CODEX ALIMENTARIUS COMMISSION



Food and Agriculture Organization of the United Nations



Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - E-mail: codex@fao.org - www.codexalimentarius.org
Agenda item 5
CX/FH 19/51/5

JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON FOOD HYGIENE Fifty-first Session Cleveland, Ohio, United States of America, 4 - 8 November 2019

DRAFT CODE OF PRACTICE ON FOOD ALLERGEN MANAGEMENT FOR FOOD BUSINESS OPERATORS Replies to comments at Step 6 to CL 2019/69-FH

Comments of Argentina, Australia, Colombia, Costa Rica, Honduras, Indonesia, Iran, Malawi, Malaysia, Nicaragua, Panama, Syrian Arab Republic, Uruguay, USA, ARSO, FoodDrinkEurope, IDF, IUFOST

Background

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2019/69-FH issued in August 2019. 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 <u>Annex I</u> and are presented in table format.

ANNEX I

GENERAL COMMENT	MEMBER/OBSERVER
no comments	Syrian Arab Republic
We would like to thank the electronic working group (eWG) chaired by Australia and Co-Chaired by the United Kingdom and the United States of America for preparing this document. The document has significantly advanced and would like to support the progress of this document.	FoodDrinkEurope
Indonesia appreciates the effort has been done by the Working Groups and would like to thanks the Codex Committee on Food Hygiene for the opportunity to provide these comments. In general, we agree that the document should revised, however there are some recommendations as following below.	Indonesia
IUFoST fully supports all efforts to control food allergens in all foods, processed or unprocessed. This draft is quite comprehensive and shold provide guidance to all food producers, processors. food scientist, technologist and espatblishment managers on proper procedures.	IUFOST
The temperature of planting and storage will also pose a risk to the consumer when the product is being harvested this will therefore contaminate the final product to be poisonous hence not goot good for human consumption.	ARSO
We appreciate and support the document at step 6, as we consider this an important COP to ensure global consistency of allergen management. we support further development and the upcoming work of CCFL. Especially we appreciate the initiated Expert Consultation on risk assessment by FAO/WHO. We are looking forward to further development.	Norway
The document currently has some formatting issues that we recommend the Codex Secretariat fix. Specifically, in Appendix III of REP19/FH, the definition for "visibly clean" has "Section III – Primary Production" at the end. This text needs to be removed from the definition and become a bolded header just above the "Principle" box. The header "Section III – Primary Production" that has been inserted after paragraph 29 and before "3.1 Environmental hygiene" should be deleted. We also recommend that all section headers be formatted the same way; currently only Section I – Objectives is bolded upper case. We recommend that all section headers follow this format.	USA
Some of the changes can be done when the document is revised for adoption at Step 8, but others would be better to do now, since the document could remain at Step 5 for some time.	
The United States co-chaired the development of this document, which was adopted by the Codex Alimentarius Commission (CAC42) at step 5. We support this document, as it addresses a very important food safety issue. CCFH50 (November 2018) sought the advice of the Codex Committee on Food Labeling (CCFL) on the list of foods that cause allergic reactions and on the use of precautionary allergen labeling statements. CCFH50 also requested FAO/WHO to convene an expert consultation on threshold levels for priority allergens and how these could be used to determine whether cleaning procedures remove an allergen to a level that minimizes the potential for an allergic reaction and to determine whether an ingredient with a low level of an allergen due to cross-contact warrants allergen controls. There were also several questions related to analytical methods. As a result of these requests to CCFL and to FAO/WHO, a number of paragraphs and the definition of "precautionary allergen labelling" are in square brackets. CCFL45 (May 2019) agreed to start new work to clarify the provisions related to allergen labeling and develop guidance on precautionary allergen labeling. CCFL45 also requested scientific advice from FAO/WHO relating to the list of foods in section 4.2.1.4 of the General	

Standard for Labelling of Pre-Packaged Foods (CXS 1-1985) relevant to allergen labeling with respect to criteria for assessing additions and	
exclusions from the list and whether there should be additions or deletions	
Thus, scientific advice is needed for CCFL to address the request of CCFH and for CCFH to finalize the Draft Code of Practice on Food	
Allergen Management for Food Business Operators and remove the square brackets. It thus appears that the Draft Code of Practice on Food	
Allergen Management for Food Business Operators and remove the square brackets. It thus appears that the Drat code of Fractice of Food Allergen Management for Food Business Operators could remain at Step 5 for some time. We suggest that the Codex Secretariat inform	
CCFH51 about the status of a Step 5 document and how it should be viewed by countries that may wish to apply the guidance in this	
document. We also request that FAO/WHO provide an estimate of the timeframe for providing the advice requested by CCFH and CCFL.	
document. We also request that I AO/WHO provide an estimate of the timename for providing the advice requested by COT II and COT L.	
Nicaragua appreciates the work on this document and the opportunity to submit comments.	Nicaragua .
Overall, we suggest considering the work to be done in the framework of the CCFL on allergen labelling, including review of the groups and	
preventive labelling, to prevent duplicating efforts.	
	Outer
Cuba appreciates the opportunity to submit comments. In principle, we support the contents of the proposed Draft Code of Practice on Food	<mark>Cuba</mark>
Allergen Management for Food Business Operators at Step 6.	
3.2 Hygienic production of food sources	Colombia
3.3 Handling, Storage and Transport	
3.2 Hygienic production of food sources	Colombia
	Add numeral 3.3,
	which is found in the
	text of the document.
	text of the document.
	Oslambia
5.6 Management and supervision	Colombia
5.7 Documentation and records	Add numeral 5.7,
	which is found in the
	text of the document.
6.3 Pest control systems [translator's note: change does not affect the English]	Colombia
	[translator's note:
	change does not affect
	the English]
	

SPECIFIC COMMENTS	MEMBER / OBSERVER AND RATIONALE
TITLE	
PROPOSED DRAFT CODE OF PRACTICE ON FOOD ALLERGEN MANAGEMENT FOR	Costa Rica
FOOD BUSINESS OPERATORS	If the body of the document includes other substances that cause
	hypersensitivity but not allergies, the title should be consistent with
	this. It isn't clear because sulphites are excluded. What would the
	criteria be?
PROPOSED DRAFT CODE OF PRACTICE ON FOOD ALLERGEN MANAGEMENT FOR	Panama
FOOD BUSINESS OPERATORS	Panama agrees with the content of the document.

	We have made editorial corrections.
PROPOSED DRAFT CODE OF PRACTICE ON FOOD ALLERGEN MANAGEMENT FOR FOOD BUSINESS OPERATORS	IDF/FIL IDF does not see the use of this document limited to Food business operators, such as other Codex Code of Practice.
TABLE OF CONTENTS	
	 FoodDrinkEurope Members suggested separating the document following the structure which is in-line with established Codex practice: Principles for Food Allergen Management Code of Practice on Food Allergen Management Guideline on Risk Analysis for Food Allergen Management The control of allergens across supply chains is critical to food safety, the complexity of required controls is demonstrated by periodic safety incidents. As the approaches described throughout the current draft are dependent upon a common set of principles, and as some elements therein may not be familiar to all participating countries, it is necessary to establish these principles separately from the detail on supply chain controls.
	Codes of Practice define activities that are considered essential to ensure the safety and suitability of food for consumption. Although it is relevant to state the use of risk assessment within a Code of Practice, such statements are not utile unless there is guidance on application, how to define the suitability and conduct of such assessment. This type of guidance is not appropriate for a COP, but is appropriate for a Guideline.
INTRODUCTION	
	IDF/FIL It would be useful if the scope of the document should be inserted before hazard characterization. That was it would be clear what is being covered (intentional presence, unintentional and cross-contact) and also which of allergens, foods causing intolerance and even sulphites are being included (since the document isn't clear on whether they are being addressed or not). It is noteworthy that the paper is directed at undeclared allergens – this incudes when allergens are intentionally added to food but not declared.
	FoodDrinkEurope Many of the FoodDrinkEurope specific comments relate to the following topics which require further consideration in the Draft COP in order to accurately reflect the best practices of FBOs:

	 The importance of documented production site allergen management controls That 'visually and physically clean' is the primary method or preventing cross-contamination via food contact surfaces It should be recognized that the use of incorrect ingredients is a major cause of undeclared allergens in finished products, therefore appropriate controls should be in place It should be recognized that there are limited scenarios wherein the movement of personnel creates a likelihood of cross-contamination, and controls should be proportional and risk based Site and equipment design should be based on whether there is a likelihood of cross-contamination, if there is no likelihood it is not necessary to implement additional controls when processing allergen-containing foods It should be recognized that it is often not practicable for bulk shipments of ingredients (business to business), to be labelled with detailed information
	We suggest leaving the title in capital letters.
Para.1.	
Food allergies, <u>are</u> an immune-mediated food hypersensitivity, <u>are and</u> an increasing food safety issue globally. <u>and_They</u> have emerged as a major public and personal health burden. While food allergies may affect a relatively small proportion of the population, an allergic reaction can be severe or potentially fatal. Furthermore, it is increasingly apparent that people with food allergies experience a very significant reduction in quality of life, some of which could be mitigated by a harmonised approach to the management of allergens in the food chain.	Colombia We propose new wording.
Para. 2	
Based on the foregoing, Aallergens are an ongoing food safety concern for allergic consumers, those who have people with food allergies in their care, growers, transporters, ffood business operators (FBOs), transporters and competent authorities.	Nicaragua Nicaragua's proposed changes aim to improve ease of understanding. The term "growers" was eliminated as they are part of the FBOs, pursuant to the definition provided in the previous version of the document.
Para. 3	
With the increasing health burden posed by food allergens, comes the expectation that FBOs take steps to accurately declare the presence of allergenic ingredients, prevent-minimize the risk and manage unintended allergen presence and that Competent Authorities provide guidance, oversight and advice, where necessary, to FBOs on food allergen complaint investigations. FBOs including producers, processors, wholesalers, distributors, importers, exporters, retailers, transporters, and food service operators all have a role in managing allergens.	IDF/FIL Except operating in / making a "(naming the allergen)-free" claim, industry minimizes and manage the risk- therefore, "prevent" should be replaced with "minimize the risk".

With the increasing health burden posed by food allergens, comes the expectation that FBOs take steps to accurately declare the presence of allergenic ingredients, prevent and manage their unintended allergens, presence and that Competent Authorities provide guidance and oversight , and advice-, where necessary, to FBOs on food allergen complaint investigations. FBOs including producers, processors, wholesalers, distributors, importers, exporters, retailers, transporters, and food service operators all have a role in managing allergens.	Nicaragua We propose striking the word advice, given that the role of competent authorities is oversight and control.
Para. 4 In a global market, it is crucial that there is <u>international harmonised</u> understanding of this issue and of the measures required to address. Allergen management practices should be part of good hygiene practices (GHPs), and, where appropriate, HACCP systems, <u>manufacturing-food</u> <u>chain</u> , retail and food service.	Nicaragua Nicaragua proposes replacing the term international with harmonised and manufacturing with food chain to be consistent with the scope of the document. (TRANSLATION)
Para. 5	
Allergens need to be managed throughout the supply chain and production process. Treatments lethal for .microbial pathogens, pathogenic microorganisms, such as heating, high pressure processing, etc. generally do not destroy allergenic proteins. Processes that degrade proteins, such as enzymatic or acid hydrolysis, can minimise the allergenicity, but should not be relied upon to eliminate or completely destroy allergenic proteins.	Colombia We propose replacing "microbial" with "microorganisms."
Allergens <u>may be present in food due to, intentional addition, unintended addition (through</u> <u>inadequate information about the presence of the allergen in an ingredient) or from cross contact</u> <u>at any stage of production. Allergens</u> need to be managed throughout the supply chain and production process. Treatments lethal for microbial pathogens, such as heating, high pressure processing, etc. generally do not destroy allergenic proteins. Processes that degrade proteins, such as enzymatic or acid hydrolysis, can minimise the allergenicity, but should not be relied upon to eliminate or completely destroy allergenic proteins.	IDF/FIL Suggest addition of sentence to beginning of point to set context Potentially "Allergens may be present in food due to; intentional addition, unintended addition (through inadequate information about the presence of the allergen in an ingredient) or from cross contact at any stage of production".
	Suggest deletion of this sentence as the allergenicity can be both increased or decreased with further processing. Degradation of proteins leads to new epitopes and other allergenic issue. #5 raises a controversial issue and should be modified accordingly. "Allergens need to be managed specifically throughout the supply chain and production process (NB: Food chain ?). Control measures for other hazards will not be efficient for allergen management
Allergens need to be managed throughout the supply chain and production process. Treatments lethal for microbial pathogens, such as heating, high pressure processing, etc. generally do not destroy allergenic proteins. Processes that degrade proteins, such as enzymatic or acid hydrolysis, can <u>minimise-reduce</u> the allergenicity, but should not be relied upon to eliminate or completely destroy allergenic proteins.	FoodDrinkEurope The word in minimise in the final sentence is inaccurate. We suggest changing into 'reduce'.
HAZARD CHARACTERISATI	
	FoodDrinkEurope Controlled Allergens
	As new work for CCFL was approved by CAC 42 which will

	comprehensively review allergen labelling (Revision to the General Standard for the Labelling of Prepackaged Foods: allergen labelling, and guidance on precautionary allergen or advisory labelling), it is proposed referring to any mentioned food as non-exhaustive examples, as well as by making a link to the update of the work of the CCFL.	
Para. 8		
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.	Uruguay Uruguay believes it necessary to explain why "coeliac disease" is mentioned as it is not one of the allergies that had been discussed, although the components may cause allergic reactions for certain consumer groups. We suggest clearer wording. This could be as noted on the AAAAI page (https://www.aaaai.org): https://www.aaaai.org/conditions-and-treatments/library/allergy- library/celiac-disease: "It is important to note that Celiac disease and NCGS are different from having a food allergy. With a food allergy, the immune system overreacts to a particular food causing symptoms that are potentially serious or even life-threatening. In food allergic patients, symptoms begin shortly after ingestion of the food (a few minutes to an hour or so) and include hives, shortness of breath, lightheadedness or vomiting. A food allergy is an immune, but not an autoimmune, reaction."	
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.	IDF/FIL Focus should be allergens (i.e. wheat as an allergen) not on a specific disease or intolerances.	
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.	FoodDrinkEurope Coeliac disease requires different risk assessment considerations to IgE-mediated hypersensitivities. Therefore, to avoid confusion we would suggest this detail is moved to paragraph 10 – see comment on paragraph 10 with proposed text to clarify this. Rationale: Focus of this code of practice need to be on allergens (i.e. wheat as an allergen) not on a specific disease or intolerance.	
Para. 9		
[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	Argentina Argentina finds that the list is aligned with the recommendation issued by CCFL (REP 19 FL para. 100), given that it considers the same allergens on the list in point 4.2.1.4 of the General Standard for the Labelling of Prepackaged Foods (CXS 1-1985).	

