



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

Panama, 12 - 16 November 2018

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

Prepared by the Electronic Working Group chaired by Australia and co-chaired by the United Kingdom
and the United States of America

Codex members and Observers wishing to submit comments at Step 3 on this draft should do so as
instructed in CL 2018/71-FH available on the Codex webpage/Circular Letters 2018:

<http://www.fao.org/fao-who-codexalimentarius/circular-letters/en/>.

Background

1. The 49th session of CCFH (CCFH49) agreed to:
 - a) Start new work on a Code of Practice for Food Allergen Management for Food Business Operators;
 - b) Submit the project document to the Codex Alimentarius Commission for approval as new work; and
 - c) Establish an EWG, Chaired by Australia and Co-Chaired by the United Kingdom and the United States of America to prepare the proposed draft Code of Practice for circulation for comments at Step 3 and consideration at the next session of the Committee;
2. The new work was approved by CAC41 (July 2018).
3. To facilitate communication and collaboration throughout the drafting process, the EWG was conducted through the Codex bulletin board (www.forum.codex-alimentarius.net).

Work of the EWG

4. An invitation was sent to all Codex members and observers to participate in the EWG. Participants from 31 Codex members, one Member organisation and 10 Observer Organisations were registered as participants of the EWG. The list of Participants is attached as Appendix 2.
5. The draft of the Code of Practice, prepared by the Chair and Co-Chairs (referred to as the Chairs) has been organised in accordance with the *General Principles for Food Hygiene* (CXC 1-1969) (GPFH), although some EWG members commented that it could have been structured differently.
6. The draft covers allergen management throughout the supply chain. The scope covers IgE-mediated and non Ig-E-mediated food allergies and hypersensitivities (e.g. Coeliac disease) but does not cover hypersensitivities with a non-immunological aetiology such as lactose intolerance and sulphite sensitivity.
7. The draft document describes the top eight immunological response-associated food groups/types as the allergens of most significance globally and notes that there may be additional/varying foods identified by specific countries which need allergen controls. Whilst the Chairs received feedback that there were many allergenic foods//ingredients which could be listed in the document, the approach we have taken is to leave the listed allergens as those identified as the main eight identified to be of most significance globally. The concern is that if we provide a more comprehensive definitive list, it dates the document and we are mindful of remaining as consistent as possible (within scope) with the *General Standard for Labelling of Pre-packaged Foods* (CXS 1-1985).

8. The Chairs also sought feedback from the EWG on:

- the issue of thresholds/dose response: whether the Code should address this issue; and if so, the best way to do so. The Chairs developed some general text that introduces the idea of thresholds, but given that there are varying principles currently being used by the food industry globally and that there are continuing scientific developments in this area, we have not explored this idea further in the Code at this time;
- whether to include an annex titled 'The Role of Competent Authorities in Allergen Investigation', However most EWG members felt that the intended audience of the Code was food business operators (FBOs) and therefore the annex was outside the scope of the document. Some of the text previously in the annex was moved to within the document and developed into Section 5.8 Recall Procedures which provides guidance for FBOs on allergen complaint investigation;
- how to reframe the retail sections within the document to show that while there may be fewer action points, this sector is no less important.
- ensuring that the text under Primary Production outlines practical/ feasible controls which are necessary to prevent risk. The aim is to focus on principles of allergen identification and sources of risk rather than providing prescriptive guidance specific procedures for controlling risk at primary production.

13. The Chairs note that the CCFL is currently ascertaining if new work on allergens will be pursued and if so, we will continue to liaise closely with the Chairs of the CCFL WG to support alignment of the work of both committees. We also note that text under Section 9.3 of this Code may need to be revised following any work of the CCFL.

14. Based on comments received, the Chairs have prepared a revised draft Code of Practice (Appendix I) which takes into account widely supported comments but not those that were less supported. We have also identified parts of the text which require further discussion for the committee.

15. Further discussion is needed on the following points:

- is additional text needed in paragraph 69 under Monitoring and verification to cover incoming ingredients which may have low level presence of allergen/s and how precautionary allergen labelling should only reflect actual risk in the finished product.
- due to feedback received, we have included alternate text (paragraph 145 and 146) and seek feedback on the preferred option.

the Chairs have proposed new text at paragraph 116 which addresses cleaning validation. Members are asked to consider this new text for inclusion in the Code.

Recommendations

16. The EWG recommends that the Committee consider the proposed draft Code of Practice as presented in Appendix I.

Appendix I

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

(for comments at Step 3 through CL 2018/71-FH)

Table of Contents

INTRODUCTION.....	5
SECTION I – OBJECTIVES.....	7
SECTION II – SCOPE, USE AND DEFINITION.....	7
2.1 Scope.....	7
2.2 Use.....	8
2.3 Definitions.....	8
SECTION III – PRIMARY PRODUCTION.....	9
3.1 Environmental hygiene.....	9
3.2 Hygienic production of food sources.....	9
3.3 Handling, storage and transport.....	9
3.4 Cleaning, maintenance and personnel hygiene at primary production.....	9
SECTION IV – ESTABLISHMENT: DESIGN AND FACILITIES.....	10
4.1 Location.....	10
4.2 Premises and rooms.....	10
4.3 Equipment.....	11
4.4 Facilities.....	11
SECTION V – CONTROL OF OPERATION.....	11
5.1 Control of food hazards.....	11
5.2 Key aspects of hygiene control systems.....	12
5.3 Incoming material requirements.....	15
5.4 Packaging.....	16
5.5 Water.....	16
5.6 Management and supervision.....	17
5.7 Documentation and records.....	17
5.8 Recall procedures.....	17
SECTION VI – ESTABLISHMENT: MAINTENANCE AND SANITATION.....	18
6.1 Maintenance and cleaning.....	18
6.2 Cleaning programmes.....	18
6.3 Pest control systems.....	19
6.4 Waste management.....	19
6.5 Monitoring effectiveness.....	19
SECTION VII – ESTABLISHMENT: PERSONAL HYGIENE.....	20
7.1 Manufacturing.....	20
7.2 Retail and Food Service.....	20
SECTION VIII – TRANSPORTATION.....	20
8.1 General.....	20
8.2 Requirements.....	20
8.3 Use and maintenance.....	21
SECTION IX – CONSUMER AWARENESS AND PRODUCT INFORMATION.....	21

9.1	Lot identification.....	21
9.2	Product information.....	21
9.3	Labelling	22
9.4	Consumer education.....	22
	SECTION X – TRAINING.....	22
10.1	Awareness and responsibilities.....	22
10.2	Training programmes.....	22
10.3	Instruction and supervision	23
10.4	Refresher training	23

INTRODUCTION

1. Food allergies are an increasing food safety issue globally and 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.
2. Allergens are an ongoing food safety concern for allergic consumers, those who have people with food allergies in their care, growers, transporters, food business operators (FBOs) and competent authorities.
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 and manage unintended allergen presence and that Competent Authorities provide oversight and advice, where necessary, to FBOs on food allergen complaint investigations. In a global market it is crucial that there is international understanding of this issue and of the measures required to address it. Allergen management practices should be part of good hygiene practices (GHPs), and, where appropriate, HACCP systems, in manufacturing, retail and food service.
4. Allergens need to be managed throughout the supply chain and production process. Treatments lethal for microbial pathogens, such as heating, high pressure processing, etc. generally do not destroy allergenic proteins. Processes that degrade proteins, such as enzymatic or acid hydrolysis, may be effective, but these treatments should be validated for effectiveness in addressing an allergen hazard.

