

# Undeclared Allergen Incident & Investigation Protocol

**Guidelines & checklists for allergen investigations at retail/foodservice, manufacturing and food import businesses**

Implementation Subcommittee for Food Regulation  
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# Undeclared Food Allergen Incident & Investigation Protocol

## 1 PURPOSE

The purpose of this document is to outline procedures for investigating and reporting of consumer complaints and incidents of undeclared food allergens, supplementary to standard food investigation protocols. The document provides guidance to food regulators in conducting their activities and establishes expectations for stakeholders on the approach taken by food regulators.

## 2 SCOPE

This Protocol covers the requirements of the *Australia New Zealand Food Standards Code* (the Code) and the Act or Ordinance of an Australian jurisdiction under which the requirements of the Code are applied in relation to allergen control. It also provides guidelines and checklists that can be used in the investigation of food allergen complaints and incidents.

## 3 DEFINITIONS

| <i>Term defined</i> | <b>Definition</b>  |
|---------------------|--|
| <i>allergen</i>     | A substance that can cause an allergic reaction (National Allergy Strategy, 2015, p. 29). An allergen can be an ingredient that must be declared under the Code as well as any other substance[s] a consumer has demanded not be present in the food.  |
| <i>anaphylaxis</i>  | “the most severe type of allergic reaction and is potentially life threatening” (ASCIA, 2017). The signs and symptoms of anaphylaxis according to the ASCIA Action Plan include:<br><br>Signs of a mild to moderate allergic reaction: <ul style="list-style-type: none"><li>• Swelling of lips, face, eyes</li><li>• Hives or welts</li><li>• Tingling mouth</li><li>• Abdominal pain, vomiting (these are signs of anaphylaxis for insect allergy)</li></ul> |

| <i>Term defined</i>     | <b>Definition</b>   |
|-------------------------|---|
|                         | <p>Signs of a severe allergic reaction (anaphylaxis):</p> <ul style="list-style-type: none"> <li>● Difficult/noisy breathing</li> <li>● Swelling of tongue</li> <li>● Swelling/tightness in throat</li> <li>● Wheeze or persistent cough</li> <li>● Difficulty talking and/or hoarse voice</li> <li>● Persistent dizziness or collapse</li> <li>● Pale and floppy (young children)</li> </ul> <p>“If untreated anaphylaxis may cause death or permanent brain damage. It is usually caused by foods, medicines or insects to which a person has developed an allergy”. (National Allergy Strategy, 2015, p. 29)</p> |
| <i>food allergy</i>     | “an adverse reaction to foods (e.g. peanuts, tree nuts, fish, shellfish, egg, soy, wheat, sesame and cow's milk) that involves the immune system.” (National Allergy Strategy, 2015, p. 30)   |
| <i>investigation</i>    | an inquiry, usually involving the use of statutory powers, in order to ascertain the nature and extent of non-compliance with food legislation.   |
| <i>food legislation</i> | the Australia New Zealand Food Standards Code (Code) and the Act or Ordinance of a jurisdiction under which the requirements of the Code are applied.   |

## 4 INTRODUCTION

### 4.1 FOOD ALLERGY

Managing food allergy risk is an important health issue due to the potential for severe and life threatening reactions.

Food allergy is estimated to occur in 10% of Australian infants (Osborne, N.J et al (2011), 4 to 8% of children under five years of age (SA Department of Health, 2010), and around 2-3% of the adult population (AIHW, 2001). Most food allergies are caused by an adverse immune reaction (hypersensitivity) to food proteins. Allergy to food can be classified by their immune mechanism:

- immunoglobulin E (IgE)-mediated,
- non-IgE mediated, and
- mixed IgE and non-IgE mediated

Once an individual develops IgE-mediated sensitivity to a food protein (or proteins), the presence of this food protein can cause life-threatening anaphylactic reactions.

It is important to note that there may be other reasons why a consumer needs to avoid certain foods. Intolerance to food is not an IgE-mediated immune response and does not cause anaphylaxis but can significantly impact on quality of life. Coeliac disease is an autoimmune disease that is neither an allergy or an intolerance. Symptoms of Coeliac disease can be severe but are generally not life threatening in the short term. They can impact on life expectancy.

The risk posed by allergens can arise in one of two circumstances. The first is where a consumer relies on information provided with or on the labelling of a food product to determine whether it contains an allergen. The second is where, usually in a food service situation, a consumer specifically requests that food served does not contain a specific allergen[s]. These risks are regulated through numerous provisions in food legislation as even small amounts of an allergen may trigger an allergic reaction, including anaphylaxis.

Australia and New Zealand were among the first countries to recognise the need to regulate food allergen labelling with the introduction, in 2002, of mandatory declaration requirements in the Code.

In addition to general labelling requirements requiring the identification of ingredients, the Code sets out additional labelling requirements for certain ingredients that commonly trigger allergy, intolerance or autoimmune conditions. Common allergens are wheat, milk and milk products, eggs, peanuts, tree-nuts, soy, fish, shellfish and Lupin. Gluten, which can be found in certain cereals, triggers symptoms in individuals suffering from Coeliac disease. Gluten-containing cereals include wheat, rye, barley, oats, spelt and their hybridised strains. The Code also recognises bee pollen, and royal jelly as allergens and added sulphites ( $\geq 10\text{mg/g}$ ) in food as potential causes of adverse reactions in sensitive populations.

In addition, food legislation in each jurisdiction also makes it an offence for food businesses to supply a consumer with a food that is not what they demanded.

## 4.2 REQUIREMENTS OF FOOD LEGISLATION

### 4.2.1 Food Service Situation

In a food service situation individuals with food allergies will often rely on information provided by a food retailer to make a decision about the food[s] they buy and consume. Retailers are required to provide consumers with the food they demand. The Model Food Act has been adopted in each jurisdiction. Section 15 of the Model Food Act provides:

#### ***Sale of food not complying with purchaser's demand***

- (1) *A person must not, in the course of carrying on a food business, supply food by way of sale if the food is not of the nature or substance demanded by the purchaser.*

### 4.2.2 Packaged Food

Individuals with food allergies also rely on ingredient and allergen declaration information provided with packaged food to make decisions about the foods they buy and consume. Food businesses are required to comply with Standard 1.2.4 of the Code which specifies the requirements for a 'statement of ingredients' (Cl 1.2.4—2) to be provided, subject to limited exemptions and the requirements set out in Standard 1.2.1, when supplying packaged food.

In addition to this requirement, Clause 1.2.3—4 of the Code, specifies requirements for mandatory declarations of common allergens:

#### ***Standard 1.2.3 – Information requirements – warning statements, advisory statements and declarations***

##### ***1.2.3—4 Mandatory declaration of certain foods or substances in food***

- (1) *For the labelling provisions, if any of the following foods or substances is present in a food for sale in a manner listed in subsection (2), a declaration that the food or substance is present is required:*
- (a) *added sulphites in concentrations of 10 mg/kg or more;*
  - (b) *any of the following foods, or products of those foods:*
    - (i) *cereals containing \*gluten, namely, wheat, rye, barley, oats and spelt and their hybridised strains other than where these substances are present in beer and spirits;*
    - (ii) *crustacea;*

- (iii) *egg;*
  - (iv) *fish, except for isinglass derived from swim bladders and used as a clarifying agent in beer or wine;*
  - (v) *milk;*
  - (vi) *peanuts;*
  - (vii) *soybeans;*
  - (viii) *sesame seeds;*
  - (ix) *tree nuts, other than coconut from the fruit of the palm *Cocos nucifera*.*
  - (x) *lupin.*
- (2) *For subsection (1), the food or substance may be present as:*
- (a) *an ingredient or as an ingredient of a \*compound ingredient; or*
  - (b) *a substance \*used as a food additive, or an ingredient or component of such a substance; or*
  - (c) *a substance or food \*used as a processing aid, or an ingredient or component of such a substance or food.*

Schedule 9—2 of the Code also sets out mandatory advisory and declarations for the presence of bee pollen in food.

In addition clause 1.2.3—3 sets out requirements for a mandatory warning statement for the presence of royal jelly in food.

Standard 1.2.1 sets out the responsibility of the supplier of a food (e.g. importers, manufacturers, retailers and service providers) to either:

- declare allergens on the label (usually in the ingredient list),
- display information about allergens next to food on sale (if food is exempt from labelling), or
- provide information about allergens in food if requested by a customer.