	Argentina agrees with keeping sulphites outside the scope of the
	document.
[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 It is important to clarify that there are exceptions.
[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	Indonesia Indonesia agrees with list of foods that can cause allergic reactions
cereals containing gluten (i.e., wheat, rye, barley, oats ² , spelt or their hybridized strains and products of these)	Malaysia Spelt is a type of wheat, and 'products of these' is already mentioned in the above lines with '(eight foods/ food groups (and derived products). Propose to avoid repetition.
[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	Uruguay This note refers to sulphites as allergens, whereas, by definition, food allergens are proteins.
[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	FoodDrinkEurope As new work for CCFL was approved by CAC 42 which will comprehensively review allergen labelling (Revision to the General Standard for the Labelling of Prepackaged Foods: allergen labelling, and guidance on precautionary allergen or advisory labelling), it is proposed referring to any mentioned food as non-exhaustive examples, as well as by making a link to the update of the work of the CCFL. In addition, we propose revising the text by deleting spelt which is is a type of wheat, and 'products of these' which is already mentioned in the above line
Cereals containing gluten (i.e., wheat, rye, barley, oats ² , spelt or their hybridized strains and	
2 while oats do not contain gluten, they are commonly produced in the same location as gluten-contain	
cereals containing gluten (i.e., wheat, rye, barley, oats ² , spelt -or their hybridized strains and products of these))	FoodDrinkEurope <u>Footer with Superscript 2:</u> As new work for CCFL was approved by CAC 42 which will comprehensively review allergen labelling (Revision to the General Standard for the Labelling of Prepackaged Foods: allergen labelling, and guidance on precautionary allergen or advisory labelling), it is proposed referring to any mentioned food as non-exhaustive examples, as well as by making a link to the update of the work of the CCFL. If the text remains as such in the Code of Practice the wording should be extended to avoid conveying the message that only gluten is of concern when considering cross-contact from cereals containing gluten. We propose the following 'Oats pose a risk to oat- allergic consumers and require risk management in their own right. Oats do not contain gluten but are included in the cereals containing

	gluten group as they are commonly produced in the same location as gluten-containing cereals such as wheat, resulting in cross- contact which may also require risk assessment and management. ' As new work for CCFL was approved by CAC 42 which will comprehensively review allergen labelling (Revision to the General Standard for the Labelling of Prepackaged Foods: allergen labelling, and guidance on precautionary allergen or advisory labelling), it is proposed referring to any mentioned food as non-exhaustive examples, as well as by making a link to the update of the work of the CCFL. In addition, we propose revising the text by deleting spelt which is is a type of wheat, and 'products of these' which is already mentioned in the above line
cereals containing gluten (i.e., wheat, rye, barley, oats², spelt or their hybridized strains and products of these)	IDF/FIL out of scope
Para. 10	
The most common allergic reactions to tree nuts involve almonds, Brazil nuts, cashews, hazelnuts, macadamias, pecans, pistachios and walnuts. In addition, cereal grains such as wheat, barley and rye contain gluten, which can cause adverse reactions in persons with Coeliac disease, as well as those with specific allergies to those cereals.	FoodDrinkEurope We suggest adding the paragraph 8 in paragraph 10. Coeliac disease requires different risk assessment considerations to IgE- mediated hypersensitivities. As focus of this code of practice is allergens (i.e. wheat as an allergen) not a specific disease or intolerance. <i>Category : EDITORIAL</i>
The most common allergic reactions to tree nuts involve almonds, Brazil nuts, cashews, hazelnuts, macadamias, pecans, pistachios and walnuts. In addition, cereal grains such as wheat, barley and rye contain glutenrye, which can cause adverse reactions in persons with Coeliac disease, as well as those with specific allergies to those cereals.	IDF/FIL out of scope
Para. 11	
While the allergens listed above are the most common, other food allergens such as sesame seeds, buckwheat, celery, mustard, molluscs and lupin are recognised as important in many countries. The list of recognised food allergens varies among 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 where they are processed and to which they are exporting their product to managing those allergens and ensuring the necessary allergen labels are applied.	Costa Rica It would also be appropriate to include fruit examples like tomato, peach, apple, banana, mango, etc.
Para. 12	
Poor allergen management <u>and allergen-labelling information (</u> including insufficient or inaccurate labelling) can result in the presence of varying levels of undeclared and/or unintended allergens in food, which may pose a risk if consumed by an allergic individual. The doses that provoke reactions vary <u>among-between</u> individuals and <u>depend in part are dependent</u> on the type of	Australia

Iran As mentioned in paragraph 5, enzymatic or acid hydrolysis could minimize allergenic proteins.
Nicaragua We propose some changes for ease of understanding.
Costa Rica Current threshold studies do not take Latin American populations into consideration; it is thus dangerous to instruct using them as a standard for the entire world at this time. For the time being, and as a pilot plan, this methodology could be used as long as it considers highly-sensitive patients, particularly those who could present risk of anaphylaxis. There should be a way to inform them of these minimum amounts. We suggest the labelling standard establish universal terminology for different labelling situations. Consumers ask to not be labelled as "allergic," but rather they be referred to as persons suffering from food allergies. Based on this, we recommend addressing this throughout the body of the document.
IDF/FIL
of preventive measures and GHPs, and in such situations, the er, it may be possible to minimise cross-contact to an extent that the e reaction in the majority of consumers allergic to the specific allergen. Insumers with food allergies. Threshold levels can be used to reduce to consumers with food allergies.]
) (

[In some instances, it may not be possible to prevent cross-contact, despite the implementation of preventive measures and GHPs, and in such-these situations, the application of a precautionary allergen statement such as "may contain" contain: allergen x, allergen y" is substantiated. However, it may be possible to minimise cross-contact to an extent that the amount of allergen present due to cross-contact is below a threshold that would cause an adverse reaction in the majority of consumers allergic to the specific allergen. In these instances, the use of scientifically based threshold levels is a tool an appropriate approach to evaluate risk for consumers with food allergies. Threshold levels can be used to reduce precautionary allergen labelling, in turn making precautionary labelling much more meaningful for consumers with food allergies.]	Australia
	Colombia If there is a threshold, it needs to be established. These thresholds are unknown at this time.
	Honduras There is no scientific study demonstrating the thresholds for each allergen. Indonesia
	Indonesia agrees with this precautionary allergen labelling, because it may not be possible to prevent cross contact.
[In some instances, it may not be possible to prevent cross-contact, despite the implementation of preventive measures and GHPs, and in such situations, the application of a precautionary allergen statement such as "may <u>contain</u> " <u>contain (allergen)</u> " is substantiated. However, it may be possible to minimise cross-contact to an extent that the amount of allergen present due to cross-contact is below a threshold that would cause an adverse reaction in the majority of consumers allergic to the specific allergen. In these instances, the use of scientifically based threshold levels is a tool to evaluate risk for consumers with food allergies. Threshold levels can be used to reduce precautionary allergen labelling, in turn making precautionary labelling much more meaningful for consumers with food allergies.]	FoodDrinkEurope Revise the paragraph as below (insertion in bold and italics): [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 precautionary allergen statement such as "may contain (allergen)" is substantiated consumers with food allergies.] Rationale: Provide clarity to the text. IDF/FIL Paragraphs 14 & 15 would be better located in a section that deals
	with the measures to manage allergens rather than hazard characterization. Potentially this could be moved to Labelling or Section VI
Para. 15	
It is important that FBOs are able to identify the allergenic nature of the foods, including ingredients, ingredients and processing aids aids they handle and take steps to manage any potential presence of undeclared allergens.	Australia
It <u>13.15</u> . In those instances where testing is required to prove an adequate level of cleaning and allergen removal, a threshold level can be referred to in order to prove that an adequate level of cleaning has been achieved (given that test methods cannot prove allergen elimination since they have a Limit Of Detection (LOD) that is greater than zero. For example, if a test method is used to measure the amount of allergen in a rinse water or on a surface, the method has a LOD of 5 mg/kg, the serve size of the subsequent batch is 50 grams, and a not detected (< 5 mg/kg)	IDF/FIL This would provide defined direction to the food industry for how to use testing in combination with a threshold level and subsequent batch size, in order to evaluate risk and dictate the use of precautionary labelling. This would encourage consistent use of allergen cross-contact risk assessment, and precautionary labelling,

result is obtained, it could be assumed that the allergen cross-contact amount is 5 mg/kg x	which would help restore the confidence of consumers with food
50/1000 kg = 0.25 mg. If the threshold level is >0.25 mg, then precautionary labelling could be	allergy. New paragraphe suggested below before 15.
omitted, and if the threshold level is <0.25 mg the precautionary labelling could be included. is	allergy. New paragraphe suggested below before 15.
important that FBOs are able to identify the allergenic nature of the foods, including ingredients,	
and processing aids they handle and take steps to manage any potential presence of	
undeclared allergens.	
FACTORS CONTRIBUTING TO EX	
A variety of situations may result in the exposure of allergic individuals to undeclared allergens.	Australia
These include but are not limited to the following:	
A variety of situations may result in the exposure of allergic individuals to undeclared allergens.	IDF/FIL
These include but are not limited to the following:	
FOR PACKAGED FOOD MANUFACTURI	NG FACILITIES
labelling errors (e.g. mistakes during label development, label misprints, outdated labels, lost	Colombia
labels, wrong label applied to package, incorrectly translated labels or omitting the declaration of	We do not understand what "lost labels" refers to in the paragraph
an allergen, product in the wrong package);	on "For packaged food manufacturing facilities."
labelling_declaration_errors for allergenic foods;	Australia
improper use or handling of an allergen-containing ingredient;	IDF/FIL
food delivery websites which fail to communicate allergen presence in food items to the	IDF/FIL
consumer, as well failure of a delivery service to communicate a consumer's dietary	IDF notes that currently there is no Codex requirement to provide
requirements, with respect to allergens, to the FBO preparing the food; and	allergen information via websites. However this may be addressed
	in two areas of proposed work for CCFL – on e-commerce and on
	allergen labelling. The work on non-retail containers is also relevant
	because food for catering may be captured by that proposed new
	standard, rather than by the GCSLPF. IDF notes the CCFL areas of
	related work and that progression of the CCFH COP should take
	account of concurrent developments at CCFL in these areas.
Cross-contact-Allergen cross-contact can occur at many points in the food chain. Potential	IDF/FIL
points where allergen cross-contact can occur are outlined in relevant sections within this Code.	
FBOs are encouraged to shall have documented and detailed allergen management policies and	FoodDrinkEurope
procedures specific to the food business. Implementing allergen management policies and	'are encouraged' should be replaced with 'shall' as documented
procedures, and compliance with these:	allergen management policies and procedures are pre-requisites for
	food production. This is reflected in national regulations
FBOs are encouraged to have documented and detailed allergen management policies and	IDF/FIL
procedures specific to the food business. Implementing allergen management policies and	This point sits under sub-heading "factors contributing to exposure"
procedures specific to the food business. Implementing allergen management policies and procedures, and compliance with these:	which is not appropriate. Suggest a new sub-heading is inserted
ירטיפטערפס, מהע נטווויףוומווטב אונור נוובסב.	prior to this point, perhaps "FBO responsibilities"
Para. 18	
allows a business to demonstrate it is taking all necessary steps to eliminate or reduce the	Australia
likelihood of an allergen being unintentionally present in a food;	
OBJECTIVES	

This Code provides guidance to FBOs, including primary producers, to develop policies and	Costa Rica	
procedures to identify allergens in all areas of food production, preparation and service, and then	This sentence is confusing. We recommend expanding on the	
implement allergen management practices, including controls to:	intended content; otherwise, strike the sentence.	
This Code provides guidance to FBOs, including primary producers, to develop policies and	Nicaragua	
procedures to identify allergens in all areas of food production, preparation and service, and then	Nicaragua's wording changes are for ease of understanding.	
implement allergen management practices, including controls toin order to:		
 prevent or minimise the potential for <u>allergen</u> cross-contact that is of risk to the allergic consumer; 	IDF/FIL	
 ensure the correct allergen label is applied to pre-packaged foods; and 	IDF/FIL	
	Suggest that this could be reworded to "Ensure that pre-packaged	
	foods are correctly labelled for allergens" and include a cross	
	reference to the General Standard for the Labelling of Pre-packaged	
	Foods (CXS 1-1985)	
 ensure the correct allergen label is applied to pre-packaged foods; and <u>• prevent or</u> 	IDF/FIL	
minimise the potential for undeclared allergens being present in a food due to errors	Insertion covers the possibility that inaccurate information is	
arising in the supply chain	supplied and allergens are present in an input without the	
	knowledge of the manufacturer etc. This document includes	
	management practices to reduce this risk.	
Para, 20		
The management tools and guidance in this Code are a proactive approach for effectively	Nicaragua	
managing allergens in food production, preparation and service and reducing risk for consumers,	Nicaragua finds the wording of this paragraph redundant. It repeats	
rather than a reactive response once a food safety hazard has been detected in a food.	aspects covered in para. 16 and should thus be eliminated.	
SECTION II – SCOPE, USE AND DEF		
,,,	USA	
	BOLDED AND CAPITALIZED	
	Colombia	
	We suggest leaving the title in capital letters.	
2.1 SCOPE		
2.1 Scope	Malawi	
Para. 23		
This Code covers IgE-mediated, non Ig-E-mediated food allergies and hypersensitivities (e.g.	Nicaragua	
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: change does not affect		
the English] There are eight foods/food groups (and derived products) that cause the majority of		
food allergies on a global basis, these are cereals containing gluten; crustaceans; eggs; fish;		
milk; peanuts; soybeans; and tree nuts. However, since the complete list of recognised food allergens varies among countries, it is important to consider which allergens are applicable when		
exporting food.		