Hazard characterisation

5. The allergenic nature of some foods should be identified as a food safety hazard for susceptible individuals. Food allergies are caused by an adverse immune reaction (hypersensitivity) to certain food proteins. Allergies to food can be classified by their immune mechanism:
 - immunoglobulin E (IgE)-mediated (immediate hypersensitivity),
 - non-IgE mediated (cell-mediated, or delayed hypersensitivity), and
 - mixed IgE and non-IgE mediated.
6. IgE-mediated symptoms typically develop within minutes to 1-2 hours of ingesting the food, Non-IgE-mediated and mixed IgE- and non-IgE-mediated food allergies present with their symptoms several hours after the ingestion of the food. Symptoms of IgE-mediated food allergy may include itching around the mouth, hives, swelling of lips and eyes, difficulties in breathing, drop in blood pressure, diarrhoea and, in its most severe form, anaphylaxis; and may result in death. Coeliac 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.
7. 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 are¹
 - crustaceans;
 - egg;
 - fish;
 - milk;
 - peanut;
 - soybean;

¹ The listed allergens, with some exceptions (e.g. sulphites), are also referred to in the *General Standard for the Labelling of Pre-packaged Foods* (CXS 1-1985) with respect to labelling.

- tree nuts; and
 - wheat and other cereals containing gluten (and their derivatives).
8. 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.
 9. While these are the most common, other food allergens such as sesame seeds, buckwheat, celery, mustard, molluscs, kiwi fruit and lupin are recognised as important in many countries and there is the potential for additional major allergens to be identified in the future. The controls outlined in this Code of Practice (Code) would be similar for any other allergens, and FBOs should apply these as appropriate to their own business requirements and applicable legislation.
 10. Poor allergen management (including insufficient or inaccurate labelling) can result in the presence of varying levels of undeclared allergens in food, which may pose a risk if consumed by an allergic individual. The doses that provoke reactions vary among individuals and depend in part on the type of allergen. The risk of allergic reactions among a larger proportion of the allergic population increases with increasing concentration of undeclared allergen.
 11. Allergen cross-contact can result from a number of factors in processing foods, some of which pose a greater potential for cross-contact than others. The control measures implemented to minimise cross-contact should be based on risk. In some instances, it may not be possible to prevent cross-contact, despite the implementation of preventive measures and GHPs. However, it may be possible to minimise cross-contact to an extent that the amount of allergen present due to cross-contact is below a batch threshold that would cause an adverse reaction in an allergic consumer.
 12. It is important that FBOs are able to identify the allergenic nature of the foods and ingredients they handle and take steps to manage any potential presence of undeclared allergens.

Factors contributing to exposure

13. A variety of situations may result in the exposure of allergic individuals to undeclared allergens. These include the following:

For harvesting, handling, storage and transportation:

- inadequate or ineffective cleaning of, bags and transport vehicles;
- inadvertent inclusion of foreign grains;
- inadequate physical separation; and
- inadequate employee training/education on managing food allergens.

For packaged food manufacturing facilities:

- labelling errors (label misprints, outdated labels, label in a foreign language, product in the wrong package);
- unintentional presence of an allergen due to in-process or post-process cross-contact;
- inappropriate design of the establishment in terms of separation of areas, location of equipment, traffic patterns, and the ventilation system, among others;
- errors in handling of rework;
- production sequences (scheduling) that result in the unintentional presence of an allergen from a product produced earlier;
- inadequate or ineffective equipment cleaning/sanitation procedures at product changeover;
- lack of change management for changes in formulation, ingredient supply and documentation processes;
- improper use of an allergen-containing ingredient;
- undeclared allergen in a supplier ingredient; and
- inadequate or lack of employee training/education on managing food allergens.

For retail and food service establishments:

- failure of the establishment to receive accurate information from supply chain or lack of allergen information with ingredients or foods received;
 - failure to receive timely notification of ingredient changes or order substitution;
 - lack of adequate storage or preparation areas to minimise the potential for allergen cross-contact;
 - inappropriate flow of operations or improper equipment lay-out;
 - absence of, or inadequate, food preparation and service procedures to avoid allergen cross-contact;
 - inadequate employee training/education on managing food allergens, including lack of understanding of the serious nature of food allergies;
 - inability of FBOs to clearly communicate allergen information to customers;
 - food delivery websites which fail to communicate allergy requirements or allergen presence; and
 - food allergic individuals not making their allergies known.
14. Cross-contact can occur at many points in the food chain. Potential points where cross-contact can occur are outlined in relevant sections within this Code.
15. FBOs are encouraged to have documented and detailed allergen management policies and procedures specific to the food business. Having allergen management policies and procedures in place, and compliance with these, allows a business to demonstrate it is taking all necessary steps to reduce the likelihood of an allergen being unintentionally present in a food. It also provides an opportunity for businesses to demonstrate adequate skills and knowledge in allergen management and reduces the risk of an allergen incident occurring.

SECTION I - OBJECTIVES

16. This Code provides guidance to FBOs, including primary producers, to develop policies and procedures to identify allergens in all areas of food production, preparation and service, and then implement allergen management practices, including controls to:
- minimise the potential for cross-contact that is of risk to the allergic consumer;
 - ensure the correct allergen label is applied to pre-packaged foods; and
 - ensure that accurate information can be provided to consumers at point of sale when the food is not pre-packaged.
17. The management tools and guidance in this Code are a proactive approach for effectively managing allergens in food production, preparation and service and reducing risk for consumers, rather than a reactive response once a food safety hazard has been detected in a food.
18. Food allergen management also involves allergen labelling. While this Code addresses controls to ensure that the correct label is applied during manufacturing of a product or when labelled at retail for the customer, labelling requirements for food products are addressed by the *General Standard for the Labelling of Pre-packaged Foods* (CXS 1-1985) and the *Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten* (CXS 118-1979).

SECTION II – SCOPE, USE AND DEFINITION**2.1 Scope**

19. This Code covers allergen management throughout the supply chain including at primary production, during manufacturing, and at retail and food service end points. It complements Good Hygiene Practice (GHP) in manufacturing and food preparation practices in food service.