Section 17(3) of the Model Food Act makes it an offence to fail to comply with the labelling requirements set out in the Code. Section 14 of the Model Food Act also makes it an offence to make a false or misleading claim that a food is free of an allergen[s].

#### 4.2.3 Additional Offences

There are also offences under the Model Food Act that apply where a food business continues to supply a food even though it is aware, or should be aware, that the food contains an 'undeclared' allergen. An example is *NSW Food Authority v Sunfield Australia Pty Ltd & SUN* (Unreported, Magistrate Buscombe, NSW Local Court 27 May

2013) where a business sold food that did not declare egg as an ingredient when it knew it was an ingredient and ought reasonably have known that the food was falsely described and likely to cause physical harm to a consumer who relies on the description on the product label.

Section 11 of the Model Food Act provides:

***False description of food***

- (1) *A person must not cause food intended for sale to be falsely described if the person knows that a consumer of the food who relies on the description will, or is likely to, suffer physical harm.*
- (2) *A person must not sell food that the person knows is falsely described and will, or is likely to, cause physical harm to a consumer of the food who relies on the description.*

## 5 PROCEDURES

### 5.1 ASSESS ALLERGEN COMPLAINT

All food regulators have procedures in place for collecting and triaging information and complaints about undeclared allergens in foods. That procedure should cover collecting all relevant initial details including:

- name, address and phone number of the complainant;
- details of the complaint including the circumstances of the event or product (including details of symptoms of the reaction);
- details of the:
  - food product in question including date marks/batch number, contact details of manufacturer listed on the label, customer order; or
  - food ordered and how that order was made;
- whether any product or left-over food is available for analysis;
- details of the location, date and time of purchase;
- details of other people involved in the incident;
- any other relevant information

Due to the potential risk to health and safety, allegations of an undeclared allergen in food should initially be assessed as a serious (high risk) complaint. The complaint particulars should then be evaluated and a decision made as to what action to take. That decision will consider the potential risk identified along with the timeliness, motivation and plausibility of the complaint.

Although most complaints will require investigation, the following options should be considered:

- initiate full investigation (continue to 5.2);
- collecting and submitting samples for analysis;
- advise manufacturer/vendor and request a response to the complaint; or
- monitor the complaint for trends and patterns.

## **5.2 INVESTIGATION**

Four key issues frequently arise during investigation of an allergen complaint. These issues are:

- timeframe
- premises and authority
- key questions
- sampling for evidence and evaluation

### **5.2.1 Timeframe**

The presence of an undeclared allergen in food poses a significant risk to public health and safety. Consequently it is recommended that investigations into allegations that an undeclared allergen is present in a food are commenced urgently. The aim of any such investigation should be to address two key questions urgently:

1. Is there a risk to public health and safety? and
2. Has appropriate action been taken to address that risk?

### **5.2.2 Premises and food regulatory authority**

Identify the location of the premises. Inform the vendor, manufacturer or importer of the complaint. The inspection should be conducted as soon as possible, to reduce the risk of further incidents occurring and to protect public health and safety. If the manufacturer or importer is located within a different jurisdiction, the complaint should be immediately referred to the food regulatory authority responsible for that area.

### **5.2.3 Key questions**

Checklists are provided in the attachments of this document. These checklists are intended to be used as guidance material for allergen investigations in the following sectors:

- Retail/food service
- Manufacturing
- Imported food

Each checklist covers the following areas for investigation:

(1) Statutory Requirements for Allergen Investigations including the nature of the request

(2) Allergen Investigation Assessment

- a. Supplier management and product receipt
- b. Food storage
- c. Food processing
- d. Cleaning and sanitising (where applicable)
- e. Food display (where applicable)
- f. Food packaging (where applicable)
- g. Product distribution

(3) Sampling/evidence

The investigation should focus on whether the consumer received the food demanded (e.g. analyse a sample for nuts if the consumer requested a nut free product). Each checklist also has a Food Product Allergen Investigation Table. The table is to be used as a tool to audit individual food products suspected of containing undeclared allergens.

The checklists are designed to assist officers in determining the source of the undeclared allergen to prevent a further incident occurring and to gather evidence of breaches in the relevant standards of the Code and the Food Act.

Possible ways an allergen incident may have occurred:

- Labelling and disclosure – allergen containing food not labelled or information not given to customer when requested (incorrect packaging used);
- Miscommunication between staff (e.g. waiting staff did not communicate the customer requirement to the kitchen);
- Miscommunication between consumer and waiting staff or service provider
- Poor process control measures (e.g. cross-contamination of allergens during preparation, storage);
- Inadequate or incorrect labelling or information provide by the supplier;
- Changes in recipe or ingredients; or
- Lack of skills and knowledge.

Documented allergen management policies and procedures are not mandatory requirements under the Code for all food businesses. However, businesses are encouraged to have in place and comply with documented allergen management policies and procedures. Having allergen management policies and procedures in place allows a business to demonstrate they are taking all necessary steps to prevent the likelihood of food being unintentionally contaminated with an allergen.

Documented policies and procedures and compliance with these also provides an opportunity for businesses to demonstrate adequate skills and knowledge in allergen management and reduces the risk of an allergen incident occurring.

Enforcement agencies should also recognise during their investigations, that the source of allergen contamination (undeclared allergen) may be food supplied or manufactured by a third party supplier. Enforcement agencies should always conduct further investigations at suspected food businesses in a timely manner to prevent further incidents occurring. If further inspections are required of premises outside the enforcement agencies jurisdiction or authorised functions, the complaint investigation should be referred to the relevant state or territory enforcement agency for action.

#### 5.2.4 Evidence

Obtaining evidence is a crucial part of the investigation. Evidence collected often includes: samples of the implicated food, environmental swabs (where appropriate), photographic and documentary evidence.

Food samples are critical in determining the allergen status of a food and for evidential purposes. In circumstances where there is leftover food, consider submitting the sample for allergen analysis. In addition to any leftover food, consideration should be given to taking:

- a) Samples of the implicated food – where possible obtain samples of food from the same batch as well as food from an alternative batch. Samples may be obtained direct from retail outlets or obtained from the manufacturer (retention samples for example), importer or retail/foodservice business at the time of inspection. Obtaining a sample of food at the foodservice business/manufacturer immediately after processing can assist in validating their process(es) for allergen management;
- b) Samples of the individual ingredients used in preparation of the implicated food; and
- c) Environmental swabs, provided appropriate swab sites are identified.

Sample and environmental swabs will need to be analysed. Care must be taken to ensure sampling and testing is conducted by suitably qualified individuals and an appropriate test method or kit is used.

Photographic evidence should be taken where possible. Key areas for photographic evidence include;

- a) The alleged allergen-containing food, as well as packaging (if any);
- b) Menus, recipes/product specifications, allergen management policy/procedures, signage;

- c) Storage, processing, packaging/labelling and display areas; and
- d) Product samples and environmental swab sites.

Examination of records/documents at the time of inspection is critical. All relevant documents should be copied or photographed. Examples of records/documents which should be examined and obtained include:

- a) Any allergen management policy/procedures and relevant training records;
- b) Complaint records;
- c) Supplier agreements/correspondence in relation to allergen status of ingredients/food products;
- d) Product specifications/menus/display signage/advertisements;
- e) Process verification and validation records e.g. food safety program records, food sample analysis results;
- f) Food receipt/processing/cleaning/packaging records;
- g) Food labelling templates/drafts and approvals;
- h) Email orders requesting specific allergens are not present;
- i) Invoices of sale; and
- j) Shipment/import records, custom declarations.

### 5.3 ACTION AND OUTCOME

The prime objective of an investigation into undeclared allergens in a food is to ensure that public health and safety is 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 is protected.

Key considerations are:

- Nature and magnitude of the non-compliance (e.g. What is the allergen; what is the shelf life of the food; Who is the intended consumer?)
- Are there records of similar complaints against the business?
- What is the compliance history for the business?
- What is the likelihood of further and ongoing compliance?
- Has the business demonstrated awareness and/or the capacity to meet regulatory requirements?

#### 5.3.1 Address the immediate risk – consider a recall

Where the issue relates to packaged food, a food recall should be used to address any immediate risk.