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: change does not affect the English] There are eight foods/food groups (and derived products) that cause the majority of food allergies on a global basis, these are cereals containing gluten; crustaceans; eggs; fish; milk; peanuts; soybeans; and tree nuts. However, since the complete list of recognised food allergens varies among countries, it is important to consider which allergens are applicable when exporting food.	Panama [Translator's note: change does not affect the English]
This Code covers IgE-mediated, non Ig-E-mediated food allergies and <u>other</u> 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, these are cereals containing gluten; crustaceans; eggs; fish; milk; peanuts; soybeans; and tree nuts. However, since the complete list of recognised food allergens varies among countries, it is important to consider which allergens are applicable when exporting food.	Uruguay Strike this part of the sentence as it is clarified at the beginning of the document.
This Code covers IgE-mediated, non Ig-E-mediated-IgE-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, these are cereals containing gluten; crustaceans; eggs; fish; milk; peanuts; soybeans; and tree nuts. However, since the complete list of recognised food allergens varies among countries, it is important to consider which allergens are applicable when exporting food.	FoodDrinkEurope The hyphen between Ig-E in the first sentence needs removing For simplicity and reasons previously mentioned, we suggest that the wording in brackets ('e.g. coeliac disease) be deleted.
Para. 24	
This Code does not cover hypersonsitivities intolerance or adverse responses with a non- immunological aetiology such as lactose intolerance and sulphite sensitivity. Food intolerance adverse reactions usually result from a non-immune mediated reaction to food, such as a lack of an enzyme to process foods effectively (e.g. the absence or deficit of lactase in those with lactose intolerance). While intolerances are not explicitly mentioned in the following text, some of the controls described here could be applied to protect those with food intolerances.	FoodDrinkEurope We suggest changing the word 'hypersensitivities' to 'intolerances' or 'adverse responses' to clearly separate these from immune- mediated hypersensitivities.
2.2 USE	
This Code follows the format of the <i>General Principles</i> of <i>Food Hygiene</i> (CXC 1-1969) and should be used in conjunction with it, as well as with other applicable codes and standards such as the <i>General Standard for Labelling of Prepackaged Foods</i> (CXS 1-1985) and <i>Code of Hygienic Practice for the Transport of Food in Bulk and Semi-packed Food</i> (CXC 47-2001).	Colombia Justify paragraphs 25 and 28
2.3 DEFINITIONS	
	Nicaragua Nicaragua considera que es necesario incluir la definición sobre OEA dado que es un término utilizado en todo el documento. De igual manera solicita incluir la definición de gestión, aplicable al documento
	Uruguay
	Uruguay suggests expanding this section, by adding, for example, the definition of Celiac disease according to the AAAAI definition:

Refer to definitions in the <i>General Principles of Food Hygiene</i> and other applicable Codes. In addition, for the purpose of this Code, the following expressions have the meaning stated:	"Celiac disease is a an immune-mediated digestive condition. Individuals with Celiac disease experience an immune reaction when eating gluten containing products such as wheat, barley, rye and sometimes oats. Gluten can also be found in medicines, vitamins and lip balms". https://www.aaaai.org/conditions-and-treatments/conditions- dictionary/celiac-disease. The same applies to the definition of intolerance (e.g. to lactose), hypersensitivity, and non-celiac gluten sensitivity (NCGS) of the sort mentioned by the association: https://www.aaaai.org/conditions- and-treatments/library/allergy-library/celiac-disease Indonesia Indonesia agrees with this paragraph	
Refer to definitions in the General Principles of Food Hygiene and other applicable codes. In	Colombia	
addition, for the purpose of this code, the following expressions have the meaning stated:	Justify paragraph 28 and all definitions.	
Allergen means a usually harmless substance capable of triggering a response that starts in the immune system and results in an allergic reaction in certain individuals. In the case of foods, it is a protein which is found in food capable of triggering a response in individuals sensitised to it.		
Allergen means a usually harmless substance capable of triggering a response that starts in the immune system and results in an allergic reaction in certain individuals. In the case of foods, it is a protein which is found in food capable of triggering a response in individuals sensitised to it. [Translator's note: change does not affect the English]	Colombia [Translator's note: change does not affect the English]	
	Iran it's better to delete"usually harmless"	
Allergen means a usually harmless substance capable of triggering a response that starts in the immune system and results in an allergic reaction in certain individuals. In the case of foods, it is a protein which is found in food capable of triggering a response in individuals sensitised to it. [Translator's note: change does not affect the English]	Panama Change the spelling of the indicated word. [Translator's note: change does not affect the English]	
	Uruguay Keep in mind that Note 1, para. 9 refers to sulphites as a food allergen, but sulphites are not a protein.	
Allergen means a usually an otherwise harmless substance capable of triggering a response that starts in the immune system and results in an allergic reaction in certain individuals. In the case of foods, it is a protein which is found in food capable of triggering a response in individuals sensitised to it.	FoodDrinkEurope Definition of allergen 'a usually harmless' should be replaced with 'an otherwise harmless'. Rationale Improved clarity.	
Allergen means a usually harmless substance capable of triggering a response that starts in the immune system and results in an allergic reaction in certain individuals. In the case of foods, it is a protein which is found in food capable of triggering a response in individuals sensitised to it.	Costa Rica We propose the following wording: Allergen means a usually harmless substance capable of triggering a harmful immune response and pathology in certain individuals.	
Allergen profile means the food allergens present via intentional addition as well as those inadve		
Allergen profile means the food allergens present via intentional addition as well as those inadvertently present (or could indicate the absence of any allergens) in a food.	Costa Rica	

Precautionary allergen labelling means a label indicating the allergens (other than those that are unavoidable cross-contact (e.g. "may contain")	e listed as ingredients) that may be present in the product because of
[Precautionary allergen labelling means a label indicating the allergens (other than those that are listed as ingredients) that may be present in the product because of unavoidable cross-contact (e.g. "may contain").]	Nicaragua Nicaragua suggests the text relating to allergen labelling consider the work to be done in the framework of the CCFL.
[Precautionary allergen labelling means a label indicating the allergens (other than those that are listed as ingredients) that may be present in the product because of unavoidable <u>allergen</u> cross-contact (e.g. "may contain")contain [allergen]").]	IDF/FIL
[Precautionary allergen labelling means a label indicating the allergens (other than those that are listed as ingredients) that may be present present, at hazardous levels, in the product because of unavoidable cross-contact (e.g. "may contain")contain [allergen]"").]	FoodDrinkEurope Revise the paragraph as below (insertion in bold and italics): Precautionary allergen labelling means a label indicating the allergens (other than those that are listed as ingredients) that may be present, at hazardous levels, in the product because of unavoidable cross-contact (e.g. "may contain [allergen]"). Rationale: Provide clarity to the text.
Retail means a food business primarily involved in selling prepackged or non-prepackaged food d	lirectly to consumers for off-site or future consumption
Retail means a food business primarily involved in selling pre-packaged or non-prepackaged food directly to consumers for off-site or future consumption.	Colombia Colombia suggests eliminating "or."
<i>Rework</i> means clean, unadulterated food that has been removed from processing at any point up to and including final packaging for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food or a food component.	
	IDF/FIL If rework needs to be defined; so does "work in progress" Definition is unclear: rework means cross contact did occur and the food need to be reformed. Here, it already states that rework has being reconditioned. This is too far along the food process
Visibly clean means having no visible food, debris and other residues	
Visibly clean means having no visible food, debris and other residues. Visibly clean Section III – Primary Production means having no visible food, debris and other residues.	Australia
Visibly clean means having no visible food, debris and other residues. Visibly clean Section III – Primary Production means having no visible food, debris and other residues.	USA
SECTION IIIPRIMARY PRODUCTION	
	FoodDrinkEurope

SECTION III PRIMARY PRODUC This section is focused on primary production of cultivated commodities where there is a likelihood of allergen cross-contact (often referred to as adventitious presence).	The text 'Section III-Primary Production' appears at the end of the definition of visibly clean. This should appear as a 'section heading style'. Also, delete the 'Section III – Primary Production' section header that appears after paragraph 29. Rationale: Editorial amendment.
Section III – Primary Production	used elsewhere in this document. IDF/FIL Relocate this heading between the definition of Visibly clean and the boxed text.
Section III – Primary Production	Colombia Colombia suggests leaving the section in capital letters. The title is repeated on pages 46 and 47.
3.1 Environmental Hygiene	
Para. 30	
Depending on the crop, growers should consider the potential for allergen cross-contact from the growing environment. In order to assess the likelihood of allergen cross-contact, growers should know the history of the specific growing area (i.e., previous crops), and what other crops <u>or other</u> <u>plantings used for weed control</u> 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.	Australia
Depending on the crop, growers should consider the potential for allergen cross-contact from the growing environment. In order to assess the likelihood of allergen cross-contact, 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.	Costa Rica This refers exclusively to the crop, not to other areas of production, like sea production, milk, etc. Reference to allergens should be in general terms.
Depending on the crop, growers should consider the potential for allergen cross-contact from the growing environment. In order to assess the likelihood of allergen cross-contact, 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.	Honduras Are there science-based statistics (risk assessment) that show there are significant risks to the final product due to lacking risk management of allergens in the crop environment? This paragraph entails strict standards along the production chain; we need to consider the real possibilities that industry can fulfill this recommendation.
Depending on the crop, growers should consider the potential for allergen cross-contact from the growing environment. In order to assess the likelihood of allergen cross-contact, growers should know the history of the specific growing area (i.e., previous crops), and what other crops are	FoodDrinkEurope To avoid confusion through introducing the issues of 'free-from' claims and mixing limits defined for different disorders, please

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.	remove the text in brackets in the final sentence i.e. '(e.g. gluten- free)'
3.3 Hangling, storage and transport	·
Para. 34	
To prevent or minimise the likelihood of allergen cross-contact, storage facilities that hold different commodities should be visually inspected and appropriately cleaned. When handling multiple different commodities such as grains/pulses/seeds ensure that physical segregation is in place to prevent or minimise the potential for cross-contact. Having a clear "allergen map" (see section 5.2.1.1) of the storage facility will show where allergenic crops enter and are stored so the potential for cross-contact is managed.	Colombia Colombia suggests replacing the word "multiple" with "different."
To prevent or minimise the likelihood of allergen cross-contact, storage facilities that hold different commodities should be visually inspected and appropriately cleaned. When handling multiple commodities such as grains/pulses/seeds ensure that physical segregation is in place to prevent or minimise the potential for <u>allergen</u> cross-contact. Having a clear "allergen map" (see section 5.2.1.1) of the storage facility will show where allergenic crops enter and are stored so the potential for <u>allergen</u> cross-contact is managed.	IDF/FIL
Para. 37	
Transportation of food stuff should be carried out using a clean transport vehicle that is dry and free of the previous load to prevent or minimise the potential for allergen cross-contact. As necessary, transport containers should be cleaned before use. At unloading, transport containers containing allergenic commodities should be emptied of all cargo and cleaned as appropriate to prevent or minimise the potential for allergen cross-contact of the next load. The use of one-time packaging may be a useful option for some transporters. For more detail on transportation refer to Section 8.	IDF/FIL If this is intended to be single use packaging we suggest that the term is replaced to be clear what is intended.
3.4 Cleaning, maintenance and personnel hygiene at primary production	·
In addition, FBOs should ensure that the area where commodities are dried is clean and physical barriers are in place to prevent spillage and <u>allergen</u> cross-contact. Materials or containers used to lay, hang or bag commodities should be cleaned to remove allergenic residue.	IDF/FIL
SECTION IV – ESTABLISHMENT: DESIGN	AND FACILITIES
	USA BOLDED AND CAPITALIZED
	Colombia We suggest leaving the title in capital letters.
Para 41	
Food manufacturing facilities commonly handle multiple allergens, frequently on the same equipment. Ideally these facilities would be designed to use processing lines dedicated to food with specific allergen profiles and where feasible, manufacturers should consider the use of dedicated lines, however, this is not feasible in all cases. Separation by time Production sequencing should be considered as an option, especially for small businesses. An analysis of	Australia

the process, including the equipment design, should be conducted to determine the likelihood of		
allergen cross-contact and whether dedicated processing lines, equipment redesign, or other control measures are needed to prevent or minimise such cross-contact.		
Food manufacturing facilities commonly handle multiple allergens, frequently on the same equipment. Ideally these facilities would be designed to use processing lines dedicated to food with specific allergen profiles and where feasible, manufacturers should consider the use of dedicated lines, however, this is not feasible in all cases. Separation by time should be considered as an option, especially for small businesses. An analysis of the process, including the equipment design, should be conducted to determine the likelihood of allergen cross-contact and whether dedicated processing lines, equipment redesign, or other control measures are needed to prevent or minimise such <u>allergen</u> cross-contact.	IDF/FIL	
Food manufacturing facilities commonly handle multiple allergens, frequently on the same equipment. Ideally these facilities would be designed to use processing lines dedicated to food with specific allergen profiles and where feasible, manufacturers should consider the use of dedicated lines, however, this is not feasible in all cases. Separation by time should be considered as an option, especially for small businesses. An analysis of the process, including the equipment design, should be conducted to determine the likelihood of allergen cross-contact and whether dedicated processing lines, equipment redesign, or other control measures are needed to prevent or minimise such cross-contact.	FoodDrinkEurope Add sentences: 'as far as possible adequate sanitation to prevent cross-contact between products with dissimilar allergen profiles should be used' 'in cases where cross-contact cannot be adequately controlled, a decision should be taken based on risk of whether precautionary labelling should be applied to the finished product' 'Risk management decisions on food production systems, such as facility and production design, should be detailed in facility allergen management documentation' Rationale: The existing paragraph does not include the importance of sanitation as a cross-contamination design control. It does not indicate measures to manage risk when cross-contamination cannot be eliminated. It does not indicate the importance of capturing and tracking control measures via documentation.	
Para. 42		
If 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 separation to prevent or minimise the potential for <u>allergen</u> cross-contact from one line to another based on the food, the process, and the likelihood of <u>allergen</u> cross-contact. Manufacturers should eliminate cross-over points or provide a means to contain or shield food (e.g. closed pipes, enclosed or covered conveyors) to prevent food spilling from one line to another.	IDF/FIL	
4.2.1 Manufacturing		
Para. 45		
Manufacturers should consider providing appropriate barriers (e.g. walls, partitions, curtains) or adequate separation (e.g., spacing) between lines, when necessary, to prevent <u>or minimize</u> allergen cross-contact when foods with different allergen profiles are processed at the same time.	IDF/FIL	
Para. 47		

