Manufacturers should develop cleaning procedures designed to remove food allergens to the extent possible.	**IDF** The alternate text is more appropriate, as it provides definitive guidance for the validation and verification of cleaning procedures. However, the terms validation, verification and monitoring are not used in the proper way (se Codex GL 69). The changes suggested will make the guidance non-confusing In some instances where there is confidence that a cleaning procedure is standardised and consistently effective, a decreased verification frequency may be appropriate, such as once annually, which would avoid unnecessary testing costs. We recommend the following to replace the first alternate para. in para. 116:
~~Manufacturers should develop cleaning procedures designed to remove food allergens to the extent possible.~~	**Peru** Should be omitted
~~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.~~	**Philippines**
~~Having assurance that cleaning has been effective is known as cleaning validation.~~ Validation ~~is the assessment~~ of the cleaning ~~methods to ensure~~ process provides a means of assuring that ~~they~~ cleaning processes are adequate to reduce or eliminate allergens and thereby minimise allergen cross-contact. Cleaning processes should be validated through visual assessment	**USA** Rationale: Substantive. The alternate text provides additional information to explain the first sentence. The last sentence is deleted because it is covered in paragraph 124.

(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.~~	
Having assurance that cleaning has been effective is known as cleaning validation… Cleaning processes should be validated through visual assessment (checking that equipment is visibly clean) and, where feasible, through an analytical testing ~~programme~~programme (refer to section 6.5 of this Code). The effectiveness of cleaning should be monitored ~~(verified)~~ after each cleaning event to ensure the validated procedures are being performed and verified on a regular basis to ensure the validated procedures are followed.	**Canada** Canada supports the inclusion of the alternate text proposed by the chairs in paragraph 115 and keeping the sentence preceding the alternate text. We also suggest a few modifications. We suggest adding a reference to section 6.5 and also separating the words "monitored (verified)" because they have different meanings, which may also affect the "frequency" of performing the task.
Having assurance that cleaning has been effective is known as cleaning validation…	**Brazil** Brazil is of the opinion that the wording of the alternate text seems to be more detailed.
~~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~~ check (checking that equipment is visibly clean) and, where feasible, through an analytical testing programme….	**Japan** Japan proposes to modify the alternate text. The 3rd sentence provides sufficient guidance and the 1st and 2nd sentences are difficult to understand. The term of "assessment" should be replaced with "check" since the word "assessment" might give the idea as if it is the same as "risk assessment" as written in working principles for risk analysis.
~~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.~~	**Thailand** We prefer the text in paragraph 115 which is followed by the sentence "These procedures should specify the equipment, utensil, or area of the establishment to be cleaned …" in the next paragraph.
Having assurance that cleaning has been effective is known as cleaning validation…	**Egypt** The statement "Manufacturers should develop cleaning procedures designed to remove food allergens to the extent possible" mixed with the alternate text " 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."
Having assurance that cleaning has been effective is known as cleaning validation…	**Guyana** The alternate text should be included as an explanation/elaboration of the above principle stated.
~~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~~	**Kenya**

~~effectiveness of cleaning should be monitored (verified) after each cleaning event to ensure the validated procedures are being followed.~~	
Having assurance that cleaning has been effective is known as cleaning validation...	**Norway** We support the alternate text of 115 as this text gives the necessary guidance
Having assurance that cleaning has been effective is known as cleaning validation...	**Costa Rica** The sentence ...Cleaning processes should be validated through visual assessment... Costa Rica believes this is not a feasible suggestion given that validation should always be done using analytical methods.
Having assurance that cleaning has been effective is known as cleaning validation...	**Panama** Panama agrees with the wording of the alternative text. There should be a methodology for verifying the effectiveness of cleaning or have tools or equipment for performing this task.
Having assurance that cleaning has been effective is known as cleaning validation...	**Peru** we agree with the alternative text.
~~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.~~ Validation of the intended cleaning should be carried out in connection with the hazard analysis and should provide an assessment of cleaning methods to ensure that they are adequate to minimise allergen cross-contact. Where cross-contact allergens have been identified as a risk, cleaning processes can be validated by carrying out intensive verification during a short period as part of the implementation procedure. Cleaning operations should be monitored after each cleaning event through visual checking that equipment is visibly clean. Where feasible, the effectiveness of cleaning should be verified through an analytical testing programme to ensure the validated procedures have been being followed.	**IDF**
These procedures should specify the equipment, utensil, or area of the establishment to be ~~cleaned using the procedures~~cleaned; the tools and cleaning materials to be used;…	**Canada**
These procedures should specify the equipment, utensil, or area of the establishment to be cleaned using the procedures;...	**Peru** In order to maintain the proper sequence of the wording, place this paragraph before the preceding paragraph
~~Because~~ Cognizant of microbial problems that can result from introducing water into some facilities and ~~equipment can result in microbial problems~~equipment, some production procedures ~~includes~~ include a “push-through” technique in which the subsequent product, an inert ingredient (such as sugar or ~~salt),~~ salt,) or an allergen-containing ingredient (such as ~~flour)~~ flour), that will be an ingredient in the subsequent product is pushed through the system to remove food residue…	**Philippines** We support the idea of introducing an alternative dry method of removing allergen from the processing line. We propose to reword some portions of the text for clarity and delete the parenthesis in “(such as sugar or salt)” and “(such as flour)” to make them an integral part of the Code.
Because introducing water into some facilities and equipment can result in microbial problems,	**Peru**