Any business that supplies food (usually the importer/manufacture or wholesaler) is required to have a recall plan in place. That recall plan will usually outline how the

supplier of the product will assess risks and make a decision whether a recall is necessary. A decision whether or not to recall a product should always be taken promptly to protect the health and safety of consumers. Advice from the relevant jurisdiction's recall action officer is recommended.

Due to the risk of allergens to public health and safety, it is recommended that the actions required be communicated to the business as soon as possible. Suitable timeframes for completing actions should be determined by the enforcement agency.

What is required is dependent on the specific risk. Laboratory analysis of the sample may be required to determine the level of allergen present. Deciding whether a business is required to recall or withdraw a product due to undeclared allergens should be based on assessing the risk to public health and safety.

If a packaged food product contains undeclared allergen(s) and is a risk to public health, and has been sold to customers or supplied to businesses it should be recalled. Food businesses have primary responsibility for the supply of the food they sell and if the product is unsafe, the business would normally initiate a food recall. Food businesses need to liaise with Food Standards Australia New Zealand (FSANZ) and their state or territory food enforcement agency where the head office of their business is located as soon as they consider a food recall is or may be needed.

Enforcement agencies and food businesses considering a food recall should refer to the Food Standards Australia New Zealand Food Industry Recall Protocol 7<sup>th</sup> Edition May 2014. A copy of this document can be obtained from [Food Standards Australia New Zealand](#).

### 5.3.2 Address ongoing risk – Enforcement and Corrective action

Once the risk to public health and safety has been addressed it may be necessary to take enforcement and corrective action. That action should be taken in accordance with the enforcement agency's policies and procedures.

Some examples of corrective action include:

- requiring the food business to demonstrate adequate skills and knowledge by, for example, completing training in allergen management.
- Requiring the food business to review and update their allergen management plan.

Some examples of enforcement action include:

- Issuing an improvement notice;
- Seizing non-compliant product;
- Issuing a penalty notice or commencing a prosecution.

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## 7 CHECKLISTS

### 7.1 RETAIL/FOODSERVICE ALLERGEN INVESTIGATION CHECKLIST

| <b>Retail / Food service allergen investigation checklist</b>   |   |  |   |   |   |  |  |   |                               |  |   |   |  |
|---|---|--|---|---|---|--|--|---|-------------------------------|--|---|---|--|
| <b>Statutory Requirements for Allergen Investigations</b>   |   |  |   |   |   |  |  |   |                               |  |   |   |  |
| <ul style="list-style-type: none"> <li>Does the food business prepare and/or receive food containing key allergens as prescribed by Standard 1.2.3-4 of the FSC:               <table border="0" style="width: 100%;"> <tr> <td><input type="checkbox"/> Tree nuts &amp; tree nut products</td> <td><input type="checkbox"/> Crustaceans &amp; their products</td> </tr> <tr> <td><input type="checkbox"/> Peanuts &amp; peanut products</td> <td><input type="checkbox"/> Cereals containing gluten &amp; their products</td> </tr> <tr> <td><input type="checkbox"/> Soybeans &amp; soybean products</td> <td><input type="checkbox"/> Sulphites (<math>\geq 10\text{mg/kg}</math>)</td> </tr> <tr> <td><input type="checkbox"/> Milk &amp; milk products</td> <td><input type="checkbox"/> Fish</td> </tr> <tr> <td><input type="checkbox"/> Sesame seeds &amp; sesame seed products</td> <td><input type="checkbox"/> Lupin [From 26 May 2018]</td> </tr> <tr> <td><input type="checkbox"/> Egg &amp; egg products</td> <td></td> </tr> </table> </li> </ul>  |   | <input type="checkbox"/> Tree nuts & tree nut products   | <input type="checkbox"/> Crustaceans & their products | <input type="checkbox"/> Peanuts & peanut products  | <input type="checkbox"/> Cereals containing gluten & their products | <input type="checkbox"/> Soybeans & soybean products   | <input type="checkbox"/> Sulphites ( $\geq 10\text{mg/kg}$ ) | <input type="checkbox"/> Milk & milk products   | <input type="checkbox"/> Fish | <input type="checkbox"/> Sesame seeds & sesame seed products   | <input type="checkbox"/> Lupin [From 26 May 2018] | <input type="checkbox"/> Egg & egg products |  |
| <input type="checkbox"/> Tree nuts & tree nut products  | <input type="checkbox"/> Crustaceans & their products               |  |   |   |   |  |  |   |                               |  |   |   |  |
| <input type="checkbox"/> Peanuts & peanut products  | <input type="checkbox"/> Cereals containing gluten & their products |  |   |   |   |  |  |   |                               |  |   |   |  |
| <input type="checkbox"/> Soybeans & soybean products  | <input type="checkbox"/> Sulphites ( $\geq 10\text{mg/kg}$ )        |  |   |   |   |  |  |   |                               |  |   |   |  |
| <input type="checkbox"/> Milk & milk products   | <input type="checkbox"/> Fish                                       |  |   |   |   |  |  |   |                               |  |   |   |  |
| <input type="checkbox"/> Sesame seeds & sesame seed products  | <input type="checkbox"/> Lupin [From 26 May 2018]                   |  |   |   |   |  |  |   |                               |  |   |   |  |
| <input type="checkbox"/> Egg & egg products   |   |  |   |   |   |  |  |   |                               |  |   |   |  |
| <ul style="list-style-type: none"> <li>Does the food business declare mandatory allergen information for the above allergens as required by Standard 1.2.3 of the FSC for the following foods:               <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="padding: 5px;">- Packaged retail food has a label accurately identifying the allergen(s) present as ingredients in an ingredient list</td> <td style="text-align: center; vertical-align: middle;"><input type="checkbox"/></td> </tr> <tr> <td style="padding: 5px;">- Unpackaged food have allergen(s) declared on or in connection with the displayed food or to the purchaser verbally or in writing upon request of the customer</td> <td style="text-align: center; vertical-align: middle;"><input type="checkbox"/></td> </tr> <tr> <td style="padding: 5px;">- Food for catering purposes has allergens declared on the label or allergens are declared in documentation accompanying the catering food</td> <td style="text-align: center; vertical-align: middle;"><input type="checkbox"/></td> </tr> <tr> <td style="padding: 5px;">- Packaged food sold in a hamper has a label that contains accurate allergen declarations</td> <td style="text-align: center; vertical-align: middle;"><input type="checkbox"/></td> </tr> <tr> <td style="padding: 5px;">- Food sold from vending machines has allergen declaration provided on or in connection with the food (e.g. displayed on outside of vending machine)</td> <td style="text-align: center; vertical-align: middle;"><input type="checkbox"/></td> </tr> </table> </li> </ul> |   | - Packaged retail food has a label accurately identifying the allergen(s) present as ingredients in an ingredient list | <input type="checkbox"/>                              | - Unpackaged food have allergen(s) declared on or in connection with the displayed food or to the purchaser verbally or in writing upon request of the customer | <input type="checkbox"/>  | - Food for catering purposes has allergens declared on the label or allergens are declared in documentation accompanying the catering food | <input type="checkbox"/>                                     | - Packaged food sold in a hamper has a label that contains accurate allergen declarations | <input type="checkbox"/>      | - Food sold from vending machines has allergen declaration provided on or in connection with the food (e.g. displayed on outside of vending machine) | <input type="checkbox"/>                          |   |  |
| - Packaged retail food has a label accurately identifying the allergen(s) present as ingredients in an ingredient list  | <input type="checkbox"/>  |  |   |   |   |  |  |   |                               |  |   |   |  |
| - Unpackaged food have allergen(s) declared on or in connection with the displayed food or to the purchaser verbally or in writing upon request of the customer   | <input type="checkbox"/>  |  |   |   |   |  |  |   |                               |  |   |   |  |
| - Food for catering purposes has allergens declared on the label or allergens are declared in documentation accompanying the catering food  | <input type="checkbox"/>  |  |   |   |   |  |  |   |                               |  |   |   |  |
| - Packaged food sold in a hamper has a label that contains accurate allergen declarations   | <input type="checkbox"/>  |  |   |   |   |  |  |   |                               |  |   |   |  |
| - Food sold from vending machines has allergen declaration provided on or in connection with the food (e.g. displayed on outside of vending machine)  | <input type="checkbox"/>  |  |   |   |   |  |  |   |                               |  |   |   |  |
| <b>Comments/Observations:</b>   |   |  |   |   |   |  |  |   |                               |  |   |   |  |
|   |   |  |   |   |   |  |  |   |                               |  |   |   |  |