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 to mitigate the likelihood of airborne allergen cross-contact throughout the processing area, especially when powdered allergens such as wheat flour, dried milk powder, soy protein, etc. are used. Such controls could be important where powders are <u>dumped-tipped</u> into mixers, hoppers, or carts to prevent dust settling on surrounding equipment. Where dust removal systems are not in place, other controls such as cleaning surrounding areas following dumping could be used to mitigate the likelihood of allergenic proteins in powders being transferred to other foods (see section 5.2.1).	Australia
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 to mitigate the likelihood of airborne allergen cross-contact throughout the processing area, especially when powdered allergens such as wheat flour, dried milk powder, soy protein, etc. are used. Such controls could be important where powders are dumped into mixers, hoppers, or carts to prevent dust settling on surrounding equipment. Where dust removal systems are not in place, other controls such as cleaning surrounding areas or equipment following dumping could be used to mitigate the likelihood of allergenic proteins in powders being transferred to other foods (see section 5.2.1).	IDF/FIL Need to consider the equipment in the area which also may require cleaning
4.3.1 Manufacturing Para, 48	
Equipment, tools, utensils and containers (other than single-use containers and packaging) contacting in contact with foods that contain allergens should be designed and constructed to provide for effective removal of effectively remove allergens during cleaning. To prevent or minimise the potential for allergen cross-contact, ideally, equipment, tools and utensils should not contain areas where be designed or selected so that allergens, especially particulate allergens (e.g. peanuts, tree nuts, sesame seeds, crumbs from baked goods), could do not get caught in crevices and are difficult to remove by the cleaning procedures applied. Welds should be smooth, seals and hoses should not contain cracks, and "dead ends" in pipework or other areas where pockets of foods containing allergens can accumulate should be eliminated.	Australia
4.4 Facilities Para. 50	
FBOs, including retail and food service, should place hand wash basins in appropriate areas to prevent allergen cross-contact via personnel. Having convenient hand wash basins will encourage personnel to wash hands with soap and water between handling foods that have different allergen profiles. FBOs should also consider, based on the risk to allergic consumers, facilities to enable change of protective clothing, especially when personnel are moving from particular areas within the manufacturing facility such as those handling powdered allergens.	Australia
	Colombia [Translator's note: change does not affect the English]
FBOs, including retail and food service, should place hand wash basins in appropriate areas to prevent <u>or minimize</u> allergen cross-contact via personnel. Having convenient hand wash basins will encourage personnel to wash hands with soap and water between handling foods that have different allergen profiles. FBOs should also consider, based on the risk to allergic consumers,	IDF/FIL

facilities to enable change of protective clothing, especially when personnel are moving from particular areas within the manufacturing facility such as those handling powdered allergens.	The section on hand basins applies also to manufacturing but isn't included there. And, while this bit is also applicable for retail and food service, it shouldn't refer to manufacturing facility here	
SECTION V – CONTROL OF OPER	RATION	
	USA BOLDED AND CAPITALIZED Colombia We suggest leaving the title in capital letters.	
5.1 Control of food hazards Para. 51		
FBOs should control allergens by preventing or minimising the potential for allergen cross- contact, by ensuring 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. Information helpful in assessing the likelihood of allergen cross-contact resulting in a risk to the allergic consumer includes:	Costa Rica See the Codex document on risk analysis.	
FBOs should control allergens by preventing or minimising the potential for allergen cross- contact, by ensuring 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. Information helpful in assessing the likelihood of allergen cross-contact resulting in a risk to the allergic consumer includes: -Production planning.	Nicaragua Nicaragua proposes including "production planning," as this is important information to define times, production order, and reduce cross-contamination.	
FBOs should control allergens by preventing or minimising the potential for allergen cross- contact, by ensuring that information identifying the allergens present in foods <u>are-is</u> 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. Information helpful in assessing the likelihood of allergen cross-contact resulting in a risk to the allergic consumer includes:	USA	
FBOs should control allergens by preventing or minimising the potential for allergen cross- contact, by ensuring 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. Information <u>that may be</u> helpful in assessing the likelihood of allergen cross-contact resulting in a risk to the allergic consumer includes:	FoodDrinkEurope change sentence to: Information that may be helpful in assessing the likelihood of allergen cross-contact resulting in a risk to the allergic consumer includes Rationale: Clarifies that not all control measures are appropriate to apply in all cases.	
 ease of cleaning the equipment used to process foods with different allergen profiles;profiles and verification of the effectiveness of cleaning, after processing allergenic ingredients or foods and 	IDF/FIL Suggest this is added to ensure that the cleaning is checked to be adequate	

 If <u>if</u> the information is available, the maximum amount of an allergen due to cross- contact. 	Australia
 If the information is available, the maximum amount of an allergen due to cross-contact. 	Costa Rica We propose the following wording:
	 The maximum amount of an allergen due to cross-contact
	(if the information is available).
If the information is available, the maximum amount of an allergen due to <u>allergen</u>	IDF/FIL
cross-contact. This can be used in combination with the addition rate of the	This would provide clear direction to the food industry for how to use
ingredient/component with the allergen cross-contact risk to the final product, and the servinge size of the final product, to determine the dose of cross-contact allergen, and	allergen cross-contact amounts/concentrations in combination with a serve size and threshold level, to evaluate risk and dictate the use
be compared to a threshold level to evaluate the risk and the need for precautionary	of precautionary labelling. This would encourage consistent use of
labelling.	allergen cross-contact risk assessment, and precautionary labelling,
	which would help restore confidence of consumers with food allergy.
Para. 53	
 implement effective <u>allergen management</u> control procedures to prevent or minimise allergen cross-contact at those steps; 	IDF/FIL addition of context
 monitor, and when appropriate document, control procedures to ensure their continuing 	
effectiveness; and • ensure an appropriate change control procedure is in place to	Change control is a large part of ensuring that any changes are
assess the allergen risk if there are operational or input changes.	introduced in a controlled and coordinated manner and should be
E 4 4 Manufacturing	included in the responsibility of the FBO. Add a bullet point.
5.1.1 Manufacturing	Australia
Manufacturers should also identify steps in the operation that are critical to ensuring allergens are properly labelled-declared including reviewing recipes and labels on compound ingredients, and	Australia
ensuring that the correct product is packed in the correct package (i.e., with the correct label).	
When reviewing recipes, product enhancement processes, such as egg washes on baked	
products for glossy finish, should also be included.	FoodDrinkEurope
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	Change first sentence to: Manufacturers should identify steps in the
implement controls to ensure that the both correct product is packed in the ingredients and correct	operation that are critical to ensuring allergens are properly labelled
package (i.e., with the correct label)packaging (labels) are used. When reviewing recipes, product enhancement processes, such as egg washes on baked products for glossy finish, should also be	and implement controls to ensure that both correct ingredients and
included.	correct packaging (labels) are used. Rationale: The use of incorrect packaging is just one cause of
	product-label mismatch, the other major cause is the use of
	incorrect ingredients.
5.2.1.1 Minimising cross-contact during processing	

5.2.1.1 Minimising allergen cross-contact during processing	IDF/FIL
Para. 56	
If the same production area is used for foods with different allergen profiles, manufacturers should, where feasible, implement production scheduling to separate by time the manufacture of products with different food allergen profiles, e.g. process foods that do not contain allergens before foods with allergens. e.g. process foods that do not contain allergens before foods with allergens. For instance, production schedules could be established in some cases whereby products that do not contain allergen profiles, to reduce the potential for allergen cross-contact (e.g. all frozen desserts containing only milk are run before those containing both milk and egg). Where possible, allergenic ingredients should be added as late in the production process as possible, or as far downstream as possible in the processing line (e.g. closest to the filling and packaging equipment), to minimise the amount of equipment in the production area that comes in contact with the allergen. This will help prevent or minimise potential allergen cross-contact and facilitate cleaning.	Iran This part mentioned in the next sentence and no need to repetition.
Para. 57	
Manufacturers should design traffic flow of allergen-containing ingredients, packaging supplies and personnel during the manufacture of foods to prevent or minimise the potential for allergen cross-contact. This should include consideration for managing the movement for of transient people such as managers, quality assurance personnel, inspectors, maintenance personnel, and visitors.	Australia
Manufacturers should design traffic flow of allergen-containing ingredients, packaging supplies, personnel, and the waste they generate during the manufacture of foods to prevent or 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
Manufacturers should design traffic flow of allergen-containing ingredients, packaging supplies and personnel during the manufacture of foods to prevent or 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.	FoodDrinkEurope Change to: FBOs should maintain an awareness of traffic flows of allergen- containing ingredients, packaging supplies and personnel during the manufacture of foods and, where necessary based on likelihood of cross-contact and risk, implement appropriate controls. Rationale: we don't believe it can be definitively stated that the movement of packaging supplies and personnel is not a risk for all FBOs.
Para. 58	
<u>"Allergen-When appropriate based on the complexity of a production facility and the controls in place, "allergen</u> mapping" (a diagram that identifies where allergens are stored, handled and prepared on site, overlaid with the processes involved) can be useful in identifying areas where controls should be applied to prevent or minimise allergen cross-contact.	FoodDrinkEurope Change to: When appropriate based on the complexity of a production facility and the controls in place, "allergen mapping" Rationale: It should be made clear that allergen mapping is not appropriate in all situations

Para. 59	
Where there is a likelihood of allergen cross-contact by personnel, <u>personnel-operators</u> 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 personnel working on lines manufacturing foods containing different allergen profiles, e.g. different coloured uniform or hair net.	Australia
Where there is a likelihood of allergen cross-contact by personnel, personnel working on processing lines that contain an allergen should be restricted from working simultaneously on lines that do not contain that allergen. Manufacturers should consider a system to clearly identify personnel working on lines manufacturing foods containing different allergen profiles, e.g. different coloured uniform or hair net.	Honduras
Where there is a likelihood of 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 personnel working on lines manufacturing foods containing different allergen profiles, e.g. different coloured uniform or hair net. Change to: Where there is a risk of allergen cross-contact by personnel, controls should be implemented to prevent cross-contamination. This could include restricting personnel working on processing lines that contain an allergen from working on lines that do not contain an allergen or using a system to clearly identify personnel working on lines with different allergen profiles.	FoodDrinkEurope Change to: Where there is a risk of allergen cross-contact by personnel, controls should be implemented to prevent cross- contamination. This could include restricting personnel working on processing lines that contain an allergen from working on lines that do not contain an allergen or using a system to clearly identify personnel working on lines with different allergen profiles.
Para. 60	
Containers and utensils 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 <u>and utensils</u> before use for a food with a different allergen profile. Disposable liners can also be an effective strategy.	IDF/FIL Addition to be consistent with the intent of para to cover both containers and utensils
Para. 61	
Manufacturers should 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 should dedicate utensils and tools for processing lines with different food allergen profiles; these utensils and tools should be distinguishable (e.g. through marking, tagging or colour-coding) to prevent or minimise the potential for allergen cross-contact. Similarly, manufacturers could consider duplicating certain pieces of equipment (e.g. scales) and dedicating them for specific allergen-containing production runs. Allergen-containing ingredients should, if feasible and necessary to prevent or minimise the potential for cross-contact, be opened and weighed in designated areas before being transferred in covered or closed containers to the processing line.	Australia
Manufacturers-When there is a likelihood of allergen cross-contact, based on risk manufacturers should 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 should dedicate utensils and tools for processing lines with different food allergen profiles; these utensils and tools should	FoodDrinkEurope Add to start of paragraph: When there is a likelihood of allergen cross-contact, based on risk Rationale: It should be clarified that equipment controls such as shielding are only necessary when there is a potential for allergen