20. This Code covers IgE-mediated, non Ig-E-mediated food allergies and hypersensitivities (e.g. Coeliac disease) that can be triggered by small amounts of the offending food allergen (thus requiring attention to GHPs in addition to labelling). There are eight foods/food groups (and derived products) that cause the majority of food allergies on a global basis and these include crustaceans, egg, fish, milk, peanut, soybean, tree nuts, wheat and other cereals containing gluten.
21. This Code does not cover hypersensitivities 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.

2.2 Use

22. This Code follows the format of the *General Principles of Food Hygiene* (CXC 1-1969) and should be used in conjunction with it, as well as with other applicable codes and standards such as the *General Standard for Labelling of Pre-packaged Foods* (CXS 1-1985) and *Code of Hygienic Practice for the Transport of Food in Bulk and Semi-packed Food* (CXC 47-2001).
23. The provisions in this document should be applied as appropriate for the food business (e.g. manufacturing, retail, food service), with consideration of the diversity of ingredients, processes, and control measures of the products and various degrees of risk involved in managing allergenic ingredients/foods.
24. The document has been structured to outline the principles of food allergen management which apply broadly to food business operators, as well as identify those which should be specifically applied to retail and food service sectors. In this document, **retail** means a food business primarily involved in selling pre-packaged or non-prepackaged food directly to consumers for off-site or future consumption and **food service** means a food business that produces and serves food for direct consumption.

2.3 Definitions

25. For the purpose of this Code, the following expressions have the meaning stated:

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 Cross-contact occurs when an allergenic food is unintentionally incorporated into another food that is not intended to contain that allergenic food.

Allergen Profile means the food allergens present (or the absence of any allergens) in a food.

Competent Authority means the official government agency responsible for implementing food law.

Food business operator (FBO) means the persons responsible for ensuring that the requirements of food law are met within the food business under their control, and includes producers, processors, wholesalers, distributors, importers, exporters, retailers, and food service operators.

Good Hygienic Practices (GHPs) means guidelines, procedures, or activities designed to promote and maintain sanitary conditions in food production.

Hazard Analysis and Critical Control Points (HACCP) means an established set of principles which provides a systematic way of identifying food safety hazards and making sure that they are being controlled.

Rework 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.

Visibly clean means having no visible food or other residues.

SECTION III – PRIMARY PRODUCTION**PRINCIPLE:**

Where the introduction of an allergen may adversely affect the allergen profile of food at later stages of the food chain, primary production should be managed in a way that reduces the likelihood of introducing such allergens.

26. This section is focused on primary production of cultivated commodities where there is a risk of allergen cross-contact (often referred to as adventitious presence).

3.1 Environmental hygiene

27. Depending on the crop, growers should consider the potential for allergen cross-contact from the growing environment. In order to assess the risk, growers should know the history of the specific growing area i.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.

3.2 Hygienic production of food sources

28. During growing, minimise the potential for maintenance machinery (e.g. used for weeding) to contain other plant material which could result in allergen cross-contact.

3.3 Handling, storage and transport

29. Prior to harvest, inspect equipment used for harvesting of crops to determine if the equipment is clear of visible plant debris and signs of previous crops/ food material.

30. Harvested commodities should be cleaned to the extent possible using various methods such as sifting via size, aeration, and mechanical cleaning to remove foreign allergenic matter where feasible and consistent with Codex standards.

32. To minimise the risk 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 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.

33. Where a commodity is bagged, bags should be clean. Bags that have been used for an allergenic commodity should not be reused for a different commodity. For example, avoid the re-use of jute / canvas bags for non-allergenic commodities if they have already been used for allergenic commodities. Where grains or pulses are bagged and stored together, store allergens on the bottom shelves so that spillages can be easily managed from the perspective of preventing contact with non-allergenic commodities.

34. Transportation of food stuff should be carried out using a clean transport vehicle that is dry and free of the previous load to minimise the potential for allergen cross-contact. As necessary, transport containers should be cleaned before use. At unloading, transport containers containing allergenic commodities should be emptied of all cargo and cleaned as appropriate to minimise the potential for allergen cross-contact of the next load. For more detail on transportation refer to Section 8.

3.4 Cleaning, maintenance and personnel hygiene at primary production

35. Refer to the *General Principles for Food Hygiene* (CXC 1-1969).

36. In addition, FBOs should ensure that the area where commodities are dried is clean and physical barriers are in place to prevent spillage and cross-contact. Materials or containers used to lay, hang or bag commodities should be cleaned to remove allergenic residue. FBOs should ensure storage areas and storage materials designated for allergenic commodities are clearly labelled or colour coded to prevent unintentional mix of commodities.

SECTION IV – ESTABLISHMENT: DESIGN AND FACILITIES**PRINCIPLE:**

Establishment design should minimise the potential for cross-contact with allergens with respect to delimitation and isolation of areas, location of equipment, process flow, personnel movement and ventilation systems.

4.1 Location**4.1.1 Establishments**

37. FBOs producing food at more than one site should consider whether it is feasible to consolidate production, processing and storage of products containing specific allergens at one location. Although this may not always be feasible, particularly for small businesses, it could be used to limit cross-contact. If this is not possible, the production could be separated in time (see 5.2.1.) or space (separate rooms or lines for different allergens) and the establishment may be designed to have a linear flow in the production. Effective cleaning procedures, such as those outlined in Section 6, are also important in managing allergen cross-contact.

4.1.2 Equipment4.1.2.1 Manufacturing

38. 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 most cases. An analysis of the process, including the equipment design, should be conducted to determine the risk to the allergic consumer and whether dedicated processing lines, equipment redesign, or other control measures are needed to ensure appropriate consumer protection.

39. 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 minimise the potential for cross-contact from one line to another based on the food, the process, and the likelihood of cross-contact. Manufacturers should eliminate cross-over points or provide a means to contain or shield food (e.g. closed pipes, enclosed or covered conveyors) to prevent food spilling from one line to another.

4.1.2.2 Retail and food service

40. Retail and food service operators also commonly handle multiple allergens, frequently on the same equipment. They should, where feasible, use equipment dedicated to foods with a particular allergen (e.g. use a separate slicer for cheese, which contains milk, and for meats that do not contain milk).

4.2 Premises and rooms

41. Where feasible, FBOs (manufacturers, as well as retail and food service operators) should consider the need, based on risk to provide a dedicated production area within the establishment for the preparation of foods that do not contain allergens, or provide dedicated production areas, or use screens to set up temporary segregated areas, for foods with different allergen profiles. For example, an establishment that handles different types of tree nuts could dedicate separate rooms or other areas for handling each type of nut. One that handles different types of protein powders such as soy protein and milk powder could dedicate separate areas for handling these powders. Where applicable, the rooms should be appropriately designed such that effective cleaning could be administered to reduce cross-contact.

42. FBOs should store allergens separately from other allergens as well as separate them from non-allergenic ingredients.

4.2.1 Manufacturing

43. Manufacturers should consider providing barriers (e.g. walls, partitions, curtains) or adequate separation between lines, when necessary, to prevent allergen cross-contact when foods with different allergen profiles are processed at the same time.