| <b>Retail / Food service allergen investigation checklist</b>   |  |
|---|--|
| <b>Allergen Investigation Assessment</b>  |  |
| <ul style="list-style-type: none"> <li>Has the food business prepared and/or sold food product(s) which "claim" to be allergen free or free from a specific ingredient at the request of the consumer?<br/>Food/Product _____</li> </ul>  | <input type="checkbox"/>                             |
| <ul style="list-style-type: none"> <li>Has the food business received a complaint regarding a product suspected of containing undeclared allergen/s or specified ingredient?<br/>Food product _____</li> </ul> <p><i>*Refer to Food Product Allergen Investigation Table (7.1.1)</i></p>  | <input type="checkbox"/>                             |
| <ul style="list-style-type: none"> <li>Does the food business have a documented policy or procedure for allergen management?</li> <li>Does this procedure cover allergen declarations on product labels, store signage and/or handling specific customer requests?</li> </ul>   | <input type="checkbox"/><br><input type="checkbox"/> |
| <ul style="list-style-type: none"> <li>Are all food handlers trained in food allergen management procedures?</li> <li>Is there a training register/records available?</li> </ul>  | <input type="checkbox"/><br><input type="checkbox"/> |
| <ul style="list-style-type: none"> <li>Can food handlers identify allergens of concern?</li> </ul>  | <input type="checkbox"/>                             |
| <ul style="list-style-type: none"> <li>Can food handlers demonstrate process control measures to prevent allergen contamination?</li> </ul>   | <input type="checkbox"/>                             |
| <b>Comments/Observations:</b>   |  |
|   |  |
| <b>Supplier Management and Product Receipt</b>  |  |
| <ul style="list-style-type: none"> <li>Does the food business purchase food/ingredients from a commercial supplier with an audited food safety program?</li> <li>Where appropriate, does the supplier provide validation that the food/ingredients supplied are free of specific allergens or specified ingredients?</li> </ul> | <input type="checkbox"/><br><input type="checkbox"/> |
| <ul style="list-style-type: none"> <li>Does the food business have valid invoices to enable trace back to the food supplier?</li> </ul>   | <input type="checkbox"/>                             |
| <ul style="list-style-type: none"> <li>Does the food business have a procedure/policy for assessing the allergen status of foods/ingredients received from suppliers?</li> </ul>  | <input type="checkbox"/>                             |

| <b>Retail / Food service allergen investigation checklist</b>  |  |
|--|--|
| <ul style="list-style-type: none"> <li>Is there a procedure/policy for ensuring any change in supplier is accompanied by an allergen status review of the product?</li> </ul>  | <input type="checkbox"/>                             |
| <ul style="list-style-type: none"> <li>Does the food business review all product specifications/labelling of food/ingredients received and used in the preparation/sale of foods for allergen status?</li> </ul>   | <input type="checkbox"/>                             |
| <ul style="list-style-type: none"> <li>Do suppliers notify the food business of any changes in the allergen status of foods/ingredients they supply?</li> <li>Has the business requested this notification from their suppliers?</li> </ul>  | <input type="checkbox"/><br><input type="checkbox"/> |
| <ul style="list-style-type: none"> <li>Does the food business only accept foods that are adequately protected from contamination?</li> </ul>   | <input type="checkbox"/>                             |
| <ul style="list-style-type: none"> <li>Does the food business only accept foods with adequate labelling and/or provided with appropriate documentation (unpackaged foods for catering purposes) to determine the allergen status of the food?</li> </ul>   | <input type="checkbox"/>                             |
| <b>Comments/Observations:</b>  |  |
| <br>   |  |
| <b>Food Storage</b>  |  |
| <ul style="list-style-type: none"> <li>Are general/allergen free ingredients/foods stored separately and/or adequately contained to prevent cross-contamination? E.g. use of clean, enclosed storage containers</li> </ul>   | <input type="checkbox"/>                             |
| <ul style="list-style-type: none"> <li>Is there a procedure/policy in place to identify general/allergen free foods/ingredients? E.g. colour coding, tags</li> </ul>   | <input type="checkbox"/>                             |
| <b>Comments/Observations:</b>  |  |
| <br>   |  |
| <b>Food Processing</b>   |  |
| <ul style="list-style-type: none"> <li>Does the business prepare food free of specific allergens at the request of customers?</li> <li>Does the food business have a procedure in place to ensure all ingredients used in the preparation of foods requested to be free of specific allergens are reviewed for their allergen status? E.g. product specifications/work instructions</li> </ul> | <input type="checkbox"/><br><input type="checkbox"/> |
| <ul style="list-style-type: none"> <li>Are recipes/product specifications regularly reviewed to validate their allergen status?</li> <li>Has the business validated the preparation process and end food product to determine the allergen status of the food?</li> </ul>  | <input type="checkbox"/><br><input type="checkbox"/> |

| <b>Retail / Food service allergen investigation checklist</b>  |                          |
|--|--------------------------|
| • Is evidence available e.g. sample results, food safety program records   | <input type="checkbox"/> |
| • Is dedicated or appropriately cleaned equipment used for the preparation/handling of general/allergen free foods? E.g. dedicated serving utensils  | <input type="checkbox"/> |
| • Is there a dedicated area for the preparation of foods free of specific allergens?   | <input type="checkbox"/> |
| • Are equipment and preparation areas adequately cleaned/sanitised between preparing general and allergen free foods to prevent cross-contamination? | <input type="checkbox"/> |
| • Do food handlers wear dedicated protective clothing when preparing foods free of specific allergens to prevent contamination?                      | <input type="checkbox"/> |
| • Is dedicated cooking media, such as water or oil used for general/allergen free foods to prevent contamination?                                    | <input type="checkbox"/> |
| • Is there a risk of airborne allergen contamination throughout the processing area?   | <input type="checkbox"/> |
| • Are there adequate hand wash basin(s) situated in the relevant areas?  | <input type="checkbox"/> |
| • Hand wash basin(s) supplied with soap and paper towels?  | <input type="checkbox"/> |
| • Hand wash basin(s) only used for hand washing?   | <input type="checkbox"/> |
| <b>Comments/Observations:</b>  |                          |
| <b>Cleaning and Sanitising</b>   |                          |
| • Is adequate cleaning demonstrated to control allergen contamination throughout all aspects of the processing environment, equipment and utensils?  | <input type="checkbox"/> |
| • Are designated cleaning cloths or equipment used in areas where allergen free foods are prepared?  | <input type="checkbox"/> |
| • Is there a system of validating that cleaning is effective?  | <input type="checkbox"/> |
| <b>Comments/Observations:</b>  |                          |

| <b>Retail / Food service allergen investigation checklist</b>  |                          |
|--|--------------------------|
| <b>Food Display</b>  |                          |
| • Are foods free of specific allergens adequately protected from contamination during display?   | <input type="checkbox"/> |
| • Is allergen/ingredient information provided on or in connection with the displayed food or is it able to be provided upon request by the purchaser?  | <input type="checkbox"/> |
| • Are designated serving utensils provided for foods free of specific allergens?   | <input type="checkbox"/> |
| <b>Comments/Observations:</b>  |                          |
| <b>Food Packaging</b>  |                          |
| • Are foods free from specific allergens packaged in a clean, dedicated area to prevent contamination?   | <input type="checkbox"/> |
| • Do food handlers take all practicable measures to prevent unnecessary contact with food to prevent contamination?  | <input type="checkbox"/> |
| • Is packaging material stored adequately to prevent contamination?  | <input type="checkbox"/> |
| • Are labels/product specifications for foods regularly reviewed to ensure they contain an accurate ingredient list and any required allergen declarations?  | <input type="checkbox"/> |
| • Is there a procedure for destroying old packaging and/or product specifications when recipe formulations have been changed?  | <input type="checkbox"/> |
| <b>Comments/Observations:</b>  |                          |
| <b>Product Distribution</b>  |                          |
| • Are foods distributed to other retail businesses or food service facilities?   | <input type="checkbox"/> |
| • Does the food business only distribute foods that have compliant labelling and/or provided with appropriate documentation (unpacked foods for catering purposes) to determine the allergen status of the food? | <input type="checkbox"/> |
| • Are all foods for distribution adequately contained or packaged to protect against contamination?  | <input type="checkbox"/> |