some production procedures includes a “push-through” technique in which the subsequent product, an inert ingredient (such as sugar or salt), or an allergen-containing ingredient (such as flour) that will be an ingredient in the subsequent product is pushed through the system to remove food residue. ~~When~~ In the event it is feasible, and the use of a test kit allows it, ~~should be used to evaluate~~ “push-through” material, or the first product through the line should be evaluated, to demonstrate that a food allergen from a previous production run has been removed by this process.	
Because introducing water into some facilities and equipment can result in microbial problems,… Where feasible, test kits should be used to evaluate “push-through” material, or the first product through the line, to demonstrate that a food allergen from a previous production run has been adequately removed by this process.	**IDF** At then of the paragraph, it is stated that the FBO should demonstrate that a food allergen from a previous production run has been removed by this process. However, it is practically impossible to prove that a substance, such as an allergen, is completely removed, since all analytical methods have a lower limit of detection, where it cannot be proven that lower amounts are absent or present, thus it is more appropriate to state removal is adequate. Without this it could be perceived that complete removal is always required (which cannot be proven), or that a low level of removal is sufficient – which would also not be appropriate. We recommend inserting the word “adequately” before “removed”
~~Manufacturers should develop allergen clean up procedures for the manufacturing line~~ In the event of spills of allergen-containing ingredients, manufacturers should develop allergen clean up procedures for the manufacturing line.	**Peru** 3E
In addition, pest control system should not use allergens (e.g. peanut butter, cheese) as bait in traps...	**Panama** Panama suggests revising the translation to Spanish: Panama we propose using the word Pest Control Systems [Translator's Note: this change does not apply to the English version]
6.5 Monitoring effectiveness [Translator's Note: this change does not apply to the English version]	**Colombia** Colombia proposes considering that the correct translation to Spanish is monitoreo. [Translator's Note: this change does not apply to the English version]
If a manufacturer uses CIP systems to clean pipe work, equipment and machinery,...	**Panama** Panama proposes: Tests validated by recognized agencies be used.
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…	**Brazil** Rationale: ATP testing is not able to detect systematically commodities containing allergens.
Manufacturers should periodically conduct ~~tests (e.g. rapid ATP (adenosine triphosphate)~~ tests 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…	**India** Since 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.
SECTION VII – ESTABLISHMENT: PERSONAL HYGIENE	
~~Food~~ Where necessary, food handlers should wear dedicated clothing in areas where specific	**Japan**

allergens are handled and there is a high risk of allergen cross-contact…	The recommendations should be applied Depending on the separation of areas/ processing lines in each establishment.
Food handlers should wear dedicated clothing in areas where specific allergens are handled and there is a high risk of allergen cross-contact. The wearing of this clothing should be restricted to those areas. It may be appropriate to visually identify which personnel work on processing lines with different allergen profiles (e.g. different coloured clothing such as smocks or hair nets). [Translator's Note: this change does not apply to the English version]	**Colombia** Colombia proposes considering that the correct translation to Spanish is batas. [Translator's Note: this change does not apply to the English version]
7.2 Retail and Food Service [Translator's Note: this change does not apply to the English version]	**Costa Rica**
SECTION VIII – TRANSPORTATION	
FBOs should only distribute foods that have appropriate allergen labelling and/or be able to provide appropriate documentation (e.g. non-prepacked foods for catering purposes) for recipients to determine the allergen status of the food. [Translator's Note: this change does not apply to the English version]	**Costa Rica**
The transporter/ haulier should demonstrate a clear understanding of the food they carry and ensure personnel can identify and understand potential allergen cross-contact situations. [Translator's Note: this change does not apply to the English version]	**Colombia** Colombia proposes considering that the correct translation to Spanish is conoce. [Translator's Note: this change does not apply to the English version]
SECTION IX – CONSUMER AWARENESS AND PRODUCT INFORMATION	
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.	**USA** We recommend using original paragraph 146 with modifications: 146. 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 contains an allergen. This includes any applicable precautionary allergen labelling (e.g. “may contain”). However, such statements should be truthful and not misleading and not used in lieu of GHPs (see section 9.3). Rationale: Substantive. The alternate text provides additional information, but it needs to include consumers. The deleted sentence is covered in paragraph 155.
~~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.~~	**Japan**
~~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.~~	**Thailand** For para 144 and 145, we prefer para 145 which is clearer with the additional information related to precautionary allergen labelling.
~~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.~~	**Peru** This paragraph should be omitted.
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	**Canada** Canada supports the alternate text in paragraph 145 with the addition