44. 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 risk 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 following dumping could be used to mitigate the risk of allergenic proteins in powders being transferred to other foods.

4.3 Equipment

4.3.1 Manufacturing

45. Equipment, tools, utensils and containers (other than single-use containers and packaging) contacting foods that contain allergens should be designed and constructed to provide for effective removal of allergens during cleaning. To minimise the potential for allergen cross-contact, ideally, they should not contain areas where allergens, especially particulate allergens (e.g. peanuts, tree nuts), could get caught in crevices such that they are not removed by the cleaning procedures applied. Welds should be smooth, seals and hoses should not contain cracks, and “dead ends” or other areas where pockets of foods containing allergens can accumulate should be eliminated.

4.3.2 Retail and Food Service

46. Retail and food service operators should use equipment, tools, utensils and containers (other than single-use containers and packaging) that have been designed and constructed to ensure that allergens can be easily and effectively removed during cleaning.

4.4 Facilities

47. 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 employees 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.

SECTION V – CONTROL OF OPERATION

PRINCIPLE:

The unintentional presence of allergens in food is minimised by taking preventive measures through GHPs and HACCP at appropriate stages in the operation.

5.1 Control of food hazards

48. FBOs should control allergens by 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 risk include:

- allergens present in the facility;
- the nature of the allergen (i.e. whether the food itself is an allergen, derived from an allergen, or the allergen is a component in an ingredient);
- whether the allergen is a particle, powder, liquid or paste;
- the processing steps where the allergen is used; and
- the amount of allergen used in products.

49. It is important that FBOs educate and train personnel to have awareness of food allergens and their health impact in order to ensure they implement the necessary allergen controls.

50. FBOs should:

- identify any steps in their operations that pose a risk of allergen cross-contact, assess the level of risk at those steps and ascertain the ones that are critical;
- implement effective control procedures to minimise allergen cross-contact at those steps;
- monitor control procedures to ensure their continuing effectiveness;
- review allergen control procedures periodically, particularly when the operations change;

- ensure suppliers are familiar and comply with food allergen specifications; and
- ensure personnel are aware of and follow allergen control procedures.

5.1.1 Manufacturing

51. Manufacturers should also identify steps in the operation that are critical to ensuring allergens are properly labelled including reviewing recipes and labels on compound ingredients, and ensuring that the correct product is packed in the correct package.

5.1.2 Retail and food service

52. Retail and food service operators should also manage menus, including in-store and on websites, if they contain allergen information, to assure content is current and matches the food product.

5.2 Key aspects of hygiene control systems

5.2.1 Manufacturing

5.2.1.1 Minimising cross-contact during processing

53. 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. For instance, production schedules could be established in some cases whereby products that do not contain allergens are handled at the beginning of the schedule and different products containing the same food allergen profile could be run sequentially before products with different 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 minimise potential allergen cross-contact and facilitate cleaning.
54. Manufacturers should develop traffic flow of allergen-containing ingredients, packaging supplies and employees during the manufacture of foods to minimise the potential for allergen cross-contact. This should include consideration for managing the movement for transient people such as managers, quality assurance personnel, inspectors, maintenance personnel, and visitors.
55. "Allergen 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 minimise allergen cross-contact.
56. Where there is a risk of contamination by personnel, personnel working on processing lines that contain an allergen should be restricted from working on lines that do not contain that allergen. Manufacturers should consider a system to clearly identify employees working on lines manufacturing foods containing different allergen profiles, e.g. different coloured uniform or hair net.
57. 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 before use for a food with a different allergen profile. Disposable liners can also be an effective strategy.
58. 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 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.
59. 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 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.

60. Dry ingredients that are, or contain, a food allergen should be added in a manner that minimises the potential for unintentional dispersion by dust. 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 to allow sufficient time for the air handling system to evacuate any residual allergenic dust from the establishment environment overnight.
61. Manufacturers should evaluate the potential for cross-contact due to cooking media, such as water or oil. Frying oil may need to be filtered to remove allergen-containing particulate material if it is likely that such particles could end up in a food with a different allergen profile.
62. Spills that contain food allergens should be cleaned up immediately, avoiding further dispersion (e.g. care not to generate aerosols with high pressure washers, or to re-suspend dust using compressed air hoses).

5.2.1.2 Rework and Work-in-Process

63. Rework and Work-in-Process (WIP) that contains allergens should be stored in sturdy containers with secure covers in designated, clearly marked areas. The rework or WIP should be appropriately labelled with all food allergens specifically highlighted, and properly inventoried and accounted for during storage and when used, to minimise the potential for incorporation into the wrong product.
64. Manufacturers should implement a policy for rework to be added back to same finished product whenever feasible. Alternatively, rework can be added to another product with the same food allergen profile.

5.2.1.3 Application of Product Labels

65. Manufacturers should implement procedures to ensure that allergen information and labels are accurate (see 5.3 Incoming Material Requirements) and verify that the correct product labels are used on the production line when packaging/labelling products. This could involve manual checks and/or automated checks such as bar code recognition to ensure the correct packaging is used.
66. Labels and labelled containers should be stored in a way that minimises the potential to pull incorrect labels or containers during production. All labels and labelled containers should be removed at the end of the production run and returned to their designated storage area.
67. Manufacturers should implement procedures to segregate 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.

5.2.1.4 Monitoring and verification

68. Regular internal audits of production systems should be conducted to verify that the product formulation matches the records of allergenic ingredient use, that the final product matches the ingredients specified on the label, that allergen cross-contact controls are properly implemented and that line personnel are appropriately trained.
69. Manufacturers should regularly review suppliers to ensure that multi-component ingredients (e.g. sauces, spice mixes) have not changed and verify that precautionary allergen labelling (such as "may contain" statements) are only applied in instances where the manufacturer cannot reasonably prevent allergen cross-contact when such cross-contact could present a risk to allergic consumers.

5.2.1.5 Product development and change

70. 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.
71. 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 cross-contact with existing products.
72. Procedures for preventing 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.

73. Product labels should be developed and verified to match the formulation before the new product or changed formulation is produced, and product and label specifications that are no longer used should be destroyed or archived in a manner that prevents accidental use.

5.2.2 Retail and Food Service

74. 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 cleaned between use for foods with different allergen profiles.

75. Food that contains allergens should also be stored separate from food that does not contain allergens, or from food with a different allergen profile.

5.2.2.1 Minimising cross-contact during preparation

76. Retail and food service personnel should ask customers if they have any food allergies, even if they are not told by the customer. They should also know and understand the risks of allergen cross-contact from the processes followed in the preparation of food items. Cross-contact during preparation primarily occurs in the following ways:

- food to food, e.g. by foods touching or one food dripping onto another food;
- food to hand to food, e.g. handling by cooking personnel, front service personnel or using hands in multiple containers of ingredients containing different allergen profiles without washing in between, such as adding toppings to pizzas, assembling sandwiches etc;
- food to equipment/utensils/surface to food, e.g. sharing of utensils, for example, using a whisk to stir a milk-based sauce and then using the same whisk to stir eggs, without thoroughly washing and drying the whisk between procedures, or using the same cutting board, griddle/frying pan, or other surface to prepare fish and shellfish; and
- food to cooking media, e.g. shared fryers or boiling vats for cooking food.