| <b>Retail / Food service allergen investigation checklist</b>   |                          |
|---|--------------------------|
| • Does the food business have a documented food recall plan?  | <input type="checkbox"/> |
| • Can the business demonstrate compliance with their recall plan when recalling unsafe food?                    | <input type="checkbox"/> |
| <b>Comments/Observations:</b>   |                          |
| <b>Sampling / Evidence</b>  |                          |
| • Sample of implicated batch ingredients  | <input type="checkbox"/> |
| • Sample of product (same batch if available)   | <input type="checkbox"/> |
| • Sample of end product (validate relevant process(es))   | <input type="checkbox"/> |
| • Environmental swabs targeting relevant equipment, utensils and surfaces                                       | <input type="checkbox"/> |
| • Photograph storage, processing and display areas  | <input type="checkbox"/> |
| • Photograph food samples and swab sites, relevant processing areas, ingredient and product packaging/labelling | <input type="checkbox"/> |
| • Photograph/copy menus, recipes, product specifications  | <input type="checkbox"/> |
| <b>Comments/Observations:</b>   |                          |
| <b>Monitoring</b>   |                          |
| • Does the business monitor allergen management?  | <input type="checkbox"/> |
| <b>Comments/Observations:</b>   |                          |
| <b>Signature</b>  | <b>Date</b>              |

7.1.1 Retail/Food Service Sector Food Product Allergen Investigation Table

| Food Product     | Manufacturer   | Suspected Undeclared Allergen | Food Product Allergen Review<br>(label/product specification review)<br>Ingredient | Ingredient List<br>Review   | Allergen Identified                   |
|------------------|----------------|-------------------------------|--|---|---------------------------------------|
| <i>Apple Pie</i> | <i>On-site</i> | <i>dairy</i>                  | <i>Pre-made Pastry</i><br><br><i>apple filling</i>                                 | <i>flour-wheat flour<br/>sugar<br/>eggs<br/>margarine - canola oil, salt, milk<br/>protein solids, emulsifiers(322 from soy),<br/>preservative 222,<br/>apple, all-spice,<br/>sugar</i> | <i>Wheat<br/>Milk protein<br/>Soy</i> |

## 7.2 MANUFACTURING SECTOR ALLERGEN INVESTIGATION CHECKLIST

| <b>Manufacturing Sector Allergen Investigation Checklist</b>   |  |
|--|--|
| <b>Statutory Requirements for Allergen Investigations</b>  |  |
| <ul style="list-style-type: none"> <li>Does the food business receive and manufacture food containing allergens as prescribed by Standard 1.2.3-4 of the FSC:</li> </ul>   |  |
| <input type="checkbox"/> Tree nuts & tree nut products<br><input type="checkbox"/> Peanuts & peanut products<br><input type="checkbox"/> Soybeans & soybean products<br><input type="checkbox"/> Milk & milk products<br><input type="checkbox"/> Sesame seeds & sesame seed products<br><input type="checkbox"/> Egg & egg products | <input type="checkbox"/> Crustaceans & their products<br><input type="checkbox"/> Cereals containing gluten & their products<br><input type="checkbox"/> Sulphites ( $\geq 10\text{mg/kg}$ )<br><input type="checkbox"/> Fish & fish products<br><input type="checkbox"/> Lupin [From 26 May 2018] |
| <ul style="list-style-type: none"> <li>Does the food business declare mandatory allergen information for the above allergens as required by Standard 1.2.3 of the FSC for the following foods:</li> </ul>  |  |
| <ul style="list-style-type: none"> <li>Packaged retail food has a label detailing an accurate allergen declaration</li> </ul>  | <input type="checkbox"/>   |
| <ul style="list-style-type: none"> <li>Food for catering purposes has allergens declared on the label or allergens are declared in documentation accompanying the catering food</li> </ul>   | <input type="checkbox"/>   |
| <ul style="list-style-type: none"> <li>Packaged food sold in a hamper has a label that contains accurate allergen declarations</li> </ul>  | <input type="checkbox"/>   |
| <ul style="list-style-type: none"> <li>Food sold from vending machines has allergen declaration provided on or in connection with the food (e.g. displayed on outside of vending machine)</li> </ul>   | <input type="checkbox"/>   |
| <b>Comments/Observations:</b>  |  |
| <b>Allergen Investigation Assessment</b>   |  |
| <ul style="list-style-type: none"> <li>Has the food business prepared and/or sold food product(s) which "claim" to be allergen free?<br/>           Food/Product _____<br/>           _____</li> </ul>   | <input type="checkbox"/>   |

| <b>Manufacturing Sector Allergen Investigation Checklist</b>   |                          |
|--|--------------------------|
| <p>Has the food business received a complaint regarding a product suspected of containing undeclared allergen(s)?</p> <p>Food product _____</p> <p>_____</p> <p><i>*Refer to Food Product Allergen Investigation Table (7.2.1)</i></p>   | <input type="checkbox"/> |
| <ul style="list-style-type: none"> <li>• Does the food business have a documented policy or procedure for allergen management?</li> </ul>  | <input type="checkbox"/> |
| <ul style="list-style-type: none"> <li>• Does this procedure cover allergen declarations on product labels and documentation required for unpackaged (catering) food?</li> </ul>   | <input type="checkbox"/> |
| <ul style="list-style-type: none"> <li>• Are all employees trained in food allergen management procedures?</li> </ul>  | <input type="checkbox"/> |
| <ul style="list-style-type: none"> <li>• Is there a training register available to verify training?</li> </ul>   | <input type="checkbox"/> |
| <ul style="list-style-type: none"> <li>• Can employees identify allergens of concern?</li> </ul>   | <input type="checkbox"/> |
| <ul style="list-style-type: none"> <li>• Can employees demonstrate process control measures to prevent allergen contamination?</li> </ul>  | <input type="checkbox"/> |
| <b>Comments/Observations:</b>  |                          |
| <br><br><br>   |                          |
| <b>Supplier Management and Product Receipt</b>   |                          |
| <ul style="list-style-type: none"> <li>• Does the food business purchase food/ingredients from a commercial supplier with a certified food safety program?</li> </ul>  | <input type="checkbox"/> |
| <ul style="list-style-type: none"> <li>• Where appropriate, does the supplier provide validation that the food/ingredients supplied are free of specific allergens?</li> </ul>   | <input type="checkbox"/> |
| <ul style="list-style-type: none"> <li>• Does the food business have valid invoices to enable trace back to the food supplier?</li> </ul>  | <input type="checkbox"/> |
| <ul style="list-style-type: none"> <li>• Does the food business have a procedure/policy for assessing the allergen status of foods/ingredients received from suppliers?</li> </ul>   | <input type="checkbox"/> |
| <ul style="list-style-type: none"> <li>• Does the food business validate the allergen status of foods from suppliers? E.g. Supplier audit/survey (Assess supplier's allergen management plan, cleaning program &amp; range of general foods produced at their site)</li> </ul> | <input type="checkbox"/> |
| <ul style="list-style-type: none"> <li>• Is there a procedure/policy for ensuring any change in supplier is accompanied by an allergen status review of the product?</li> </ul>  | <input type="checkbox"/> |
| <ul style="list-style-type: none"> <li>• Do suppliers notify the food business of any changes in the allergen status of foods/ingredients they supply?</li> </ul>  | <input type="checkbox"/> |
| <ul style="list-style-type: none"> <li>• Has the business requested this notification from their suppliers?</li> </ul>   | <input type="checkbox"/> |

