Allergen Bureau

ASSESSING AGRICULTURAL CROSS CONTACT

AUGUST 2022

Informing the food industry

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1. INTRODUCTION

Allergens may be present in foods in the form of cross contact. The Allergen Bureau's Voluntary Incidental Trace Allergen Labelling (VITAL®) Program defines cross contact as a residue or other trace amount of a food allergen that is unintentionally incorporated into another food. Some reasons why cross contact may occur are due to: -

- agricultural co-mingling into a raw material; or
- carry over from an ingredient that contains cross contact; or
- processes using shared manufacturing equipment or concurrent lines; or
- inadequate cleaning of equipment.

Identifying the allergens present in foods and ingredients can be a complex process which requires consulting with suppliers and obtaining detailed raw material specifications. By ensuring that all allergens, including the unexpected ones, are identified, and included in the product risk assessment, the food industry can meet regulatory requirements, mitigate the need for allergen recalls and withdrawals, and provide important information to consumers with food allergy.

1.1 About this guide

Assessing Agricultural Cross Contact (this Guide) provides the food industry with guidance on identifying and assessing agricultural commodities that may contain allergens due to cross contact events.

This guide provides background on agricultural cross contact and questions food business operators can ask their suppliers to support the allergen risk review process.

Furthermore, the document is intended to aid in assessing the level of allergen cross contact risk that may be associated with agricultural commodities, through the application of the Raw Material Risk Matrix Questionnaire to determine a risk rating. The risk rating can be used to inform sampling approaches for verification activities, such as analytical analysis, to understand the presence and prevalence of cross contact.

Thank you to the Food Business Operators (FBO), including processors, manufacturers, traders, and analysts who kindly shared their expertise. FBOs who wish to share their experience on assessing agricultural cross contact are invited to contact the Allergen Bureau: info@allergenbureau.net.

In this Guide, 'allergens' are the foods that require mandatory declaration as described in the Australia New Zealand Food Code. The information in this Guide is however applicable across all regions.

1.2 Scope

This Guide is relevant to all areas of the food industry, including but not limited to:

- growers
- primary producers
- food ingredient manufacturers, importers, and suppliers – both local and imported
- FBOs of packaged food for bulk sale including business to business
- FBOs of packaged retail ready foods
- FBOs in food service and hospitality
- importers of packaged foods.

2. AGRICULTURAL CO-MINGLING

Agricultural co-mingling is the result of different crops being grown in close proximity with each other, sharing the same fields due to crop rotation, and/or sharing the same equipment/facilities for harvesting, transport and storage, despite the application of allergen controls as part of Good Agricultural Practices (GAPs). This means that the presence of variable amounts of one crop may be found in another crop. In particular, the presence of allergens, such as cereals containing gluten, peanuts, soy, and lupin. Although it is possible to apply processes to clean crops and reduce the concentration of co-mingled grains, seeds, or pulses, these do not generally remove them completely and thus allergen identification and declaration is an important consideration.

2.1 Crops and commodities

Tables 1 and 2 are provided as a guide to assist FBOs with identifying allergen co-mingling that may be present in crops or commodities, including those that have undergone primary and/or minimal processing (such as sorting, milling, drying, or freezing). FBOs who source such commodities should consider the questions posed in Tables 1 and 2 in their assessment of raw materials as part of their vendor assurance program.

Table 1 provides a list of general questions which should be considered for all materials sourced from agricultural origin. If the FBO is a supplier of commodity ingredients, they should be able to provide a considered allergen specification to their customer, who is encouraged to also refer to the tables when reviewing their ingredient information. Table 2 provides question for consideration which are specific to certain categories of agricultural commodities along with examples of known agricultural co-mingling from industry experience.

As previously stated in the introductory section of this document, information obtained through the risk review process can be the be used to inform the final risk assessment of the product being manufactured.

It should be noted that the application of the commodity including further processing of the commodity should be considered in the final risk assessment process.

Further information on agricultural cropping practices and controls are discussed in Table 3 and Table 4.

Table 1: General considerations for allergens associated with agricultural co-mingling

Food	Details
Applicable to all foods from agricultural sources	What other crops are being (or can be) grown nearby? What other crops are used for crop rotation by the grower? What seasons are the crops harvested in? This provides information about other plants nearby and shared equipment. What measures are in place to effectively reduce physical remains of other crops? What crops are purchased from contract farms or wholesalers? What effective measures are in place to minimise potential allergen cross contact from maintenance machinery and harvesting equipment? What effective measures are in place to minimise potential allergen cross contact from shared storage equipment and facilities and/or transportation? Does the primary and secondary processor have allergen controls within their facility? What is the form of the crop or processed crop? Is the cross contact similar in appearance?