77. Preparation processes should be designed to minimise the potential for allergen cross-contact during food preparation, e.g. separate equipment and utensils that are used for foods with different allergen profiles, dedicate utensils/equipment for allergen-containing products, or clean equipment, utensils and preparation surfaces thoroughly between uses for foods with different allergen profiles.

78. Retail and food service operators should consider, where feasible, assigning one individual to prepare an allergenic food (e.g. deveining prawns/shrimp). Where this is not possible, allergen control procedures should be in place between preparation of foods with different allergen profiles.

79. Containers and tools used to hold or transfer foods that contain allergens should, where possible, be dedicated to holding a specific allergen and be marked, tagged, or colour-coded to identify the allergen. Where such dedication is not possible, effective cleaning procedures should be in place to clean containers before use for a food with a different allergen profile.

80. 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. Operators should not use foods for which the allergen profile is unknown, and should never guess or assume that an allergen is not present. Personnel 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. Frying oil may need to be filtered to remove allergen-containing particulate material if it is likely that such particles could end up in food with a different allergen profile.

81. Foods displayed for consumer purchase should be protected from 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.

82. 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.

5.2.2.2 Rework

83. Rework and WIP should be stored in sturdy containers with secure covers in designated, clearly marked areas. The rework or WIP should be appropriately labelled to minimise the potential for incorporation into the wrong product. Food handlers should implement a policy for rework to be added back to the same finished product) whenever feasible. Alternatively, rework can be added into another product with the same food allergen profile.

5.2.2.3 Application of Product Labels

84. In retail and food service operations that package and label foods sold directly to consumers, the label or allergen information is usually generated and provided on site, and often at the point of purchase. Retail and food service operators should implement procedures to ensure that product labels are accurate and the correct product labels/information are provided when packaging/labelling products. They should implement procedures to segregate and then re-label or destroy food products that have been labelled incorrectly.

5.2.2.4 Monitoring and verification

85. Supervisors of food preparation and service staff in retail and food service operations should periodically verify that employees are following the procedures established to minimise the potential for allergen cross-contact and inform the consumer about allergens in foods, including applying the appropriate label to packaged foods and providing the relevant information with respect to unpackaged foods. Regular review of ingredients, recipes, and labels, to ensure accuracy of allergen information should also be undertaken.

5.2.2.5 Product development and change

86. When introducing a new product or recipe with a different allergen profile, procedures for minimising cross-contact should to be reviewed and possibly revised. Employees that handle these foods, in particular those who have direct interaction with customers should be made aware of the changes in a timely manner. Allergen information on menus should also be updated.

5.3 Incoming material requirements

5.3.1 Manufacturing

87. The source of an allergen unintentionally present 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 for their suppliers that address allergen controls as appropriate to the supplier and the use of the ingredient by the manufacturer.
88. Suppliers should have good allergen management practices to minimise the risk 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 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.
89. 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 with each lot can also be useful in addressing a supplier's control of food allergens.
90. Manufacturers should have procedures/policies in place for suppliers to notify, in a timely manner, the manufacturer of any changes in the supplier's operation that could impact the allergen profile of the ingredient from the supplier (e.g., a change in formulation affecting the allergen profile or the introduction of a new allergen into the supplier's establishment, particularly if that allergen will be used on the same line as the ingredient provided to the manufacturer). Manufacturers should have a procedure/policy for ensuring that any change in supplier is accompanied by a review of the product(s) being supplied with respect to that supplier's allergen control program.
91. 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, 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 with respect to the labelling of finished food containing that ingredient and controls to minimise allergen cross-contact based on the risk to the allergic consumer.

92. Manufacturers should inspect ingredients, especially allergen-containing ingredients, upon receipt to ensure that the containers are intact and that the contents have not leaked or spread. If containers have leaks, tears, or other defects, manufacturers should inspect nearby containers for evidence of allergen cross-contact. Manufacturers should reject (or properly dispose of) ingredients when a container is not intact or there is evidence of allergen cross-contact, or handle damaged containers in a manner that minimises the potential for allergen cross-contact (e.g. place a damaged container inside another container, or move the contents of the damaged container to a different container).
93. Manufacturers should clearly identify allergen-containing ingredients and processing aids (such as pan-release agents that could contain soy) using a system that adequately distinguishes between ingredients with different food allergen profiles (e.g. tags or colour coding of cases/pallets/bags) to alert personnel that these materials are subject to special precautions and handling procedures throughout the establishment.
94. 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 minimise the opportunity for allergen cross-contact in the event of a spill or leak.

5.3.2 Retail and Food Service

95. Retail and food service operators should purchase ingredients for which the allergen profile is known, e.g. packaged foods that list all ingredients. For example, if a bag of dried porcini mushroom and herb risotto mix does not list the contents, then the product should not be used. Sourcing ingredients from the same supplier may minimise changes in the allergen profile of foods supplied.
96. Retail and food service operators should inspect ingredients, especially allergen-containing ingredients, upon receipt to ensure that the containers are intact and that the contents have not leaked or spread. If containers have leaks, tears, or other defects, operators should inspect nearby containers for evidence of allergen cross-contact. Retail and food service operators should reject (or properly dispose of) ingredients when a container is not intact or there is evidence of allergen cross-contact, or handle damaged containers in a manner that minimises the potential for allergen cross-contact (e.g. place a damaged container inside another container, or move the contents of the damaged container to a different container).
97. The labels of incoming packaged ingredients used in the preparation of foods should be reviewed for allergens to ensure knowledge about the allergens present in the final prepared food. Retail and food service operators should store allergen-containing ingredients in a manner to minimise the potential for allergen cross-contact e.g. store allergen-containing ingredients below those that do not contain allergens.

5.4 Packaging

98. 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. 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.

5.5 Water

99. Water that has come in to contact with a food that is or that contains an allergen (e.g. water used for cooking or washing) should not be recirculated for use on a food that does not contain that allergen if such use could result in allergen cross-contact that could present a risk to allergic consumers.
100. Re-use of clean-in-place (CIP) rinse water from washing equipment containing an allergen should be avoided if this could result in allergen cross-contact that could present a risk to allergic consumers.

5.6 Management and supervision

101. FBO managers and supervisors need to have enough knowledge and understanding of allergen control principles and practices to be able to judge potential risks and determine the need for new or revised procedures to prevent the presence of undeclared allergens or the need to take corrective action when allergen control procedures are not properly implemented. In addition, retail and food service managers need to be able to recognise when a customer is having an allergic reaction, and how to proceed with emergency services.