| <b>Manufacturing Sector Allergen Investigation Checklist</b>   |  |
|--|--|
| <ul style="list-style-type: none"> <li>Does the food business only accept foods with adequate labelling and/or provided with appropriate documentation (unpackaged foods) to determine the allergen status of the food?</li> </ul>   | <input type="checkbox"/>   |
| <ul style="list-style-type: none"> <li>Does the food business only accept foods provided with documentation (unpackaged foods) that is regularly updated to determine the allergen status of the food?</li> </ul>  |  |
| <ul style="list-style-type: none"> <li>Does the food business review all product specifications documentation/labelling of incoming raw ingredients for their allergen status?</li> </ul>  | <input type="checkbox"/>   |
| <ul style="list-style-type: none"> <li>Does the food business have a system in place to clearly identify foods containing allergens at Receipt? E.g. Tags/colour coding of cases/pallets/bags</li> </ul>   | <input type="checkbox"/>   |
| <ul style="list-style-type: none"> <li>Does the food business only accept foods that are adequately protected from contamination?</li> <li>Does the food business have a system in place to remove damaged containers/packages of foods containing allergens at Receipt to prevent contamination?</li> </ul>                                       | <input type="checkbox"/><br><input type="checkbox"/>                             |
| <b>Comments/Observations:</b>  |  |
| <br>   |  |
| <b>Food Storage</b>  |  |
| <ul style="list-style-type: none"> <li>Are general/allergen free ingredients/foods stored separately and/or adequately contained to prevent contamination? E.g. use of clean, enclosed storage containers</li> </ul>   | <input type="checkbox"/>   |
| <ul style="list-style-type: none"> <li>Is there a procedure/policy in place to identify general/allergen free foods/ingredients? E.g. colour coding, tags</li> </ul>   | <input type="checkbox"/>   |
| <b>Comments/Observations:</b>  |  |
| <br>   |  |
| <b>Food Processing</b>   |  |
| <ul style="list-style-type: none"> <li>Are product specifications regularly reviewed to validate their allergen status?</li> <li>Has the business validated the preparation process and end food product to determine the allergen status of the food?</li> <li>Is evidence available e.g. sample results, food safety program records?</li> </ul> | <input type="checkbox"/><br><input type="checkbox"/><br><input type="checkbox"/> |

| <b>Manufacturing Sector Allergen Investigation Checklist</b>   |  |
|--|--|
| <ul style="list-style-type: none"> <li>• Is there a dedicated production area for the preparation of general/allergen free foods?</li> </ul>   | <input type="checkbox"/>                             |
| <ul style="list-style-type: none"> <li>• If the same production area is used, are allergen free foods processed before foods with allergens?</li> </ul>  | <input type="checkbox"/>                             |
| <ul style="list-style-type: none"> <li>• Are dedicated processing lines used for the processing of general/allergen free foods?</li> </ul>   | <input type="checkbox"/>                             |
| <ul style="list-style-type: none"> <li>• If separate production lines are used for general and allergen free foods, are they in close proximity or have cross-over points?</li> <li>• Are there adequate protection/barriers to prevent contamination?</li> </ul>        | <input type="checkbox"/><br><input type="checkbox"/> |
| <ul style="list-style-type: none"> <li>• Is dedicated equipment, utensils, containers used for the production of general/allergen free foods?</li> <li>• Is there a system in place to clearly identify them? E.g. colour coded, marked?</li> </ul>                      | <input type="checkbox"/><br><input type="checkbox"/> |
| <ul style="list-style-type: none"> <li>• Is equipment, utensils, containers adequately cleaned/sanitised immediately after the production of general foods to prevent contamination of allergen free foods?</li> </ul>   | <input type="checkbox"/>                             |
| <ul style="list-style-type: none"> <li>• Do food handlers wear dedicated protective clothing when preparing allergen free foods to prevent contamination?</li> </ul>   | <input type="checkbox"/>                             |
| <ul style="list-style-type: none"> <li>• Is dedicated cooking media, such as water or oil used for general/allergen free foods to prevent contamination?</li> <li>• If re-used, is it tested to validate the contamination risk?</li> </ul>                              | <input type="checkbox"/><br><input type="checkbox"/> |
| <ul style="list-style-type: none"> <li>• Is there a risk of airborne allergen contamination throughout the processing area?</li> </ul>   | <input type="checkbox"/>                             |
| <ul style="list-style-type: none"> <li>• Is there a system in place to clearly identify general foods during processing? E.g. colour coding, tagging</li> </ul>  | <input type="checkbox"/>                             |
| <ul style="list-style-type: none"> <li>• Is the traffic flow of raw materials, packaging supplies &amp; employees limited during the manufacture of general foods to prevent contamination?</li> </ul>   | <input type="checkbox"/>                             |
| <ul style="list-style-type: none"> <li>• Are employees working on general processing lines restricted from allergen free lines?</li> <li>• Is there a system to clearly identify employees working on general lines? E.g. different coloured uniform/hair net</li> </ul> | <input type="checkbox"/><br><input type="checkbox"/> |
| <ul style="list-style-type: none"> <li>• Do employees wear clean protective clothing when processing general/allergen free foods in a way to prevent cross-contamination?</li> </ul>   | <input type="checkbox"/>                             |
| <ul style="list-style-type: none"> <li>• Are there adequate hand wash basin(s) situated in the relevant areas?</li> </ul>  | <input type="checkbox"/>                             |
| <ul style="list-style-type: none"> <li>• Are hand wash basin(s) supplied with soap and paper towels?</li> </ul>  | <input type="checkbox"/>                             |

| <b>Manufacturing Sector Allergen Investigation Checklist</b>   |                          |
|--|--------------------------|
| • Are hand wash basin(s) only used for hand washing?   | <input type="checkbox"/> |
| • Is equipment designed and located to allow for easy and effective cleaning and inspection?   | <input type="checkbox"/> |
| <b>Comments/Observations:</b>  |                          |
| <b>Cleaning and Sanitising</b>   |                          |
| • Does the business have an effective, regular cleaning program in place?  | <input type="checkbox"/> |
| • Does the food business use Clean in Place (CIP) systems to clean pipe work, equipment and machinery?<br>Is the CIP system verified for allergen status? (swabs/rinse waters)             | <input type="checkbox"/> |
| • Are cleaning times scheduled appropriately to prevent cross-contact?   | <input type="checkbox"/> |
| • Are processing lines adequately cleaned immediately after the production of general foods to prevent contamination?  | <input type="checkbox"/> |
| • Are designated cleaning cloths or equipment used in areas where general/allergen free foods are manufactured?  | <input type="checkbox"/> |
| • Is adequate cleaning demonstrated throughout all aspects of the processing environment, equipment and utensils?  | <input type="checkbox"/> |
| • Does the food business have cleaning records to verify cleaning procedures?  | <input type="checkbox"/> |
| • Does the business have any verification procedures e.g. environmental swabs to verify cleaning   | <input type="checkbox"/> |
| <b>Comments/Observations:</b>  |                          |
| <b>Food Labelling / Packaging</b>  |                          |
| • Is there a procedure in place to review and approve labels and product specifications for new products and/or changes to current products?   | <input type="checkbox"/> |
| • Does the procedure address the allergen status of the ingredients list and any required allergen declarations?   | <input type="checkbox"/> |
| • Has the food business demonstrated compliance with this procedure?   | <input type="checkbox"/> |
| • Do product labels comply with the Food Standard Code requirements to ensure information is correct & product traceability is achievable?<br>E.g. batch coding, accurate ingredients list | <input type="checkbox"/> |

| <b>Manufacturing Sector Allergen Investigation Checklist</b>   |  |
|--|--|
|  | <input type="checkbox"/>   |
| <ul style="list-style-type: none"> <li>• Is there a procedure for destroying old packaging and/or product specifications when product formulations have been changed?</li> <li>• Has the food business demonstrated compliance with this procedure?</li> </ul>   | <input type="checkbox"/><br><input type="checkbox"/>                             |
| <ul style="list-style-type: none"> <li>• Is packaging material stored adequately to prevent contamination?</li> </ul>  | <input type="checkbox"/>   |
| <ul style="list-style-type: none"> <li>• Is there a procedure in place to ensure and verify correct product labels are used on the production line when packaging products?</li> <li>• Are employees adequately trained in complying with this procedure?</li> <li>• Has the food business demonstrated compliance with this procedure?</li> </ul> | <input type="checkbox"/><br><input type="checkbox"/><br><input type="checkbox"/> |
| <ul style="list-style-type: none"> <li>• Are allergen free foods packaged separately and/or in a clean, dedicated area to prevent contamination?</li> </ul>  | <input type="checkbox"/>   |
| <ul style="list-style-type: none"> <li>• Do employees take all practicable measures to prevent unnecessary contact when packaging food to prevent contamination?</li> </ul>  | <input type="checkbox"/>   |
| <b>Comments/Observations:</b>  |  |
|  |  |
| <b>Product Distribution</b>  |  |
| <ul style="list-style-type: none"> <li>• Are food products distributed to other manufacturing / retail / food service facilities?</li> </ul>   | <input type="checkbox"/>   |
| <ul style="list-style-type: none"> <li>• Are all foods for distribution adequately contained or packaged to protect against contamination?</li> </ul>  | <input type="checkbox"/>   |
| <ul style="list-style-type: none"> <li>• Does the food business only distribute foods that have adequate labelling and/or provided with appropriate documentation (unpackaged foods for catering purposes) to determine the allergen status of the food?</li> </ul>  | <input type="checkbox"/>   |
| <ul style="list-style-type: none"> <li>• Does the food business have a documented food recall plan?</li> </ul>   | <input type="checkbox"/>   |
| <ul style="list-style-type: none"> <li>• Can the food business demonstrate compliance with their recall plan when recalling unsafe food?</li> </ul>  | <input type="checkbox"/>   |