be distinguishable (e.g. through marking, tagging or colour-coding) to prevent or minimise the potential for allergen cross-contact. Similarly, manufacturers could consider duplicating certain pieces of equipment (e.g. scales) and dedicating them for specific allergen-containing production runs.	cross-contact that presents risk to health
Para. 62	
Manufacturers should not use ingredients for which the allergen profile is unknown, and should never guess or assume that an allergen is not present. Allergen-containing ingredients should, if feasible and necessary to prevent or minimise the potential for cross-contact, be opened and weighed in designated areas before being transferred in covered or closed containers to the processing line.	Australia
Manufacturers should not use ingredients for which the allergen profile is unknown, and should never guess or assume that an allergen is not present. Allergen-containing ingredients should, if feasible and necessary to prevent or minimise the potential for cross-contact, be opened and weighed in designated areas before being transferred in covered or closed containers to the processing line.	Nicaragua [Translator's note: change does not affect the English]
Manufacturers should not use ingredients for which the allergen profile is unknown, and should never guess or assume that an allergen is not present. Allergen-containing ingredients should, if feasible and necessary to prevent or minimise the potential for <u>allergen</u> cross-contact, be opened and weighed in designated areas before being transferred in covered or closed containers to the processing line.	IDF/FIL
Para. 63	
Dry-When there is a likelihood of allergen cross-contact from the dust of dry ingredients that are, or contain, a food allergen should be added allergen, resulting in a manner that minimises-risk to consumers, the potential for unintentional dispersion-cross-contact by dustsuch dust should be controlled. For example, the formation and dispersion of allergen dust can be minimised by adding liquid ingredients to mixers at the same time as powders, using dust collection systems (e.g. local exhaust, ventilation systems and/or vacuum systems), controlling surrounding dust sources, and/or covering equipment. The use of dry allergens with a propensity for dust formation should, where feasible, be scheduled at the end of a production/processing day	FoodDrinkEurope Change first sentence to: When there is a likelihood of allergen cross-contact from the dust of dry ingredients that are, or contain, a food allergen, resulting in risk to consumers, the cross-contact by such dust should be controlled. Rationale: Controls are only required if there is a likelihood of cross- contact.
Para. 64	
Manufacturers should evaluate the potential for cross-contact due to cooking media, such as water or oil. It may be necessary to use an appropriate method to eliminate any allergen- containing particulate material dedicated cooking media if it is likely that such the allergen risk cannot be prevented or minimized to a safe level; for example in the case where particles could end up in a food with a different allergen profile.	Australia
Manufacturers should evaluate the potential for <u>allergen</u> cross-contact due to cooking media, such as water or oil. It may be necessary to use an appropriate method to eliminate any allergen-containing particulate material if it is likely that such particles could end up in a food with a different allergen profile.	IDF/FIL
Manufacturers should <u>Manufacturers should</u> evaluate the potential for cross-contact due to cooking media, such as water or oil. It may be necessary to use an appropriate method to eliminate any allergen containing particulate material <u>dedicated cooking media</u> if it is likely that <u>such the</u>	FoodDrinkEurope Propose to revise the paragraph as below (insertion in bold and italics): Manufacturers should evaluate the potential for cross-contact due to

allergen risk cannot be prevented or minimized to a safe level; e.g. in case particles could end up in a food with a different allergen profile.	 cooking media, such as water or oil. It may be necessary to use dedicated cooking media if it is likely that the allergen risk cannot be prevented or minimized to a safe level; e.g. in case particles could end up in a food with a different allergen profile. Rationale: We are not discussing particulate allergens only. Allergen proteins which accumulate homogeneously in cooking media (e.g. fish proteins in cooking oil) also could represent a significant cross-contact risk if other (non-fish) foods are cooked in the same oil.
Para. 65	
Spills that contain food allergens should be cleaned up immediatelyas soon as possible, avoiding further dispersion (e.g., for liquids, spill kits could be used or vacuums for dust). Care should be taken not to generate aerosols with high pressure washers, or to re-suspend dust using compressed air hoses.	FoodDrinkEurope Change first sentence to: Spills that contain food allergens should be cleaned up as soon as possible, Rationale: Clarification, as the word 'immediately' is open to interpretation, furthermore an operator immediately dealing with an allergen spillage may result in other food safety or occupational hazards, for example equipment may need to be stopped before a spillage can be safely cleaned.
5.2.1.2 Rework and Work-in-Process Para. 67	
Manufacturers should implement procedures to segregate, re-package, and re-label food products that have been labelled incorrectly. If it is not possible to re-label such food, they should have a procedure to destroy the food.	Honduras
Manufacturers should implement a policy for rework to be added back to the same product whenever feasible feasible and ensure that traceability is maintained.	IDF/FIL Suggest addition to point and cross reference to para 112.
5.2.1.4 Monitoring and verification Para. 71	
Regular internal audits <u>or verification</u> of production systems should be conducted to verify that the product formulation, including changes to product formulation, matches the records of allergenic ingredient use, that the final product matches the ingredients specified on the label, that allergen cross-contact controls are properly implemented and that line personnel are appropriately trained.	Honduras
Regular internal audits of production systems should be conducted to verify that the product formulation, including changes to product formulation, matches the records of allergenic ingredient use, that the final product matches the ingredients specified on the label, that allergen cross-contact controls are properly implemented and that line personnel are appropriately trained.	Costa Rica We recommend replacing the term audits with inspections (for the version in Spanish), as it is the correct term for what is described.
Para. 72	
[There should be a regular review of suppliers to ensure that all ingredients, including multi- component ingredients (e.g. sauces, spice mixes), processing aids, or operations, have not changed in a manner that introduces a new allergenic ingredient or that results in allergen cross- contact. Manufacturers should verify that precautionary allergen labelling is only applied in	Australia

instances where allergen cross-contact cannot be reasonably prevented (e.g. disassembly of equipment that results in major loss of production time) through GHPs and when such cross-contact could present a risk to allergic consumers. Periodic In case of doubt, product testing for undeclared allergens may also be considered.]	
[There should be a regular review of suppliers to ensure that all ingredients, including multi- component ingredients (e.g. sauces, spice mixes), processing aids, or operations, have not changed in a manner that introduces a new allergenic ingredient or that results in allergen cross- contact. Manufacturers should verify that precautionary allergen labelling is only applied in instances where allergen cross-contact cannot be reasonably prevented (e.g. disassembly of equipment that results in major loss of production time) through GHPs and when such cross- contact could present a risk to allergic consumers. <u>Adequate</u> periodic product <u>analysis</u> testing for <u>specific</u> undeclared allergens may also be considered.]	Costa Rica
[There should be a regular review of suppliers to ensure that all ingredients, including multi- component ingredients (e.g. sauces, spice mixes), processing aids, or operations, have not changed in a manner that introduces a new allergenic ingredient or that results in allergen cross- contact. Manufacturers should verify that precautionary allergen labelling is only applied in instances where allergen cross-contact cannot be reasonably prevented (e.g. disassembly of equipment that results in major loss of production time) through GHPs and when such cross- contact could present a risk to allergic consumers. Periodic product testing for undeclared allergens may also be considered.]	Indonesia Indonesia agrees with this paragraph
[There should be a regular review of suppliers to ensure that all ingredients, including multi- component ingredients (e.g. sauces, spice mixes), processing aids, or operations, have not changed in a manner that introduces a new allergenic ingredient or that results in allergen cross- contact. Manufacturers should verify that precautionary allergen labelling is only applied in instances where allergen cross-contact cannot be reasonably prevented (e.g. disassembly of equipment that results in major loss of production time) through GHPs and when such cross- contact could present a risk to allergic consumers. Periodic In case of doubt, occasional product testing for undeclared allergens may also be considered.]	Malaysia Asking manufacturers to do periodic testing of 'undeclared' allergens in supplied materials is not appropriate. Manufacturers and suppliers must work hand in hand and allergen information provided by suppliers must be trusted and trustable.
[There should be a regular review of suppliers to ensure that all ingredients, including multi- component ingredients (e.g., sauces, spice mixes), processing aids, or operations, have not changed in a manner that introduces a new allergenic ingredient or that results in allergen cross- contact. Manufacturers should verify that precautionary allergen labelling is only applied in instances where allergen cross-contact cannot be reasonably prevented (e.g. disassembly of equipment that results in major loss of production time) through GHPs and when such cross- contact could present a <u>significant</u> risk to allergic consumers <u>In case of doubt, occasional</u> Periodic product testing for undeclared allergens may also be considered. <u>Controls can include agreed specification and contractual arrangement that changes</u> to allergen status will be prior notified.]	FoodDrinkEurope Propose to revise the paragraph as below (insertion in bold and italics): There should be a regular review of suppliers to ensure that all ingredients, including multi-component ingredients (e.g. sauces, spice mixes), processing aids, or operations, have not changed in a manner that introduces a new allergenic ingredient or that results in allergen cross-contact. Manufacturers should verify that precautionary allergen labelling is only applied in instances where allergen cross-contact cannot be reasonably prevented (e.g. disassembly of equipment that results in major loss of production time) through GHPs and when such cross-contact could present a significant risk to allergic consumers. In case of doubt, occasional Periodic product testing for undeclared allergens may also be considered. Rationale: Provide clarity to the text. Asking manufacturers to do periodic testing of 'undeclared' allergens in supplied materials is not

[There should be a regular review of suppliers to ensure that all ingredients, including multi- component ingredients (e.g. sauces, spice mixes), processing aids, or operations, have not changed in a manner that introduces a new allergenic ingredient or that results in allergen cross- contact. Manufacturers should verify that precautionary allergen labelling is only applied in instances where allergen cross-contact cannot be reasonably prevented <u>or minimized</u> (e.g. disassembly of equipment that results in major loss of production time) through GHPs and when such <u>allergen</u> cross-contact could present a <u>significant</u> risk to allergic consumers. <u>Periodic-In</u> <u>case of doubt</u> , <u>occasional</u> product testing for undeclared allergens may also be considered.]	 appropriate. Manufacturers and suppliers must work hand in hand and allergen information provided by suppliers must be trusted and trustable. Add: Controls can include agreed specification and contractual arrangement that changes to allergen status will be prior notified. Rationale: Supplier control should be a combination of documentation and verification including audit. IDF/FIL Promoting manufacturers do periodic testing of 'undeclared' allergens in supplied materials is not appropriate. Manufacturers and suppliers must work hand in hand and allergen information provided by suppliers must be reliable. This paragraph duplicates what is in paragraph 94 under 5.3 Incoming material requirements, the two paragraphs should be combined and in one place.
Para. 74	
Where the introduction of a new allergen into the establishment or a processing line is unavoidable e.g. during factory trials or consumer testing, care should be given to avoid <u>allergen</u> cross-contact with existing products.	IDF/FIL
Para. 75	
Procedures for preventing <u>or minimizing allergen</u> cross-contact, as well as relevant HACCP documents, operating procedures and associated personnel training, may need to be reviewed and revised to address a new product or formulation with a different allergen profile, especially when an allergen new to the production facility is involved.	IDF/FIL
Para. 76	
Product labels should be <u>developed_designed</u> 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 in a manner that prevents accidental use. Where there is a change in the formulation which results in a change of allergenic profile, manufacturers should indicate this on the packaging and on their <u>websiteswebsites for an appropriate period</u> , with information such as "new formulation".	Australia
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 in a manner that prevents accidental use. Where there is a change in the formulation which results in a change of allergenic profile, manufacturers should indicate this on the packaging and on their websites, with information such as "new formulation". Where possible, they should change the color of the packaging when a new allergen is added to the formulation.	Costa Rica
5.2.2 Retail and Food Service Para. 77	

Equipment that has been is used for allergen-containing foods should be marked, tagged, or colour-coded to identify the allergen. Where this is not practical, equipment should be cleaned between use for foods with different allergen profiles.	Australia
Equipment that has been used for allergen-containing foods should be marked, tagged, or colour-coded to identify the allergen. Where this is not practical, equipment should be <u>effectively</u> cleaned between use for foods with different allergen profiles.	Costa Rica Prior to paragraph 77, include a paragraph with the following content: 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.
Para. 78	
Allergen-containing food that is not in sealed packages, should also be <u>labelled with the allergen</u> and stored separate from food that does not contain allergens, or from food with a different allergen profile (e.g., separation that prevents physical contact).	Australia
5.2.2.1 Minimising cross-contact during preparation	
5.2.2.1 Minimising allergen cross-contact during preparation	IDF/FIL
Para. 79	
Retail and food service personnel should be aware of allergens in the foods provided to customers in order to provide appropriate information when a customer indicates they have a food allergy. They should also know and understand the likelihood of allergen cross-contact from the processes followed in the preparation of food items. Cross-contact-Allergen cross-contact during preparation primarily occurs in the following ways:	IDF/FIL
Para. 83	
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. To assist with the understanding of foods or ingredients of allergenic significance to the FBO, there could be a list of relevant allergens available in the kitchen area. Operators should not use foods for which the allergen profile is unknown, and should never guess or assume that an allergen is not present.	Nicaragua [Translator's note: change does not affect the English]
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. To assist with the understanding of foods or ingredients of allergenic significance to the FBO, there could be a list of relevant allergens available in the kitchen area. Operators should not use foods for which the allergen profile is unknown, and should never guess or assume that an allergen is not present. Any change of ingredient should be pre-approved in the product specification or managed via a change control system.	IDF/FIL Change control is a large part of ensuring that any changes are introduced in a controlled and coordinated manner and should be included in the responsibility of the FBO
Para. 84	
FBOs should consider whether it is feasible and necessary to dedicate cooking media, such as water or oil, to foods with specific allergen profiles to prevent allergen cross-contact, for example, not using oil to fry both battered / breaded fish and potatoes, as batter / breaderumb particles could end up in the potatoes. It may be necessary to use an appropriate method to eliminate any	Australia

allergen-containing particulate material present in frying oil if it is likely that such particles could end up in food with a different allergen profile.	
FBOs should consider whether it is feasible and necessary to dedicate cooking media, such as water or oil, to foods with specific allergen profiles to prevent allergen cross-contact, for example, not using oil to fry both battered / breaded fish and potatoes, as batter / breadcrumb particles could end up in the potatoes. It may be necessary to use an appropriate method to eliminate any allergen containing particulate material present in frying oil if it is likely that such particles could end up in food with a different allergen profile.	Costa Rica It is recommended to remove the recommendation at the end of this paragraph, to not make alternative suggestions for reuse. OTHERWISE, indicate that it is necessary to use a validated method.
FBOs should consider whether it is feasible and necessary to dedicate cooking media, such as water or oil, to foods with specific allergen profiles to prevent <u>or minimize</u> allergen cross-contact, for example, not using oil to fry both battered / breaded fish and potatoes, as batter / breadcrumb particles could end up in the potatoes. It may be necessary to use an appropriate method to eliminate any allergen-containing particulate material present in frying oil if it is likely that such particles could end up in food with a different allergen profile.	IDF/FIL Allergen particles are a clear danger to sensitive consumers, but allergen proteins homogeneously distributed in the cooking media could also represent a significant risk – discussing particles only is not correct. Therefore propose to delete this text. <i>Category : TECHNICAL</i>
FBOs should consider whether it is feasible and necessary to dedicate cooking media, such as water or oil, to foods with specific allergen profiles to prevent allergen cross-contact, for example, not using oil to fry both battered / breaded fish and potatoes, as batter / breadcrumb particles could end up in the potatoes. It may be necessary to use an appropriate method to eliminate any allergen-containing particulate material present in frying oil if it is likely that such particles could end up in food with a different allergen profile.	FoodDrinkEurope Propose to revise the paragraph as below: FBOs should consider whether it is feasible and necessary to dedicate cooking media, such as water or oil, to foods with specific allergen profiles to prevent allergen cross-contact. Rationale: Allergen particles are a clear danger to sensitive consumers, but allergen proteins homogeneously distributed in the cooking media could also represent a significant risk, so propose to amend the paragraph as proposed.
Para. 85	
Foods displayed for consumer purchase should be protected from <u>allergen</u> cross-contact during display, e.g. by wrapping or by separation that could include plastic barriers. Designated serving utensils should be provided to handle foods with different allergen profiles, where feasible, and should only be used for that food, or the utensils should be cleaned between uses for foods with different allergen profiles.	IDF/FIL
Para. 86	
Personnel handling product at display and consumer purchase, as well as servers in restaurants and other food service operations, should be knowledgeable about the allergens in products; alternatively, the personnel should know how to obtain the information about the allergens in products rapidly - especially when the food does not contain labelling that identifies the allergens. Furthermore, it should be noted visibly and in writing whether the food service operation can provide information to the consumer on the allergen profile.	Costa Rica
5.2.2.2 Rework	
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 prevent or minimise the potential for incorporation into the wrong product. Food handlers should implement a policy for rework to <u>only</u> be added back to the same product whenever feasible.	Australia