food contains an allergen…	of “consumers” in that paragraph.
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 contains an allergen. This includes any applicable precautionary allergen labelling (e.g. “may contain”). Nevertheless, it`s desirable to avoid the ~~systematic~~ unjustified and unmotivated use of such statements, which can reduce the available food in the market for allergic consumers.	**Brazil** Rationale: The consumers were excluded in the alternative text.
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.	**India** We support alternate text as text is more clear and easy to understand
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 contains an allergen…	**Japan** Alternate text gives deleted explanations and specific examples. Information should be provided to consumers as well and the addition is consistent with the third sentence.
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 is an allergen or contains or may contains an allergen. This includes any applicable precautionary allergen labelling (e.g. “may contain”). Nevertheless, it`s desirable to avoid the ~~systematic~~ unnecesary use of such statements, which can reduce the available food in the market for allergic consumers.	**Argentina**
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…	**Egypt** Egypt agrees to the alternate text as it is.
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…	**Guyana** The alternate text is more explanatory and should be used instead.
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.~~	**Kenya**
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...	**Norway** We support the text as drafted in paragraph 146 with an addition. "and consumers" in the first sentence. In order to manage their condition, consumers with food allergies must be informed about the composition of the products they are buying. Procedures to ensure that food is labelled appropriately is therefore essential. This includes any applicable precautionary allergen labelling (e.g. “may contain”). Nevertheless, it is desirable to avoid the systematic use of such statements, which can reduce the available products in the market for allergic consumers.
All food products and ingredients should be accompanied by or bear adequate information to	**Costa Rica**

ensure other food manufacturers or processors and consumers 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.~~*Nevertheless, it`s desirable to avoid the systematic use of such statements, which can reduce the available food in the market for allergic consumers.*	In the phrase, "may contain" Costa Rica believes it should be clarified. That is, in what instances should “may contain” not be used without impacting consumer health. In the following text: Nevertheless, it`s desirable to avoid the systematic use of such statements, which can reduce the available food in the market for allergic consumers. Costa Rica believes that the preventive labelling may be used in cases in which the FBOs demonstrate that they have done everything possible to prevent cross-contact and were unable to prevent it.
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...	**Colombia** Colombia supports the alternative text as it considers it to be comprehensive and relevant.
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 contains an allergen...	**Peru** we agree with the paragraph.
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.	**Association Of European Coeliac Societies** AOECS prefers this sentence and not the "may contain" labelling. Any "may contain" statement leaves the risk to the consumer whether or not to consume a food bearing this claim. As a matter of fact, the very large majority of prepackaged foods which do not contain or consist of gluten containing ingredients bears the claim "may contain gluten". We know from our contacts with various Quality Managers of several companies that the claim "may contain gluten" is written on prepackaged foods because of the request of the legal advisors and not because of a real existing risk. We kindly ask Codex to spend further work how to stop this development and to revise para 153 accordingly.
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~~ information relevant to assess the cross-contact allergen ~~labelling (e.g~~risk, such as those outline in paragraph 48. ~~“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~~consumers , and can cause complacency behavior in consumers that have food allergies, where they would disregard precautionary allergen labelling.	**IDF** IDF prefers the alternative text, as it is important to provide allergen information with food products and ingredients, so purchasers can perform allergen cross-contact risk assessments. As pointed out in our comments to paragraph 69 (5.2.1.4 Monitoring and verification), it is important to distinguish between ingredients and finished product. Cross contact information should be provided with ingredients, not necessarily as a label. The information related to labelling statements could benefit from additional text providing the rationale – see suggested addition
Manufacturers should have procedures in place to ensure that food is labelled appropriately, as per section 9.3. These procedures should include precautionary measures to prevent cross-contact of allergenic and non-allergenic foods from raw material receiving to actual product preparation process. Ingredient information from primary suppliers provide data to support the allergen risk assessment that forms the framework of an allergen labelling procedure.	**Philippines** We propose to consolidate the statement into one encompassing responsibility of allergen risk assessment of a Food Business Operator without being redundant to the requirements of section 9.3 on labelling.
Manufacturers should have procedures in place to ensure that food is labelled appropriately, as per section 9.3.	**Panama** FBOs must establish labelling for internal packages and for consumer