| <b>Manufacturing Sector Allergen Investigation Checklist</b>   |                          |
|--|--------------------------|
| <b>Comments/Observations</b>   |                          |
| <b>Sampling / Evidence</b>   |                          |
| • Sample of implicated batch ingredients   | <input type="checkbox"/> |
| • Sample of product (same batch if available)  | <input type="checkbox"/> |
| • Sample of end product – different batch (Validate relevant process(es))  | <input type="checkbox"/> |
| • Environmental swabs targeting relevant equipment, utensils and surfaces  | <input type="checkbox"/> |
| • Photograph storage, processing and packaging areas   | <input type="checkbox"/> |
| • Photograph food samples and swab sites, relevant processing areas, ingredient and product packaging/labelling                | <input type="checkbox"/> |
| • Photograph/copy product specifications, supplier information, label drafts & approvals, food processing/verification records | <input type="checkbox"/> |
| <b>Comments/Observations:</b>  |                          |
| <b>Monitoring</b>  |                          |
| • Does the business monitor allergen management?   | <input type="checkbox"/> |
| <b>Comments/Observations:</b>  |                          |
| <b>Signature</b>   | <b>Date</b>              |

### 7.2.1 Food Product Allergen Investigation Table – Manufacturing Sector

| <b>Food Product</b>            | <b>Labelled Ingredient</b> | <b>Food Product Specification Review</b>   | <b>Allergens Identified</b> | <b>Undeclared Allergen Identified</b> |
|--------------------------------|----------------------------|--|-----------------------------|---------------------------------------|
| <i>Packaged Apple Pie 500g</i> | <i>Wheat flour</i>         | <i>Wheat flour</i>   | <i>Wheat</i>                |                                       |
|                                | <i>Water</i>               | <i>Water</i>   |                             |                                       |
|                                | <i>Sugar</i>               | <i>Sugar</i>   | <i>Milk Protein</i>         |                                       |
|                                | <i>Margarine</i>           | <i>vegetable oil, salt, milk protein solids, emulsifiers(322 from soy), preservative 222</i> |                             | <i>Milk Protein</i>                   |
|                                | <i>Apple</i>               | <i>Apple</i>   | <i>Soy</i>                  | <i>Soy</i>                            |
|                                | <i>Spices</i>              | <i>Cinnamon</i>  |                             |                                       |

### 7.3 IMPORTED FOOD - ALLERGEN INVESTIGATION CHECKLIST

| <b>Imported Food Allergen Investigation Checklist</b>   |  |  |  |
|---|--|--|--|
| <b>Statutory Requirements for Allergen Investigations</b>   |  |  |  |
| <ul style="list-style-type: none"> <li>Does the food business import food[s] containing allergens as prescribed by Standard 1.2.3-4 of the FSC: <table border="0" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; vertical-align: top;"> <input type="checkbox"/> Tree nuts &amp; tree nut products<br/> <input type="checkbox"/> Peanuts &amp; peanut products<br/> <input type="checkbox"/> Soybeans &amp; soybean products<br/> <input type="checkbox"/> Milk &amp; milk products<br/> <input type="checkbox"/> Sesame seeds &amp; sesame seed products<br/> <input type="checkbox"/> Egg &amp; egg products </td> <td style="width: 50%; vertical-align: top;"> <input type="checkbox"/> Crustaceans &amp; their products<br/> <input type="checkbox"/> Cereals containing gluten &amp; their products<br/> <input type="checkbox"/> Sulphites (<math>\geq 10\text{mg/kg}</math>)<br/> <input type="checkbox"/> Fish &amp; fish products<br/> <input type="checkbox"/> Lupin [From 26 May 2018] </td> </tr> </table> </li> </ul> |  | <input type="checkbox"/> Tree nuts & tree nut products<br><input type="checkbox"/> Peanuts & peanut products<br><input type="checkbox"/> Soybeans & soybean products<br><input type="checkbox"/> Milk & milk products<br><input type="checkbox"/> Sesame seeds & sesame seed products<br><input type="checkbox"/> Egg & egg products | <input type="checkbox"/> Crustaceans & their products<br><input type="checkbox"/> Cereals containing gluten & their products<br><input type="checkbox"/> Sulphites ( $\geq 10\text{mg/kg}$ )<br><input type="checkbox"/> Fish & fish products<br><input type="checkbox"/> Lupin [From 26 May 2018] |
| <input type="checkbox"/> Tree nuts & tree nut products<br><input type="checkbox"/> Peanuts & peanut products<br><input type="checkbox"/> Soybeans & soybean products<br><input type="checkbox"/> Milk & milk products<br><input type="checkbox"/> Sesame seeds & sesame seed products<br><input type="checkbox"/> Egg & egg products  | <input type="checkbox"/> Crustaceans & their products<br><input type="checkbox"/> Cereals containing gluten & their products<br><input type="checkbox"/> Sulphites ( $\geq 10\text{mg/kg}$ )<br><input type="checkbox"/> Fish & fish products<br><input type="checkbox"/> Lupin [From 26 May 2018] |  |  |
| <ul style="list-style-type: none"> <li>Does the food business declare mandatory allergen information for the above allergens as required by Standard 1.2.3-4 of the FSC for the following foods:</li> </ul>   |  |  |  |
| <ul style="list-style-type: none"> <li>- Packaged retail food has a label detailing an accurate allergen declaration</li> </ul>   | <input type="checkbox"/>   |  |  |
| <ul style="list-style-type: none"> <li>- Foods exempt from product labelling have allergen(s) declared on or in connection with the displayed food or to the purchaser verbally or in writing upon request of the customer</li> </ul>   | <input type="checkbox"/>   |  |  |
| <ul style="list-style-type: none"> <li>- Food for catering purposes has allergens declared on the label or allergens are declared in documentation accompanying the catering food</li> </ul>  | <input type="checkbox"/>   |  |  |
| <ul style="list-style-type: none"> <li>- Packaged food sold in a hamper has a label that contains accurate allergen declarations</li> </ul>   | <input type="checkbox"/>   |  |  |
| <ul style="list-style-type: none"> <li>- Food sold from vending machines has allergen declaration provided on or in connection with the food (e.g. displayed on outside of vending machine)</li> </ul>  | <input type="checkbox"/>   |  |  |

| <b>Imported Food Allergen Investigation Checklist</b>   |  |
|---|--|
| <b>Comments/Observations:</b>   |  |
| <b>Allergen Investigation Assessment</b>  |  |
| <ul style="list-style-type: none"> <li>Does the food business import food product(s) which "claim" to be allergen free?<br/>Food product<br/>_____</li> </ul>                                 | <input type="checkbox"/>                             |
| <ul style="list-style-type: none"> <li>Has the food business received a complaint/s regarding a product suspected of containing undeclared allergen(s)?<br/>Food product<br/>_____</li> </ul> | <input type="checkbox"/>                             |
| <i>* Refer to Food Product Allergen Investigation Table (7.3.1)</i>   |  |
| <ul style="list-style-type: none"> <li>Does the food business have a documented procedure for allergen identification for all imported food product(s)?</li> </ul>                            | <input type="checkbox"/>                             |
| <ul style="list-style-type: none"> <li>Are all employees trained in food allergen identification procedures?</li> <li>Is there a training register available to verify training?</li> </ul>   | <input type="checkbox"/><br><input type="checkbox"/> |
| <ul style="list-style-type: none"> <li>Can employees identify allergens of concern?</li> </ul>  | <input type="checkbox"/>                             |
| <b>Comments/Observations:</b>   |  |
| <b>Supplier Management</b>  |  |
| <ul style="list-style-type: none"> <li>Does the food business import food(s) from a commercial supplier with a certified food safety program?</li> </ul>                                      | <input type="checkbox"/>                             |
| <ul style="list-style-type: none"> <li>Where appropriate, does the supplier provide validation that the food(s) supplied are free of specific allergens?</li> </ul>                           | <input type="checkbox"/>                             |
| <ul style="list-style-type: none"> <li>Does the food business have valid documentation to enable trace back to the food supplier? E.g. Shipment records/invoices</li> </ul>                   | <input type="checkbox"/>                             |