5.2.2.4 Monitoring and verification Para, 89	
Supervisors of food preparation and service personnel in retail and food service operations should periodically verify that personnel are following the procedures established to prevent or minimise the potential for allergen cross-contact and inform the consumer about allergens in foods, including applying the appropriate label to packaged foods and providing the relevant information with respect to unpackaged foods. Regular review <u>using adequate analytical methods</u> of ingredients, recipes, and labels, to ensure accuracy of allergen information should also be undertaken.	Costa Rica
5.2.2.5 Product development and change Para. 90	
When introducing a new product or recipe with a different allergen profile, procedures for minimising <u>allergen</u> cross-contact should to be reviewed and possibly revised. Personnel 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 websites should also be updated.	IDF/FIL
5.3.1 Manufacturing Para. 91	
The source of an allergen unintentionally presenting in a finished product may be an ingredient obtained directly from a supplier, or an ingredient manufactured by a third-party supplier. Manufacturers should establish specifications indicate requirements for their suppliers that address allergen controls as appropriate to the supplier and the use of the ingredient by the manufacturer.	Australia
The source of an allergen unintentionally presenting in a finished product may be an ingredient obtained directly from a supplier, or an ingredient manufactured by a third-party supplier. Manufacturers should indicate requirements and/or establish specifications for their suppliers that address allergen controls as appropriate to the supplier and the use of the ingredient by the manufacturer.	FoodDrinkEurope Revise the paragraph as below: Manufacturers should indicate requirements and/or establish specifications for their suppliers that address allergen controls as appropriate to the supplier and the use of the ingredient by the manufacturer. Rationale: Provide clarity to the text.
Para. 92	
Manufacturers should ensure that their suppliers have good allergen management practices to prevent or minimise the likelihood of cross-contact between foods with different allergen profiles. Suppliers should also ensure that all food allergens, including allergens in ingredients they use to manufacture another product, are listed in product information <u>specifications</u> or on the label of the finished product (e.g. milk in a spice blend ingredient used in a food) and should have processes in place to manage allergen labelling.	Australia
Manufacturers should ensure that their suppliers have good allergen management practices to prevent or minimise the likelihood of <u>allergen</u> cross-contact between foods with different allergen profiles. Suppliers should also ensure that all food allergens, including allergens in ingredients they use to manufacture another product, are listed in product information or on the label of the	IDF/FIL

31

finished product (e.g. milk in a spice blend ingredient used in a food) and should have processes	
in place to manage allergen labelling.	
Para. 93	
Manufacturers should have programs in place to assess the allergen control programs of suppliers when necessary, e.g. a supplier questionnaire/survey and/or an audit to assess the allergen profile of foods produced at the supplier's site and the supplier's allergen management plan, including cross-contact controls and cleaning programs. A specification sheet, certificate of analysis, or vendor guarantee periodically or with each lot can also be useful in addressing a supplier's control of food allergens, as well as periodic testing for undeclared allergens.	Australia
Manufacturers should have programs in place to assess the allergen control programs of suppliers when necessary, e.g. a supplier questionnaire/survey and/or an audit to assess the allergen profile of foods produced at the supplier's site and the supplier's allergen management plan, including cross-contact controls and cleaning programs. A specification sheet, certificate of analysis, or vendor guarantee periodically or with each lot can also be useful in addressing a supplier's control of food allergens, as well as periodic testing for undeclared allergens.	Malaysia Promoting manufacturers do periodic testing of 'undeclared' allergens in supplied materials is not appropriate. Manufacturers and suppliers must work hand in hand and allergen information provided by suppliers must be trusted and trustable.
Manufacturers should have programs in place to assess the allergen control programs of suppliers when necessary, e.g. a supplier questionnaire/survey and/or an audit to assess the allergen profile of foods produced at the supplier's site and the supplier's allergen management plan, including <u>allergen</u> cross-contact controls and cleaning programs. A specification sheet, certificate of analysis, or vendor guarantee periodically or with each lot can also be useful in addressing a supplier's control of food allergens, as well as periodic testing for undeclared allergens.	IDF/FIL This paragraph duplicates what is in paragraph 73 under 5.2.1 Monitoring and Verification, the two paragraphs should be combined
Manufacturers should have programs in place to assess the allergen control programs of suppliers when necessary, e.g. a such programs may include contractual obligation for prior-notification of changes to allergen status, supplier questionnaire/survey and/or an-questionnaire / survey and / or audit to assess the allergen profile of foods produced at the supplier's site and the supplier's allergen management plan, including cross-contact controls and cleaning programs. A specification sheet, certificate of analysis, or vendor guarantee periodically or with each lot can also Based on risk there should be useful in addressing a supplier's control of food allergens, as well as periodic testing for undeclared allergens verification.	FoodDrinkEurope Revise the paragraph and delete part of the last sentence, as below: Manufacturers should have programs in place to assess the allergen control programs of suppliers when necessary, such programs may include contractual obligation for prior-notification of changes to allergen status, supplier questionnaire / survey and / or audit to assess the allergen profile of foods produced at the supplier's site and the supplier's allergen management plan, including cross-contact controls and cleaning programs. Based on risk there should be periodic verification.
Para. 95	
Incoming foods that are, or that contain, allergens should be labelled to identify the allergens that are present using common terms (e.g. 'milk' when casein is an ingredient). Manufacturers should review labels on, on the products and documents accompanying, accompanying shipments of ingredients (including minor-ingredients used in small amounts such as spice blends and flavours) to confirm that the ingredient contains only the expected food allergen(s). Particular attention should be given to multi-component pre-mixed ingredient packagespackages where allergen information may be difficult to locate. Manufacturers should have policies in place to address ingredients that contain advisory statements on the label with respect to the labelling of finished food containing that ingredient and controls to prevent or minimise allergen cross-contact based on the risk to the allergic consumer.	Australia

Incoming foods that are <u>Allergens associated with incoming foods</u> , or that contain, allergens should be labelled to identify the allergens that are present using common terms (e.g. 'milk' when casein stated on accompanying documentation and label if one is an ingredient)present. Manufacturers should review labels on, and documents accompanying, shipments of ingredients (including minor ingredients such as spice blends and flavours) to confirm that the ingredient contains only the expected food allergen(s). Particular attention should be given to multi-component pre-mixed ingredient packages. Manufacturers should have policies in place to address ingredients that contain advisory statements on the label <u>or accompanying documents</u> with respect to the labelling of finished food containing that ingredient and controls to prevent or minimise minimize allergen cross-contact based on the risk to the allergic consumer.	FoodDrinkEurope Change first sentence to: Allergens associated with incoming foods, should be stated on accompanying documentation and label if one is present. Change last sentence to: Manufacturers should have policies in place to address ingredients that contain advisory statements on the label or accompanying documents with respect to the labelling of finished food containing that ingredient and controls to prevent or minimize allergen cross- contact based on the risk to the allergic consumer. Rationale: Bulk shipments of ingredients business to business do not always carry written labels that list composition, unique identifiers may be used that are linked to shipment/ product documentation.
Para. 98	
SecureWhere practical secure, closable containers should be used to store allergen-containing ingredients and processing aids. Manufacturers should segregate allergen-containing ingredients based on allergen type and from ingredients that do not contain allergens e.g. in a dedicated storage room or area of the establishment, or in separate bays or areas of a storage room. When this is not feasible, ingredients that contain allergens should be stored below those that do not contain allergens to prevent or minimise the opportunity for allergen cross-contact in the event of a spill or leak.	Australia
Secure, closable containers should be used to store allergen-containing ingredients and processing aids. Manufacturers should segregate allergen-containing ingredients based on allergen type and from ingredients that do not contain allergens e.g. in a dedicated storage room or area of the establishment, or in separate bays or areas of a storage room. When this is not feasible, ingredients that contain allergens should be stored below those that do not contain allergens to prevent or minimise the opportunity for allergen cross-contact in the event of a spill or leak.	IDF/FIL bays: Is this intended to be bags as in packaging or bays. Suggest this comment is clarified to be either "containers (including packaging)" or "bays"
Secure, closable-Secure containers should be used to store allergen-containing ingredients and processing aids. Manufacturers should segregate allergen-containing ingredients based on allergen type and from ingredients that do not contain allergens e.g. in a dedicated storage room or area of the establishment, or in separate bays or areas of a storage room. When this is not feasible, ingredients that contain allergens should be stored below those that do not contain allergens to prevent or minimise the opportunity for allergen cross-contact in the event of a spill or leak.	FoodDrinkEurope Remove the word 'closable' Rationale: 'closable' is open to interpretation, the use of the word 'secure' is sufficient.
5.3.2 Retail and Food Service	
Para. 101	
Incoming packaged ingredients should be checked to ensure that the product received is an approved ingredient. 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 prevent or minimise the potential for allergen cross-contact e.g. store allergen-containing ingredients below those that do not contain allergens.	Australia

5.4 Packaging	
Para. 102	
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 the allergens are declared accurately and that they are updated with any change in the formulation of the product. To avoid allergen labelling errors, there should be a procedure for destroying old packaging and labels (and to maintain electronic document control of old labels) when recipes/formulations have been changed.	Australia
Re-use of clean-in-place <u>RWhere clean in place (CIP) solutions</u> reclaim systems exist, including rinse water, from washing equipment containing an allergen <u>fresh water</u> should be avoided if this could result in allergen cross-contact_used for final rinsing after the cleaning step. The CIP system should be validated to ensure that could present a risk-it effectively controls allergen cross contact and have procedures in place to allergic consumersreduce or mitigate contributing to cross contact. For example - detergent/caustic chemical are dumped after cleaning products which contain an allergen, and fresh solution prior to running non allergen containing products.	Australia
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 and that they are updated with any change in the formulation of the product. To avoid allergen labelling errors, there should be a procedure for destroying old packaging and labels (and to maintain electronic document control of old labels) when recipes/formulations have been changed. Furthermore, there should be procedures in place to ensure the correct packaging is used and for checking that the correct labels are applied to both primary and secondary packaging. There should also be a procedure in place to ensure that unused packaging is removed at the end of a production run. All procedures and records should be audited regularly.	FoodDrinkEurope In addition to the existent text, add the sentence: Furthermore, there should be procedures in place to ensure the correct packaging is used and for checking that the correct labels are applied to both primary and secondary packaging. There should also be a procedure in place to ensure that unused packaging is removed at the end of a production run. All procedures and records should be audited regularly.
5.6 Management and supervision Para. 105	
FBO managers and supervisors need to have enough knowledge and understanding of allergen control principles and practices to be able to judge the potential for allergen cross-contact and determine the need for new or revised procedures to prevent <u>or minimize</u> the presence of undeclared allergens or the need to take corrective action when allergen control procedures are not properly implemented.	IDF/FIL
5.7.1 Manufacturing	
Records could include those for:	Honduras Consider that there are small- and medium-scale establishments and that these requirements could exceed those that may be applicable. We suggest re-analyzing and defining records on a basic scale, in keeping with general principles of food hygiene. Current international standards are not as demanding.
 suppliers' allergen management (e.g. questionnaire, <u>self-declaration</u>, survey and/or an audit to assess the allergen profile of foods produced at the supplier's site and the supplier's allergen management plan, including cross-contact controls and cleaning schedules); 	Honduras

 suppliers' allergen management (e.g. questionnaire, survey and/or an audit to assess the allergen profile of foods produced at the supplier's site and the supplier's allergen management plan, including <u>allergen</u> cross-contact controls and cleaning schedules); cleaning (Standard Operating Procedures (SOPs)) (SOPs) and documentation that 	IDF/FIL USA
cleaning has been done);	
SOPs to minimize/prevent allergen cross-contact • <u>HACCP</u> <u>Cross-contact risk assessment</u> Allergen Map	IDF/FIL suggest additionnal documents to this list.
Para. 111	
	Honduras
A traceability/product tracing system should be designed and implemented according to the <i>Principles for Traceability/Products tracing as a tool within a Food Inspection and Certification</i> <i>System</i> (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 (e.g., an allergic reaction to an undeclared allergen).	We suggest striking from "Procedures and processes" and just mention the principles.
5.8.1 Consumer complaints and Resolution Para. 112	
FBOs should have procedures in place for handling consumer complaints with regard to undeclared <u>allergens</u> and food allergens in <u>foodsaccidents</u> . 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.	IDF/FIL Suggest that procedures should cover incidents as well as undeclared allergens.
Para. 113	
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, communicating publicly the details of the food allergen incident). The decision on action will consider the potential risk to consumers identified along with the timeliness, motivation and plausibility of the complaint. FBOs may need to contact the relevant competent authority for assistance in determining the most appropriate course of action. It is, thus, important to have an updated contact list.	Costa Rica
SECTION VI – ESTABLISHMENT: MAINTENAN	CE AND SANITATION
	USA
	BOLDED UPPERCASE
	Colombia
6.1.1 Manufacturing	We suggest leaving the title in capital letters.
Para. 115	
Inspect and remove any hand tools and utensils if they are damaged and not easily cleanable. Where feasible and appropriate, <u>consider dedicated tools for specific equipment, and/or</u> label or colour code maintenance tools to correspond with specific allergens.	Australia
Para. 116	