5.7 Documentation and records

102. Refer to the *General Principles of Food Hygiene* (CXC 1-1969).

5.7.1 Manufacturing

103. Records could include those for:

- 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 cross-contact controls and cleaning schedules);
- suppliers allergen information / specification
- procedures for handling and storage of allergens;
- label review;
- label application;
- scheduling;
- batching (putting together the ingredients in a food);
- rework;
- cleaning (SOPs and documentation that cleaning has been done);
- line clearance procedures for label and packaging material removal at changeover;
- packaging label and print manufacturing records;
- validation data for allergen cleaning efficacy;
- verification activities (including any analytical test results for allergens); and
- training (personnel trained, type of training, and date of training).

5.7.2 Retail and Food Service

104. Records could include those for:

- allergenic ingredients associated with each menu item;
- cleaning (SOPs); and
- training (personnel trained, type of training, and date of training).

5.8 Recall procedures

105. Refer to the *General Principles of Food Hygiene* (CXC 1-1969).

106. A traceability/product tracing system should be designed and implemented according to the *Principles for Traceability/Products tracing* as a tool within a *Food Inspection and Certification System* (CXG 60-2006) to enable the withdrawal of products where necessary. 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.

5.8.1 Consumer complaints

107. FBOs should have procedures in place for handling consumer complaints with regard to undeclared allergens in foods. The procedures should define the steps to be followed in handling complaints and include complaint collection, investigation, analysis, record keeping and reporting to competent authorities where appropriate.

108. 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. The decision on action will consider the potential risk 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.
109. The prime objective of an investigation into undeclared allergens in a food is to ensure that public health and safety are protected and the incident will not re-occur. The action plan depends on the outcome of the investigation. Action should always be taken in a timely manner to ensure further incidents do not occur, and public health and safety are protected.

SECTION VI – ESTABLISHMENT: MAINTENANCE AND SANITATION

PRINCIPLE:

The effective management of food allergens is facilitated by establishing effective maintenance and cleaning programs that minimise the potential for allergen cross-contact.

6.1 Maintenance and cleaning

6.1.1 Manufacturing

110. Inspect and remove any hand tools and utensils if they are damaged and not easily cleanable. Where feasible and appropriate, label or colour code maintenance tools to correspond with specific allergens.
111. Equipment and preparation areas should be adequately cleaned between manufacturing foods with different allergen profiles to 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. This should be taken into account in the allergen management program.
112. 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 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. Cleaning should include the ductwork in ventilation systems where necessary to minimise allergen cross-contact.
113. 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 cross-contact.
114. 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 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.

6.1.2 Retail and Food Service

115. Equipment, utensils, containers and preparation areas should be adequately cleaned (at a minimum visually clean) immediately after the preparation, storage, and dispensing of foods to prevent allergen cross-contact.

6.2 Cleaning programmes

6.2.1 Manufacturing

116. Manufacturers should develop cleaning procedures designed to remove food allergens to the extent possible.

(OR ALTERNATE TEXT)

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

These procedures should specify the equipment, utensil, or area of the establishment to be cleaned using the procedures; 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.

117. Because introducing water into some facilities and equipment can result in microbial problems, some production procedures includes a “push-through” technique in which the subsequent product, an inert ingredient (such as sugar or salt), or an allergen-containing ingredient (such as flour) that will be an ingredient in the subsequent product is pushed through the system to remove food residue. Where feasible, test kits should be used to evaluate “push-through” material, or the first product through the line, to demonstrate that a food allergen from a previous production run has been removed by this process.
118. Manufacturers should develop allergen clean up procedures for the manufacturing line in the event of spills of allergen-containing ingredients.
119. Manufacturers should maintain cleaning records, including any test results, and review them to verify that cleaning procedures have been conducted and adequately remove allergens.

6.2.2 Retail and Food Service

120. Retail and food service operators should develop allergen clean up procedures for the food service preparation, storage and presentation areas and in the event of spills involving allergen-containing foods.

6.3 Pest control systems

121. Refer to the *General Principles of Food Hygiene* (CXC 1-1969).
122. In addition, pest control system should not use allergens (e.g. peanut butter, cheese) as bait in traps. 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.

6.4 Waste management

123. FBOs should place waste materials that contain food allergens in covered bins, totes, or containers that are identified as holding waste and handled in a manner to minimise the potential for allergen cross-contact.

6.5 Monitoring effectiveness

124. Manufacturers should verify cleaning procedures, where feasible, to 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.
125. 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. testing rinse samples or swabs).
126. Manufacturers should periodically conduct tests (e.g. rapid ATP (adenosine triphosphate) or protein or allergen swabs, or test kits) to detect food residues that remain after cleaning as verification that the cleaning procedures have been appropriately implemented and are effective. Where feasible, these tests should include using 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 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 test kit supplier or an accredited testing laboratory).

SECTION VII – ESTABLISHMENT: PERSONAL HYGIENE**PRINCIPLE:**

Personal hygiene practices should manage the potential for food handlers to contribute to allergen cross-contact.

127. FBOs should consider the potential for cross-contact of products with allergenic materials via food handlers. For example, food handlers may become a vector for 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.

128. FBOs should encourage employees to wash hands between handling foods that have different allergen profiles, or after having been in contact with other sources of potential allergens.

7.1 Manufacturing

129. Food handlers should wear dedicated clothing in areas where specific allergens are handled and there is a high risk of allergen cross-contact. The wearing of this clothing should be restricted to those areas. It may be appropriate to visually identify which personnel work on processing lines with different allergen profiles (e.g. different coloured clothing such as smocks or hair nets).

130. Personnel should not be permitted to bring food or drink into areas where product, ingredients or primary packaging is exposed, as these foods may contain allergens and result in allergen cross-contact.

7.2 Retail and Food Service

131. Where it is not feasible to assign one individual to prepare an allergenic food (e.g. deveining prawns/shrimp), ensure that the individual's hands are thoroughly cleaned before handling another food.

SECTION VIII – TRANSPORTATION**PRINCIPLE:**

Foods containing allergens should be managed during transportation so that allergen cross-contact is prevented.

8.1 General

132. FBOs should only distribute foods that have appropriate allergen labelling and/or be able to provide appropriate documentation (e.g. non-prepacked foods for catering purposes) for recipients to determine the allergen status of the food.

133. Foods that are being distributed should be adequately contained or packaged to protect against allergen cross-contact.

8.2 Requirements

134. Foods should be arranged for transport in such a way that unpackaged products with different 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 risk 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 a risk of cross-contact.

135. The food transportation unit² and associated transport receptacles, should be suitably designed and constructed to facilitate inspection and cleaning, refer to the *Code of Hygienic Practice for the Transport of Food in Bulk and Semi-packed Food* (CXC 47-2001).

136. The transporter/ haulier should demonstrate a clear understanding of the food they carry and ensure personnel can identify and understand potential allergen cross-contact situations.