| <b>Imported Food Allergen Investigation Checklist</b>   |  |
|---|--|
| <ul style="list-style-type: none"> <li>Does the food business have a procedure/policy for assessing the allergen status of food/s received from suppliers?</li> </ul>   | <input type="checkbox"/>   |
| <ul style="list-style-type: none"> <li>Is there a procedure in place to review and approve all proposed product labels of all imported food(s) to ensure they are accurate and comply with the Food Standards Code? E.g. full ingredients list, batch coding (traceability), product specification, in English</li> <li>Does the procedure address the allergen status of the ingredients list and any required allergen declarations?</li> <li>Has the food business demonstrated compliance with this procedure?</li> </ul> | <input type="checkbox"/><br><input type="checkbox"/><br><input type="checkbox"/> |
| <ul style="list-style-type: none"> <li>Is there a procedure/policy for ensuring any change in supplier is accompanied by an allergen status review of the product?</li> </ul>   | <input type="checkbox"/>   |
| <ul style="list-style-type: none"> <li>Do suppliers notify the food business of any changes in the allergen status and/or product formulation of food(s) they supply?</li> <li>Has the business requested this notification from their suppliers?</li> </ul>  | <input type="checkbox"/><br><input type="checkbox"/>                             |
| <b>Comments/Observations:</b>   |  |
| <br>  |  |
| <b>Product Validation</b>   |  |
| <ul style="list-style-type: none"> <li>Has the business validated the manufacturing process and end food product(s) to determine the allergen status of all imported food?</li> <li>Is evidence available? E.g. end product testing results, food safety program records, supplier certifications, assess supplier's allergen management plan, cleaning program &amp; range of general foods produced at their site.</li> </ul>   | <input type="checkbox"/><br><input type="checkbox"/>                             |
| <b>Comments/Observations:</b>   |  |
| <br>  |  |
| <b>Product Receipt</b>  |  |
| <ul style="list-style-type: none"> <li>Does the food business only accept foods that are adequately protected from contamination?</li> </ul>  | <input type="checkbox"/>   |
| <ul style="list-style-type: none"> <li>Does the food business only accept food(s) with adequate labelling and/or provided with appropriate documentation to determine the allergen status of the food?</li> </ul>   | <input type="checkbox"/>   |
| <ul style="list-style-type: none"> <li>Does the food business have a procedure to review all product</li> </ul>   |  |

| <b>Imported Food Allergen Investigation Checklist</b>   |  |
|---|--|
| <ul style="list-style-type: none"> <li>specifications/documentation of imported food(s) for their allergen status upon receipt of a shipment?</li> <li>Has the food business demonstrated compliance with this procedure?</li> </ul>  | <input type="checkbox"/><br><input type="checkbox"/>                             |
| <ul style="list-style-type: none"> <li>Does the food business have a procedure in place to review all food product labels upon receipt to ensure they accurately reflect the product specification(s) and comply with the requirements of the Food Standards Code?</li> <li>Has the food business demonstrated compliance with this procedure?</li> <li>Is there a procedure in place to destroy or re-label food products which have been labelled incorrectly?</li> </ul> | <input type="checkbox"/><br><input type="checkbox"/><br><input type="checkbox"/> |
| <ul style="list-style-type: none"> <li>Does the food business have a system in place to clearly identify foods containing allergens at receipt? E.g. Tags/colour coding of cases/pallets</li> </ul>   | <input type="checkbox"/>   |
| <b>Comments/Observations:</b>   |  |
| <b>Food Labelling</b>   |  |
| <ul style="list-style-type: none"> <li>Does the food business apply any labels to imported food products?</li> <li>Do product labels comply with the Food Standard Code requirements to ensure information is correct &amp; product traceability is achievable? E.g. batch coding, accurate ingredients list, allergen declarations, in English</li> </ul>  | <input type="checkbox"/><br><input type="checkbox"/>                             |
| <ul style="list-style-type: none"> <li>Is there a procedure in place to ensure and verify correct product labels are used when labelling food products?</li> <li>Are employees adequately trained in complying with this procedure?</li> <li>Has the food business demonstrated compliance with this procedure?</li> </ul>  | <input type="checkbox"/><br><input type="checkbox"/><br><input type="checkbox"/> |
| <ul style="list-style-type: none"> <li>Are labels applied to product(s) so they do not cover/obstruct other labelling information required by the Food Standards Code?</li> </ul>   | <input type="checkbox"/>   |
| <ul style="list-style-type: none"> <li>Is there a procedure in place to verify correct labels have been placed on products prior to distribution?</li> <li>Has the food business demonstrated compliance with this procedure?</li> </ul>  | <input type="checkbox"/><br><input type="checkbox"/>                             |
| <ul style="list-style-type: none"> <li>Is there a procedure for destroying old labels when product formulations have been changed?</li> <li>Has the food business demonstrated compliance with this procedure?</li> </ul>   | <input type="checkbox"/><br><input type="checkbox"/>                             |

| <b>Imported Food Allergen Investigation Checklist</b>   |                          |
|---|--------------------------|
| <b>Comments/Observations:</b>   |                          |
| <b>Product Distribution (Food Recall)</b>   |                          |
| • Are food products distributed to manufacturing / retail / food service facilities?  | <input type="checkbox"/> |
| • Are all foods for distribution adequately contained or packaged to protect against contamination?   | <input type="checkbox"/> |
| • Does the food business only distribute foods that have adequate labelling as required by the FSC and/or provided with appropriate documentation to determine the allergen status of the food? | <input type="checkbox"/> |
| • Does the food business have a documented food recall plan?  | <input type="checkbox"/> |
| • Can the food business demonstrate compliance with their recall plan when recalling unsafe food?   | <input type="checkbox"/> |
| <b>Comments/Observations:</b>   |                          |
| <b>Sampling / Evidence</b>  |                          |
| • Sample of product (same batch if available)   | <input type="checkbox"/> |
| • Sample of product – (different batch)   | <input type="checkbox"/> |
| • Photograph of product packaging and labelling   | <input type="checkbox"/> |
| • Photograph/copy product specifications, supplier information, label drafts & approvals, shipment/import documentation, invoices of sale   | <input type="checkbox"/> |
| <b>Comments/Observations:</b>   |                          |
| <b>Monitoring</b>   |                          |
| • Does the business monitor allergen management?  | <input type="checkbox"/> |

| <b>Imported Food Allergen Investigation Checklist</b> |             |
|---|-------------|
| <b>Comments/Observations:</b>                         |             |
| <b>Signature</b>                                      | <b>Date</b> |

### 7.3.1 Food Product Allergen Investigation Table – Importers

| <b>Food Product</b>            | <b>Labelled Ingredient</b>   | <b>Food Product Specification Review<br/>Ingredients Detailed In Product Specification/Import Documents</b>  | <b>Allergens Identified</b>                     | <b>Undeclared Allergen Identified</b> |
|--------------------------------|--|--|---|---------------------------------------|
| <i>Packaged Apple Pie 500g</i> | <i>Wheat flour<br/>Water<br/>Sugar<br/>Margarine<br/><br/>Apple<br/>Spices</i> | <i>Wheat flour<br/>Water<br/>Sugar<br/>canola oil, salt, milk protein solids, emulsifiers(322 from soy), preservative 222<br/>Apple<br/>Cinnamon</i> | <i>Wheat<br/><br/>Milk Protein<br/><br/>Soy</i> | <i>Milk Protein<br/><br/>Soy</i>      |