	packages.
All food products and ingredients should be accompanied by or bear adequate information to ensure customers can be informed whether a food is, or contains (or may contain) an allergenic ingredient. Restaurants should ensure that any allergen information on the ~~menu~~menu and/or over the counter, both on site and online, is current. Similarly, retail operations should make sure allergen information they make available, e.g. online, is current and correct.	**Brazil** Rationale: To give alternatives to the food service.
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 the information)…	**USA** As noted for a similar change in paragraph 76, it is up to customers to indicate they have a food allergy, rather than putting the burden on retail and food service to ask each customer about food allergies.
Self-serve areas where consumers handle unpackaged food products may pose a particular risk for cross-contact. Provision of information on the risk of cross-contact should be considered in these instances (e.g. allergen alert signage or symbol/icons). Dedicated ~~equipment~~ equipment, utensils and tools for handling allergenic food should not be used for non-allergenic food.	**USA**
The *General Standard for the Labelling of Pre-packaged Foods* lists the foods and ingredients known to cause hypersensitivity that should always be declared on the label~~.~~. add Clearly and attract attention in different colour	**Iraq**
The *General Standard for the Labelling of Pre-packaged Foods* lists the foods and ingredients known to cause hypersensitivity that ~~should~~ shall always be declared on the label.	**Malaysia** 152. The General Standard for the Labelling of Pre-packaged Foods lists the foods and ingredients known to cause hypersensitivity that should shall always be declared on the label. Justification: The term “shall” means that it is compulsory to declare ingredients known to cause hypersensitivity. This is also to be consistent with: i) The word “shall” used in para 4.2.1.4 under The General Standard for the Labelling of Prepackaged Foods (CXS 1-1985) ii) Malaysia Food Regulations 1985 on Particulars in Labelling.
Precautionary allergen labelling (e.g. “may contain…”) 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:	**Canada** To improve the clarity of the sentence, we suggest deleting the statement in brackets because if an ingredient is in a food then it should not appear in a “may contain” statement.
Precautionary allergen labelling (e.g. “may ~~contain…”)~~ contain (name of the 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:	**India** For providing better clarity
allergen cross-contact for a specific food cannot be prevented using GHPs,	**USA**
the allergen is detected at levels that, based on an assessment of risk, could result in adverse health consequences to a significant proportion of the population of allergic consumers.	**IDF** As addressed in our comment to paragraph 11, we suggest amending the 3rd indent.
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… Paragraph 154 bis: In case of a change in the formulation in which there is an addition of allergenic information, manufacturers should promote campaign informing the change, with	**Brazil** Rationale: The rational is the same of the one in the item in which is stated manufacturer should communicate “any changes in the supplier’s operation that could impact the allergen profile of the ingredient”.

indication on the packaging - "new formulation" - and on their websites.	
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~~ where there is potential for the cross-contact ~~cannot be controlled~~ amount to ~~the extent~~ be greater than a threshold dose that ~~the product does not present~~ would elicit an adverse reaction in a ~~risk to~~ significant proportion of the ~~allergic consumer~~population. ~~For example, areas of processing equipment that cannot be accessed for cleaning, or that cannot be cleaned in a manner where allergens are adequately removed (e.g. certain dry cleaning methods).~~	**IDF**
SECTION X – TRAINING	
All personnel involved in the production, manufacturer, preparation, ~~distribution~~ distribution, retail and service of foods should understand their role in allergen management and the food safety implications of the presence of undeclared food allergens. This includes temporary and maintenance personnel.	**Japan**
general allergen awareness, including the serious nature and possible health consequences of the unintended or undeclared presence of allergens in products from a consumer perspective;	**Canada** To be consistent with paragraph 13.
hygienic design of facilities and equipment ~~in relation to allergens~~preventing allergen cross-contact and minimizing allergen transfer;	**Japan** For clarification.
handling of rework materials to prevent unintended allergens from being incorporated into a food; [Translator's Note: this change does not apply to the English version]	**Costa Rica**