² Food transportation unit (as outlined in the *Code of Hygienic Practice for the Transport of Food in Bulk and Semi-packed Food* (CXC 47-2001) refers to food transport vehicles or contact receptacles (such as boxes, containers, bins, bulk tanks) in vehicles, aircraft, trailers and ships, and other transport receptacles in which food is transported.

8.3 Use and maintenance

137. Vehicles such as bulk tankers used to transport liquids (e.g. raw milk, dairy mixes, juices, liquid egg, oil, water) must be adequately cleaned between loads to minimise allergen cross-contact. In some instances, dedicated bulk tankers may be best, for example, when transporting dry powders such as wheat flour.
138. 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.
139. Carts and trolleys used to transport food within a retail or food service establishment or to customers should be kept clean between uses; e.g. a meal of cheese omelette and toast spilled onto a cart and not properly cleaned between uses could contaminate a subsequent meal, utensils or cups transported to another customer that has allergies to egg, milk or wheat.
140. For commercial scale haulage, a record should be made when a vehicle has been inspected, even if cleaning is not needed. If feasible, designated vehicles should be used for transporting open or bulk allergenic ingredients e.g. raw tree nuts.
141. Spillages of foods containing allergens that occur during transportation should be cleaned up as soon as possible to ensure that there is no subsequent allergen cross-contact. If any incident occurs during loading, transportation or unloading which could result in allergen contamination, the circumstances should be reported to the owner of the goods or their customer for their consideration and for them to advise if specific measures are needed.

SECTION IX – CONSUMER AWARENESS AND PRODUCT INFORMATION

PRINCIPLE:

Consumers should have access to adequate and correct information on the allergenic nature of a food. This should ensure that those with allergies can avoid allergenic foods and ingredients.

9.1 Lot identification

142. Refer to the *General Principles for Food Hygiene* (CXC 1-1969).
143. The *General Standard for the Labelling of Pre-packaged Foods* (CXS 1-1985) applies.

9.2 Product information

144. Refer to the *General Principles for Food Hygiene* (CXC 1-1969).

9.2.1 Manufacturing

145. All food products and ingredients should be accompanied by or bear adequate information to ensure other food manufacturers or processors and consumers can be informed whether the food is, or contains, an allergenic ingredient.

ALTERNATE TEXT

146. All food products and ingredients should be accompanied by or bear adequate information to ensure other food manufacturers or processors can be informed whether the food contains an allergen. This includes any applicable precautionary allergen labelling (e.g. “may contain”). Nevertheless, it’s desirable to avoid the systematic use of such statements, which can reduce the available food in the market for allergic consumers.
147. Manufacturers should have procedures in place to ensure that food is labelled appropriately, as per section 9.3.

9.2.2 Retail and food service

148. All food products and ingredients should be accompanied by or bear adequate information to ensure customers can be informed whether a food is, or contains (or may contain) an allergenic ingredient. Restaurants should ensure that any allergen information on the menu, both on site and online, is current. Similarly, retail operations should make sure allergen information they make available, e.g. online, is current and correct.

149. Front of house employees that serve food to customers should be knowledgeable about the allergens in menu items and preparation practices of the business that may result in cross-contact, or know how to obtain this information. They should also ask customers about any food allergies. Where the food service operators and staff cannot ensure that a food does not contain an allergen, this should be clearly communicated to the customer.
150. Self-serve areas where consumers handle unpackaged food products may pose a particular risk for cross-contact. Provision of information on the risk of cross-contact should be considered in these instances (e.g. allergen alert signage or symbol/icons). Dedicated equipment for handling allergenic food should not be used for non-allergenic food.

9.3 Labelling

151. Refer to the *General Principles for Food Hygiene* (CXC 1-1969).
152. The *General Standard for the Labelling of Pre-packaged Foods* (CXS 1-1985) applies.
153. The *General Standard for the Labelling of Pre-packaged Foods* lists the foods and ingredients known to cause hypersensitivity that should always be declared on the label.
154. Precautionary allergen labelling (e.g. “may contain...”) should be used to inform FBOs and consumers on the risk that the products might contain an allergen (other than those that are listed as ingredients) in situations where:
- allergen cross-contact for a specific food cannot be prevented using GHPs
 - allergen cross contact occurs sporadically, and
 - the allergen is detected at levels that, based on an assessment of risk, could result in adverse health consequences to allergic consumers.
155. 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. For example, areas of processing equipment that cannot be accessed for cleaning, or that cannot be cleaned in a manner where allergens are adequately removed (e.g. certain dry cleaning methods).

9.4 Consumer education

156. Refer to the *General Principles for Food Hygiene* (CXC 1-1969).

SECTION X – TRAINING

PRINCIPLE:

Personnel engaged in food operations should have sufficient training in food allergen management to ensure measures to minimise allergen cross-contact are implemented.

10.1 Awareness and responsibilities

157. All personnel involved in the production, preparation, distribution and service of foods should understand their role in allergen management and the food safety implications of the presence of undeclared food allergens. This includes temporary and maintenance personnel.

10.2 Training programmes

158. 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 minimise the risk of allergen cross-contact and labelling errors. All appropriate personnel should be encouraged to report and/or take immediate action, if any risk of labelling errors or an undeclared allergen is suspected.
159. Training programs should include, as appropriate to the person’s duties:
- general allergen awareness, including the nature and possible health consequences of the unintended or undeclared presence of allergens in products from a consumer perspective;
 - awareness of the allergen cross-contact risks identified at each stage of the food supply chain, and the preventive measures and documentation procedures applicable in the food business;

- GHPs, for example, clothing, hand washing, and hand contact with foods to prevent allergen cross-contact;
- hygienic design of facilities and equipment in relation to allergens;
- cleaning of premises, equipment and tools and its importance in preventing allergen cross-contact;
- handling of rework materials to prevent unintended allergens from being incorporated into a food;
- waste management, for example how waste should be handled to prevent allergen cross-contact;
- situations where potential allergen cross-contact can occur between products, production lines or equipment, and prevention measures;
- procedures for corrective actions when allergen cross-contact or labelling errors are suspected;
- procedures for managing people traffic patterns around the site to minimise allergen transfer from one area to another, for example people changing production line or site, movement to the canteen/break room and of visitors;
- equipment movement around the site, for example, maintenance tools, carts, food trays, etc. to minimise allergen transfer from one area to another;
- labelling and the awareness of allergen presence in raw materials, semi-finished goods and finished products; and
- sources of allergen information, e.g. supplier specifications, supplier audit records.