Equipment and preparation areas should be adequately cleaned between manufacturing foods with different allergen profiles to prevent or minimise the potential for allergen cross-contact. Cleaning procedures to remove allergen residues depend on the nature of the food residue, the equipment, the food contact surface, the nature of the cleaning (e.g. dry cleaning or wet cleaning) and the equipment, tools and materials used for cleaning. Equipment may need to be disassembled, where feasible, to adequately remove allergen residues. <u>However, however if</u> some equipment cannot be disassembled. <u>This should be taken into account in</u> , the allergen <u>management program mangement program should take it into account</u> . Dust socks need to be removed and cleaned periodically.	Australia
Equipment and preparation areas should be adequately cleaned between manufacturing foods with different allergen profiles to prevent or minimise the potential for allergen cross-contact. Cleaning procedures to remove allergen residues depend on the nature of the food residue, the equipment, the food contact surface, the nature of the cleaning (e.g. dry cleaning or wet cleaning) and the equipment, tools and materials used for cleaning. Equipment may need to be disassembled, where feasible, to adequately remove allergen residues, however some equipment cannot be disassembled. <u>This should be considered in the allergen management program.</u> Dust socks need to be removed and cleaned periodically.	Colombia Colombia suggests using this wording.
Equipment and preparation areas should be adequately cleaned between manufacturing foods with different allergen profiles to prevent or minimise the potential for allergen cross-contact. Cleaning procedures to remove allergen residues depend on the nature of the food residue, the equipment, the food contact surface, the nature of the cleaning (e.g. dry cleaning or wet cleaning) and the equipment, tools and materials used for cleaning. Equipment may need to be disassembled, where feasible, to adequately remove allergen residues. <u>However, however if</u> some equipment cannot be disassembled. <u>This, this</u> should be taken into account in the allergen management program. <u>Dust socks need to be removed and cleaned periodically</u> .	IDF/FIL Bring clarity to text. Unsure of the addition of this sentence and why dust socks (as a type of equipment) are called out specifically. Suggest deletion.
Equipment and preparation areas should be adequately cleaned between manufacturing foods with different allergen profiles to prevent or minimise the potential for allergen cross-contact. Cleaning procedures to remove allergen residues depend on the nature of the food residue, the equipment, the food contact surface, the nature of the cleaning (e.g. dry cleaning or wet cleaning) and the equipment, tools and materials used for cleaning. Equipment may need to be disassembled, where feasible, to adequately remove allergen residues, however. However if some equipment cannot be disassembled. This should be taken into account in. The allergen management program should take it into account in. Dust socks need to be removed and cleaned periodically	FoodDrinkEurope Revise the paragraph, as below (insertion in bold and italics): Equipment and preparation areas should be adequately cleaned between manufacturing foods with different allergen profiles to prevent or minimise the potential for allergen cross-contact. Cleaning procedures to remove allergen residues depend on the nature of the food residue, the equipment, the food contact surface, the nature of the cleaning (e.g. dry cleaning or wet cleaning) and the equipment, tools and materials used for cleaning. Equipment may need to be disassembled, where feasible, to adequately remove allergen residues. However if some equipment cannot be disassembled, the allergen management program should take it into account in. Dust socks need to be removed and cleaned periodically. Rationale: Bring clarity to the text.
Para. 117	
When wet cleaning, low pressure water hoses should be used instead of high pressure water hoses for removing food residues from wet processing areas, since high pressure water hoses could spread and aerosolise food allergen residues during cleaning. When removing dry food	FoodDrinkEurope Add the sentence: The choice of cleaning method should be based on the type of

residue from difficult-to-clean areas, scrapers, brushes and vacuum cleaners (that are fit for purpose) should be used, rather than compressed air, since compressed air can disperse food allergen residues from one area to another. If compressed air is used because vacuums cannot remove such residues and it is not practical to disassemble equipment for cleaning food residue, manufacturers should take precautions to contain food residues that are removed by the compressed air. The need to clean the ductwork in ventilation systems should be considered, where necessary, when cleaning the processing environment to prevent or minimise allergen cross-contact. The choice of cleaning method should be based on the type of residue, equipment and risk resulting from subsequent cross-contact.	residue, equipment and risk resulting from subsequent cross- contact. Rationale: It should be made clear that there are various options for cleaning the choice of which is dependent on multiple criteria.
	IDF/FIL
Bins, totes, and containers used for ingredients that are, or contain, a food allergen should be cleaned as soon as possible after being emptied to avoid being a source of <u>allergen</u> cross-contact.	
Para. 119	
Where feasible, cleaning equipment, tools, cloths, sponges, and cleaning solutions should be designated for foods with specific allergen profiles and used in a manner that does not result in <u>allergen</u> 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 recontamination of surfaces with allergenic food residues.	IDF/FIL
Manufacturers should develop cleaning procedures designed to reduce or remove food allergens to the extent possible. These procedures should specify the equipment, utensil, or area of the establishment to be cleaned; the tools and cleaning materials to be used; the sequence of steps to be followed; any disassembly required; the monitoring activities; and any actions to be taken if the procedures have not been followed or if food residues have not been adequately removed.	Honduras
6.2.1 Manufacturing	
Para. 122	
Validation of the cleaning process provides a means of assuring that cleaning processes are adequate to reduce or eliminate allergens and thereby prevent or minimise allergen cross-contact. The validation process should be specific to the allergen, process and <u>product</u> matrix combination. Cleaning processes should be verified through visual observation (checking that equipment is visibly clean) and, where feasible, and through an analytical testing program (refer to section 6.5 of this Code).	Australia
Validation of the cleaning process provides a means of assuring that cleaning processes are adequate to reduce or eliminate allergens and thereby prevent or minimise allergen cross-contact. The validation process should be specific to the allergen, process and matrix combination. Cleaning processes should be verified through visual observation (checking that equipment is visibly clean) and, where feasible, through a n analytical <u>quantitative</u> testing program (refer to section 6.5 of this Code).	Costa Rica We recommend expanding this section using an example of the aspects to be considered in the validation and frequency of the process.
Validation of the cleaning process provides a means of assuring that cleaning processes are adequate to reduce or eliminate allergens and thereby prevent or minimise allergen cross-contact. The validation process should be specific to the allergen, process and matrix combination. Cleaning processes should be verified through visual observation (checking that	IDF/FIL It should be clearly stated that Cleaning for allergen management is not a PrP but a CCP, as the only active control measure to reduce a significant hazard

equipment is visibly clean) and, where feasible, through an analytical testing program (refer to section 6.5 of this Code).	
Validation of the cleaning process provides a means of assuring that cleaning processes are adequate to reduce or eliminate allergens and thereby prevent or minimise allergen cross-contact. The validation process should be specific to the allergen, process and matrix combination. Cleaning processes should be verified through visual observation (checking that equipment is visibly clean) and, where feasible when appropriate, through an analytical testing program (refer to section 6.5 of this Code).	FoodDrinkEurope Replace the phase 'where feasible' with 'when appropriate'. Rationale: The primary qualification for sanitation is 'visually and physically clean', analytical tests and the sampling they require have limited ability to detect allergen residues present on cleaned equipment, and therefore should only be used when appropriate.
Para. 23	
Because introducing water into some facilities and equipment can result in microbial problems, some production procedures include a "push-through" technique in which the subsequent product, an inert ingredient, such as sugar or salt, or an <u>allergen-containing-allergenic</u> ingredient, such as <u>wheat</u> flour, that will be an ingredient in the subsequent product is pushed through the system to remove food residue. Where the use of allergen testing is feasible and appropriate, "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 adequately removed by this process.	Australia
Para. 124	
Manufacturers should develop allergen clean up procedures for the manufacturing line to be followed in the event of spills of allergen-containing allergenic ingredients.	Australia
6.3 Pest control systems Para. 128	
In addition, <u>pest-Pest</u> control systems should not use allergens (e.g. peanut butter, cheese) as bait in <u>trapstraps when there is any likelihood of food contamination</u> . It is important for FBOs to make pest control service providers aware of concerns about the use of food allergens and potential for allergen cross-contact.	FoodDrinkEurope Change first sentence to: Pest control systems should not use allergens (eg peanut butter, cheese) as bait in traps when there is any likelihood of food contamination. Rationale: In situations where there is no likelihood of food contamination, the use of allergenic baits should not be excluded.
6.5 Monitoring effectiveness Para, 130	
Manufacturers should verify cleaning procedures, where feasible, <u>and verify procedures</u> to <u>ensure that the processes are adequate to</u> demonstrate that if the procedures are followed, allergens are effectively removed. Equipment should be inspected after each cleaning to determine whether it is visibly clean; this is particularly useful with particulate allergens.	Costa Rica
Manufacturers should verify cleaning procedures, where feasible, to demonstrate that if the procedures are followed, allergens are effectively <u>reduced or</u> removed. Equipment should be inspected after each cleaning to determine whether it is visibly clean; this is particularly useful with particulate allergens.	Honduras
Para. 131	

If a manufacturer uses CIP systems to clean pipe work, equipment and machinery, there should be verification that the CIP system is effectively removing allergens (e.g. <u>visual and physically</u> <u>clean is confirmed, and when appropriate</u> testing <u>of</u> rinse samples or swabs).	FoodDrinkEurope Change sentence to: If a manufacturer uses CIP systems to clean pipe work, equipment and machinery, there should be verification that the CIP system is effectively removing allergens (e.g. visual and physically clean is confirmed, and when appropriate testing of rinse samples or swabs). Rationale: The primary qualification for sanitation is 'visually and physically clean', analytical tests and the sampling they require have limited ability to detect allergen residues present on cleaned equipment, and therefore should only be used when appropriate.
Para. 132	
Manufacturers should periodically conduct tests to detect food residues that remain on surfaces after cleaning as verification that the cleaning procedures have been appropriately implemented and are effective. Where possible, these tests should include use of a kit specific to the allergen (if there is one for the allergen or allergens of interest in the food matrix). Tests should be fit for purpose, i.e. appropriate for the targeted allergen, e.g. a casein (milk protein) test should not be used when whey (another milk protein) is the allergen of concern and the test should be validated to work with the matrix/food of concern. FBOs should know the limit of detection of the test used and the test specificity. If necessary, the FBO should obtain expert advice on	Honduras and the test should be validated to work with the matrix/food of concern. FBOs should know the limit of What validation concept is applicable?
interpretation of results (e.g. from the test kit supplier or an accredited testing laboratory). Manufacturers should periodically conduct tests to detect food residues that remain on surfaces after cleaning as verification that the cleaning procedures have been appropriately implemented and are effective. Where possible, these tests should include use of a kit specific to the allergen (if there is one for the allergen or allergens of interest in the food matrix). Tests should be fit for purpose, i.e. appropriate for the targeted allergen, e.g. a casein (milk protein) test should not be used when whey beta-lactoglobulin (another milk protein) is the allergen of concern and the test should be validated to work with the matrix/food of concern. FBOs should know the limit of detection of the test used and the test specificity. If necessary, the FBO should obtain expert advice on interpretation of results (e.g. from the test kit supplier or an accredited testing laboratory).	Costa Rica
Manufacturers-The verification of cleaning should periodically conduct tests to detect food residues that remain-be based on food contact surfaces after cleaning as being visually and physically clean. When appropriate to support verification that the cleaning procedures have been appropriately implemented and are effective, tests to detect allergenic food residues may be useful. Where feasible, these tests should include using an allergen-specific test kit (if one is available for the food allergen(s) of interest in the food matrix). Tests should be fit for purpose, i.e. appropriate for the targeted allergen, e.g. a casein (milk protein) test should not be used when whey (another milk protein) is the allergen of concern and the test should be validated to work with the matrix/food of concern. FBOs should obtain expert advice on interpretation of results (e.g. from the test kit supplier or an accredited testing laboratory).	FoodDrinkEurope Change first sentence to: The verification of cleaning should be based on food contact surfaces being visually and physically clean. When appropriate to support verification that cleaning procedures have been appropriately implemented and are effective, tests to detect allergenic food residues may be useful. Rationale: The primary qualification for sanitation is 'visually and physically clean', analytical tests and the sampling they require have limited ability to detect allergen residues present on cleaned equipment, and therefore should only be used when appropriate.

SECTION VII – ESTABLISHMENT: PERSONAL HYGIENE	
	USA
	BOLDED AND CAPITALIZED
	Colombia
	We suggest leaving the title in capital letters.
PRINCIPLE	
PRINCIPLE:	Honduras Antonio
Personal hygiene practices should manage reduce the potential for food handlers to contribute	PRINCIPLE:
to allergen cross-contact.	Personal hygiene practices should manage reduce [sic] the
	potential for food handlers to contribute to allergen cross-contact.
Para. 133	
FBOs should encourage personnel to wash hands between handling foods that have different allergen profiles, or after having been in contact with other sources of potential allergens. Where gloves are used, consider changing regularly each time there is a change of allergen to reduce the likelihood of allergen cross-contact.	Costa Rica
FBOs should consider the potential for <u>allergen</u> cross-contact of products with allergenic materials via food handlers. For example, food handlers may become a vector for <u>allergen</u> cross-contact if food allergens on their skin or clothing are transferred directly to foods. Allergens present as dry products (powders) are more likely to be transferred by food handlers than non-volatile liquids containing allergens.	IDF/FIL
7.1 Manufacturing	
Para. 135	
Where necessary Change text to:	FoodDrinkEurope
Where there is a significant risk of allergen cross-contact by personnel who have handled	Where there is a significant risk of allergen cross-contact by
allergens, food handlers should wear visual identification of which personnel work on processing	personnel who have handled allergens, visual identification of which
lines with different allergen profiles may be appropriate. Such identification may include dedicated clothing in areas where specific allergens are handled and there is a high likelihood of	personnel work on processing lines with different allergen profiles may be appropriate. Such identification may include dedicated
allergen cross-contacthandled. The wearing of this clothing should be restricted to those areas-	clothing in areas where specific allergens are handled. The wearing
It may be appropriate to visually identify which personnel work on processing lines with different	of this clothing should be restricted to those areas.
allergen profiles (e.g. different coloured clothing such as smocks or hair nets).	or this clothing should be restricted to those areas.
SECTION VIII - TRANSPORTAT	ION
	USA
	BOLDED AND CAPITALIZED
	Colombia
	We suggest leaving the title in capital letters.
PRINCIPLE	
Foods not containing allergens should be managed during transportation so that allergen cross-	Nicaragua
contact is prevented.	Nicaragua suggests changing the wording of the principle as it is not
	consistent.
Para. 141	
Foods should be arranged for transport in such a way that unpackaged products with different	USA
allergen profiles are transported separately. If this is not possible, consider other means of	

 segregating the foods, such as inserting a pallet cover (i.e. big plastic bag used to cover the entire pallet) to reduce the likelihood of allergen cross-contact, stacking non-allergenic food on top of allergenic food, or packaging the food using poly <u>bage-bags</u>, super sacks, or bags with plastic overwrap. Manufacturers should clearly communicate special instructions to their chosen transporter/haulier e.g. to not allow mixed transportation of goods, when there is the likelihood of cross-contact. Foods should be arranged for transport in such a way that unpackaged products with different 	IDF/FIL
allergen profiles are transported separately. If this is not possible, consider other means of segregating the foods, such as inserting a pallet cover (i.e. big plastic bag used to cover the entire pallet) to reduce the likelihood of allergen cross-contact, stacking non-allergenic food on top of allergenic food, or packaging the food using poly bags super sacks, or bags with plastic overwrap. Manufacturers should clearly communicate special instructions to their chosen transporter/haulier e.g. to not allow mixed transportation of goods, when there is the likelihood of allergen cross-contact.	
8.3 Use and maintenance Para. 145	
Food transportation units (including relevant accessories, connections) and load carrying areas should be inspected and, if necessary, cleaned to remove any residue of the previous load, to the extent possible, before re-loading. The method of cleaning adopted should be appropriate to the type of commodity and type of allergen to be loaded in the unit. Records of the cleaning, including the type of cleaning conducted should be available.	Australia
SECTION IX – PRODUCT INFORMATION AND CONSUMER AWARENESS	
	USA
	BOLDED AND CAPITALIZED
	Colombia We suggest leaving the section in capital letters.
9.2.1 Manufacturing Para. 152	
[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 allergen. This includes any applicable information relevant to assess the likelihood of allergen cross-contact, such as that outlined in section 5.1, and may include precautionary allergen labelling as discussed in section 9.3. Such statements should be truthful, not misleading and not used in lieu of GHPs (see section 9.3).]	Indonesia Indonesia agrees with this paragraph
[All-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 allergen. This-[This includes any applicable information relevant to assess the likelihood of allergen cross-contact, such as that outlined in section 5.1, and may include precautionary allergen labelling as discussed in section 9.3. Such statements should be truthful, not misleading and not used in lieu of GHPs (see section 9.3).]	USA Rationale: This sentence is separate from the statements related to precautionary allergen labeling (which need to remain in square brackets pending advice from CCFL) and is analogous to the statement in paragraph 154 for retail and food service. ("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 allergen.")
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	Nicaragua Nicaragua supports the proposed text.

	1
food is, or contains, an allergen. This includes any applicable information relevant to assess the	
likelihood of allergen cross-contact, such as that outlined in Section 5.1, and may include precautionary allergen labelling as discussed in Section 9.3. Such statements should be truthful,	
not misleading and not used in lieu of GHPs (see Section 9.3). ¹	
9.2.2 Retail and food service	
Para. 1555	
Front of house personnel that serve food to customers should be knowledgeable about the	IDF/FIL
allergens in menu items and preparation practices of the business that may result in <u>allergen</u>	
cross-contact, or know how to obtain this information. Signage, whether within menus or located	
at the front counter, requesting that customers make dietary requirements with respect to	
allergens known to food service personnel, could also be used. Where the food service	
operators and personnel cannot ensure that a food does not contain an allergen, this should be	
clearly communicated to the customer.	
Para. 156	
Self-serve areas where consumers handle unpackaged food products may pose a particular risk	USA
for allergic consumers due to allergen cross-contact. Separation Provision of allergenic food	Rationale: This section is about "Product Information and Consumer
items and non-allergenic food, as well as provision of information on the likelihood of allergen	Awareness." Separation of allergenic foods and using dedicated
cross-contact, cross-contact should be considered in these instances (e.g. allergen alert signage	equipment, utensils and tools at retail and food service are
or symbol/icons). Dedicated equipment, utensils and tools for handling allergenic food should not	appropriately addressed in paragraphs 80 and 85 in Section V –
be used for non-allergenic food.	Control of Operation.
Self-serve areas where consumers handle unpackaged food products may pose a particular risk	Honduras
for allergic consumers due to allergen cross-contact. Separation of allergenic food items and	
non-allergenic food, as well as provision of information on the likelihood of allergen cross-	
contact, should be considered in these instances (e.g. allergen alert signage or symbol/icons). Where possible, equipment, utensils and tools for handling allergenic food should not be used	
for non-allergenic food, or cleaning procedures for the equipment used should be	
implemented for processing both allergenic and non-allergenic food items.	
	Iron
The General Standard for the Labelling of Pre-packaged Foods lists the foods and ingredients	Iraq
known to cause hypersensitivity that "shall always be declared" on the labellabel with a clear line	
and another color.	
9.3 Labelling	
Para. 159	
The General Standard for the Labelling of Pre-packaged Foods lists the foods and ingredients	Costa Rica
known to cause hypersensitivity that "shall always be declared" on the label. It is important to	
note that generic names should not be used when an allergenic ingredient is detected (e.g.	
vegetable oil, casein (milk)). Review the exceptions.	
Para. 160	
[Precautionary allergen labelling should only be used after an assessment of the likelihood of	Argentina
allergen cross-contact has been carried out and a risk to consumers has been identified.	Argentina believes that the text referring to precautionary labelling
Following risk assessment, all possible mitigation measures available to eliminate the likelihood	should be kept bracketed until the Codex Committee on Food
	Loballing issues guidenes on the matter
should be explored prior to the use of a precautionary allergen label. Precautionary allergen labels that are necessary following this process can help to inform FBOs and consumers on the	Labelling issues guidance on the matter.

likelihood that the products might contain an allergen (other than those that are listed as ingredients) in situations where:	
[Precautionary allergen labelling should only be used after an assessment of the likelihood of allergen cross-contact has been carried out and a risk to consumers has been identified. Following risk assessment, all possible mitigation measures available to eliminate the likelihood should be explored prior to the use of a precautionary allergen labelling statement. Precautionary allergen labels that are necessary following this process can help to inform FBOs and consumers on the likelihood that the products might contain an allergen (other than those that are listed as ingredients) in situations where:	Australia
[Precautionary allergen labelling should only be used after an assessment of the likelihood of allergen cross-contact has been carried out and a risk to consumers has been identified. Following risk assessment (refer to the Codex document), all possible mitigation measures available to eliminate the likelihood should be explored prior to the use of a precautionary allergen label. Precautionary allergen labels that are necessary following this process can help to inform FBOs and consumers on the likelihood that the products might contain an allergen (other than those that are listed as ingredients) in situations where:	Costa Rica
[Precautionary allergen labelling should only be used after an assessment of the likelihood of allergen cross-contact has been carried out and a risk to consumers has been identified. Following risk assessment, all possible mitigation measures available to eliminate the likelihood should be explored prior to the use of a precautionary allergen label. Precautionary allergen labels that are necessary following this process can help to inform FBOs and consumers on the likelihood that the products might contain an allergen (other than those that are listed as ingredients) in situations where:	Honduras The concept of preventive allergen labelling (could contain) included in paragraphs 68, 145, 153, and 154 necessitates additional review, in keeping with the FoPL document that is currently being discussed/under review.
[Precautionary allergen labelling should only be used after an assessment of the likelihood of allergen cross-contact has been carried out and a risk to consumers has been identified. Following risk assessment, all possible mitigation measures available to eliminate the likelihood should be explored prior to the use of a precautionary allergen label. Precautionary allergen labels that are necessary following this process can help to inform FBOs and consumers on the likelihood that the products might contain an allergen (other than those that are listed as ingredients) in situations where:	Indonesia Indonesia agrees with small revision of this paragraph. The word only is deleted because the use of Precautionary allergen labelling expresses protection for the hypersensitive individuals that should be encouraged.
[Precautionary allergen labelling should only be used after an assessment of the likelihood of allergen cross-contact has been carried out and a <u>significant</u> risk to consumers has been identified. Following risk assessment, all possible mitigation measures available to eliminate the likelihood should be explored prior to the use of a precautionary allergen label. Precautionary allergen labels that are necessary following this process can help to inform FBOs and consumers on the likelihood that the products might contain an allergen (other than those that are listed as ingredients) in situations where:	IDF/FIL
[Precautionary allergen labelling should only be used after an assessment of the likelihood of allergen cross-contact has been carried out and a <u>significant</u> risk to consumers has been identified. Following risk assessment, all possible mitigation measures available to eliminate the likelihood should be explored prior to the use of a precautionary allergen label. Precautionary allergen labels that are necessary following this process can help to inform FBOs and consumers on the likelihood that the products might contain an allergen (other than those that are listed as ingredients) in situations where:	FoodDrinkEurope Revise the paragraph, as below (insertion in bold and italics): Precautionary allergen labelling should only be used after an assessment of the likelihood of allergen cross-contact has been carried out and a significant risk to consumers has been identified. Following risk assessment, all possible mitigation measures available to eliminate the likelihood should be explored prior to the

	use of a precautionary allergen label. Precautionary allergen labels that are necessary following this process can help to inform FBOs and consumers on the likelihood that the products might contain an allergen (other than those that are listed as ingredients) in situations where: ()
Para. 160 bullet point 3	
• the allergen may be present at levels that, based on an assessment of risk, could result in adverse health consequences to the majority of allergic consumers.]	IDF/FIL The risk should be significant but it isn't necessarily to be at a level where the majority are affected.
	This dot point is also very restrictive. Many small food service businesses are certainly not able to ascertain the risk in terms of individuals affected or levels but they should not be discouraged from applying precautionary labeling because they have not met this condition.
 the allergen may be present at <u>levels a level</u> that, based on an assessment of risk, <u>could result in adverse health consequences to exceeds that which would protect</u> the <u>vast</u> majority of allergic consumers.]consumers from an adverse reaction 	FoodDrinkEurope In addition, we propose that the text in the third bullet is re-worded, the term 'majority' is open to different interpretations therefore we recommend the following: "the allergen may be present at a level that, based on an assessment of risk, exceeds that which would protect the vast majority of allergic consumers from an adverse reaction.".
Para. 161	
[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.]	Indonesia Indonesia propose to delete this paragraph, because already explained in paragraph 160
[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 <u>allergen</u> cross-contact cannot be controlled to the extent that the product does not present a risk to the allergic consumer.]	IDF/FIL
[However[NEW PARAGRAPH The risk assessment that will determine if precautionary labelling is required should include the following considerations as a minimum: • If ingredients carry a potential cross contamination risk • threshold doses • If the allergen risk is particulate or dispersible • Validation of different cleaning methods • Verification measurement of cleaning methodsHowever, 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.]	IDF/FIL Suggest that a paragraph is added to provide minimum considerations of the risk assessment that will inform if precautionary labelling is required or not.
[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.]	FoodDrinkEurope This paragraph is a repetition of the message in 160 and can be deleted.

SECTION X - TRAINING	
	Colombia
	We suggest leaving the section in capital letters.
10.2 Training programmes	
Para. 164	
All relevant personnel in a food business should receive food allergen training as appropriate to their job responsibilities, so they can contribute to the measures needed to prevent or minimise the likelihood of allergen cross-contact and labelling errors. Training records for the staff need to be available and competency assessment is recommended as part of the training. Training programmes should be reviewed regularly to ensure they are up to date and appropriate. All appropriate personnel should be encouraged to report and/or take immediate action, if any labelling errors or an undeclared allergen is suspected. Para. 165 sources of allergen information, e.g. supplier specifications, supplier audit records.	Australia Costa Rica add an additional bullet point with the following text: • An emergency protocol should be implemented for food service collaborators for cases in which a customer presents a
	severe reaction.
 GHPs, for example, appropriate clothing, hand washing, and minimizing hand contact with foods to prevent <u>or minimize</u> allergen cross-contact; cleaning of premises, equipment and tools, including clear between-product cleaning instructions, and its importance in preventing <u>or minimizing</u> allergen cross-contact; handling of rework materials to prevent <u>or minimize</u> unintended allergens from being incorporated into a food; waste management, for example how waste should be handled to prevent <u>or minimise</u> allergen cross-contact; 	IDF/FIL