10.3 Instruction and supervision

160. Refer to the *General Principles for Food Hygiene* (CXC 1-1969).

10.4 Refresher training

161. Refer to the *General Principles for Food Hygiene* (CXC 1-1969).

Appendix II

LIST OF PARTICIPANTS

Chair

Australia

Patricia Blenman, Food Standard Australia New Zealand (FSANZ):

patricia.blenman@foodstandards.gov.au

Co-Chairs

United States of America

Jenny Scott, US Food and Drug Administration: jenny.scott@fda.hhs.gov

United Kingdom

Chun-Han Chan, Food Standards Agency, UK: chun-han.chan@food.gov.uk

Erin Oliver, Food Standards Agency, UK: erin.oliver@food.gov.uk

Argentina

Maria Esther Carullo
mcarullo@senasa.gob.ar

Josefina Cabrera Durango
josefina@anmat.gov.ar

Erika Marco:
emarco@anmat.gov.ar

Australia

Lauren Kolstad
Food Standards Australia New Zealand (FSANZ)
Lauren.Kolstad@foodstandards.gov.au

Patricia Blenman
Food Standards Australia New Zealand (FSANZ)
Patricia.Blenman@foodstandards.gov.au

Austria

Carolin Krejci
Federal Ministry of Labour, Social Affairs, Health and
Consumer Protection:
Carolin.krejci@bmg.gv.at

Brazil

Carolina Araújo Vieira
Brazilian Health Regulatory Agency (ANVISA):
carolina.vieira@anvisa.gov.br

Lígia Lindner Schreiner
Brazilian Health Regulatory Agency (ANVISA)
ligia.schreiner@anvisa.gov.br

Canada

Cathy Breau
Health Canada
Cathy.breau@canada.ca

Chile

Constanza Vergara
constanza.vergara@achipia.gob.cl

Colombia

Giovanny Cifuentes Rodriguez
Ministerio de Salud y Protección Social de Colombia
gcifuentes@minsalud.gov.co

Croatia

Sandra Gutić
Ministry of Agriculture, Veterinary and Food Safety
Directorate
sandra.gutic@mps.hr

Denmark

Zanne Dittlau
The Danish Veterinary and Food Administration
Zadi@fvst.dk

Egypt

Zeinab Mosaad Abdel Razik
Egyptian Organization for Standardization & Quality
(EOS)
eoszienab@gmail.com

Equador

Mónica Quinatoa
Ministerio de Salud Pública (Equador)
monica.quinatoa@misp.gob.ec

Tatiana Gallegos
Ministerio de Salud Pública (Ecuador)
tatiana.gallegos@msp.gob.ec

EU

Kris de Smet
European Commission, DG Health and Food Safety
kris.de-smet@ec.europa.eu

Magdalena Haponiuk
European Commission, DG Health and Food Safety
Magdalena.haponiuk@ec.europa.eu

Finland

Minna Anthoni
Finnish Food Safety Authority Evira
minna.anthoni@evira.fi

France

Célia Azoyan
Ministry of Economy
Celia.AZOYAN@dgccrf.finances.gouv.fr

Sophie Dussours
Ministry of Economy
Sophie.DUSSOURS@dgccrf.finances.gouv.fr

India

Shine Kumar
The Marine Products Export Development Authority
(MPEDA)
shine@mpeda.gov.in

Vaniya Kishore Kumar
The Marine Products Export Development Authority
(MPEDA)
kishor@mpeda.gov.in

R.M.Mandlik
Export Inspection Council (EIC)
tech1@eicindia.gov.in

Ravindra Kumar
Dupont N&H
ravindra.kumar@dupont.com

Govind Suryawanshi
PepsicoIndia Holdings Pvt.Ltd
govind.suryawanshi@pepsico.com

Iswarya Mani
ITC Limited
National Codex Contact Point (NCCP)
codex-india@nic.in

Indonesia

Imran Agus Nurali
Ministry of Health
subdit_hsmm@yahoo.com

Iran

Narges Rahimi
Institute of Standard and Industrial Research of Iran
narges_rahimibaraghany@yahoo.com

Ireland

Patrick John O'Mahony
Food Safety Authority of Ireland, Ireland
pjomahony@fsai.ie

Jamaica

Colin Cooper
Ministry of Health
collin.cooper96@gmail.com

Japan

Kazuko Fukushima
Ministry of Health, Labour and Welfare
codexj@mhlw.go.jp

Keiko Akimoto
Ministry of Agriculture, Forestry and Fisheries
keiko_akimoto690@maff.go.jp

Hajime Toyofuku
Yamaguchi University
toyofuku@yamaguchi-u.ac.jp

Mexico

Tania Daniela Fosado Soriano
Secretaría de Economía
tania.fosado@economia.gob.mx

Maria Gpe. Arizmendi
Cofepris
mgarizmendi@cofepris.gob.mx

Pamela Suarez Brito
Cofepris
psuarez@cofepris.gob.mx

New Zealand

Lisa Horsman
Ministry for Primary Industries
Lisa.horsman@mpi.govt.nz

Elaine D'Sa
Ministry for Primary Industries
Elaine.DSa@mpi.govt.nz

Nigeria

Godwin Akwa
godwin.akwa@nafdac.gov.ng

Codex Contact Point
codexsecretariat@son.gov.ng

Singapore

Sylvester Lee
Agri-Food and Veterinary Authority
sylvester_lee@ava.gov.sg

Spain

Beatriz Martínez Zamorano
Spanish Agency for Consumer Affairs, Food Safety and
Nutrition
bmartinezz@msssi.es

Sweden

Kristina Lagestrand Sjölin
National Food Agency
Kristina.sjolin@slv.se

Viveka Larsson
National Food Agency
viveka.larsson@slv.se

Switzerland

Christina Gut
Federal Food Safety & Veterinary Office
christina.gut@blv.admin.ch

Thailand

Jeerajit Dissana
National Bureau of Agricultural Commodity and Food
Standards (ACFS)
j_aommy@hotmail.com

Turkey

Betul Vazgecer
Ministry of Food Agriculture & Livestock
betul.vazgecer@tarim.gov.tr

United Kingdom

Chun-Han Chan
Food Standards Agency, UK
chun-han.chan@food.gov.uk

Erin Oliver
Food Standards Agency, UK
erin.oliver@food.gov.uk

United States of America

Jenny Scott
US Food and Drug Administration
jenny.scott@fda.hhs.gov

Food and Agriculture Organization of the United Nation (FAO)

Cornelia J. Boesch
cornelia.boesch@fao.org

Fooddrinkeurope

Angeliki Vlachou
a.vlachou@fooddrinkeurope.eu

International Council of Beverages Associations (ICBA)

Simone SooHoo
simone@icba-net.org

IDF

Aurelie Dubois
adubois@fil-idf.org

ICGMA

Jacqueline Dillon
Jacqueline.dillon@pepsico.com

Kristen Spotz
KSpotz@gmaonline.org

Ai Kataoka
akataoka@gmaonline.org

Nicholas Gardner
ngardner@gmaonline.org

ICMSF

Suchart Chaven
suchart.chaven@pepsico.com

John Donaghy
JohnAnthony.donaghy@nestle.com

IFU

John Collins
john@ifu-fruitjuice.com

IOSTA

Sylvain Corbel
s.corbel@66laboetie.fr

USP

Steven Gendel
steven.gendel@usp.org

SSAFE

Quincy Lissaur
qlissaur@ssafe-food.org

FIA

Jiang YiFan
codex@foodindustry.asia