Table 2: Allergens associated with agricultural co-mingling

Food	Details
Vegetables & Legumes - fresh & frozen (e.g. capsicum, beans, peas, edamame)	What other crops are being (or can be) grown nearby? This includes **lupin**, **soy** and cereals containing gluten including **wheat**, wild **wheat** and **barley**. Are the crops early or late season crops? Early or late season crops may be close to other plants of different maturity e.g. immature/mature wild **wheat**. What effective measures are in place to reduce allergen cross contact from the prepared (washed, diced, de-husked, peeled, podded etc.) vegetables? Does the primary and secondary vegetable processor have allergen controls within their facility? Example of known cross contact: - • Green beans grown in fields where wild **wheat** grass (and therefore potentially **wheat** grain) also germinates. • Corn with **wheat** cross contact.
Vegetables - dehydrated / processed (e.g. capsicum, onion flakes, chili flakes)	In addition to the questions above for Vegetables & Legumes: What is the form of the processed vegetable (e.g. flakes, powder, pieces)? Is the cross contact similar in appearance to the vegetable (i.e. difficult to clean and separate)? What is the form of the cross contact (e.g. readily dispersible - powder/dust, or particulate - split, whole, seed, leaf, pod, grit, hull, pearl, kernel, coarse ground)? What effective separation processes are used by the primary and secondary processors (e.g. sorting facilities for dried vegetables can be shared with **wheat**, **soy** products or dried vegetables with an allergen cross contact etc.)? Examples of known cross contact: - • Tomato flakes with **wheat** cross contact. • Capsicum powder with **wheat** cross contact.
Dehydrated Garlic	What is the geographical origin of the garlic? Refer to Case study – Crop rotation practices can impact upon ingredient allergen status. What other crops are used for crop rotation by the grower? Does the farming source crop rotate with **peanut**? How is the garlic (fresh or dehydrated) traded/sourced (e.g. through general markets with lesser known controls; contracted farms; controlled Backward Integration programs)? Does the primary and secondary processor process batches of garlic with **peanut** cross contact and garlic without **peanut** cross contact in the same facility?

Table 2: Allergens associated with agricultural co-mingling

<table>
<tr><th>Food</th><th>Details</th></tr>
<tr><td>Pulses - mature seeds, dried (e.g. split peas, blue peas, beans, chickpeas, lupin)</td><td>Are there any wheat, barley, oats, spelt, lupin or soy crops grown in the same geographical region?

Is the allergen similar in size and colour as the pulse (i.e. difficult to clean and separate)? What is the form of the processed pulse (e.g. whole, split, grits)? What is the form of the cross contact (e.g. readily dispersible - powder/dust, or particulate - split, whole, seed, leaf, pod, grit, hull, pearl, kernel, coarse ground)? Is the cross contact similar in appearance to the pulse (i.e. difficult to clean and separate)?

Examples of known cross contact: -
Dried beans with soybean cross contact.
Dried beans with wheat cross contact.
Chickpea with barley cross contact.
Does the primary and secondary processor have allergen controls within their facility?

What effective measures are in place to minimise potential allergen cross contact from shared storage equipment and facilities and/or transportation?

What effective separation processes are used by the primary and secondary processors?

Example of known cross contact: -
Sorting facilities for dried split peas can be shared with pearl barley, wheat, soy etc.</td></tr>
<tr><td>Milled Pulses (e.g. pea powder, soy grits, lupin flakes chickpea flour (besan flour), soy flour, lupin flour)</td><td>In addition to the questions above for Pulses and general questions in Table 1:

Does the pulse processor have allergen controls within their facility?

What effective measures are in place to minimise potential allergen cross contact from shared storage equipment and facilities and/or transportation?

What effective separation processes are used by the pulse processor (e.g. pea flour milling facilities can be shared with soy etc.)?

Is the cross contact similar in appearance to the pulse (i.e. difficult to clean and separate)? What is the form of the processed pulse (e.g. splits, grits, flakes, meal, flour)? What is the form of the cross contact (e.g. readily dispersible - powder/dust, or particulate - split, whole, grit, pearl, kernel, flake, coarse ground)?

Example of known cross contact: -
Chickpea flour with wheat, barley, oats.</td></tr>
</table>

Table 2: Allergens associated with agricultural co-mingling

Food	Details
Cereal Grains (e.g. barley, buckwheat, maize, millet, oats, popcorn, rice, rye, sorghum, spelt, triticale, wheat, wild rice)	Are there any **wheat**, **barley**, **oats**, **spelt**, **lupin** or **soy** crops grown in the same geographical region? What other crops are used for crop rotation by the grower (e.g. **lupin** and **oats** can be used in crop rotation)? What other crops are being (or can be) grown nearby? This includes **lupin**, **soy** and cereals containing gluten including **wheat**, wild **wheat**, **barley**, **spelt** and **oats**. Is the allergen similar in size and colour as the cereal grain (i.e. difficult to clean and separate)? What is the form of the cereal (e.g. whole, split, grits, husked)? What is the form of the cross contact (e.g. readily dispersible - powder/dust, or particulate - split, whole, seed, leaf, pod, grit, hull, pearl, kernel, coarse ground)? Is the cross contact similar in appearance to the cereal (i.e. difficult to clean and separate)? Examples of known cross contact: - • **Oats** with **lupin** cross contact. • **Wheat** with **soy** cross contact. • Buckwheat kernel with **wheat** cross contact. • **Wheat** with mustard cross contact. Does the primary and secondary processor have allergen controls within their facility? What effective measures are in place to minimise potential allergen cross contact from shared storage equipment and facilities and/or transportation? What effective separation processes are used by the primary and secondary processors? Example of known cross contact: - • Sorting facilities for dried corn (such as popcorn) can be shared with **wheat**, **soy** etc.
Milled / Processed Cereal Grain Products (e.g. bran, flour, germ, meal, flakes)	In addition to the questions above for Cereal grains. Does the grain processor have allergen controls within their facility? What effective measures are in place to minimise potential allergen cross contact from shared storage equipment and facilities and/or transportation? What effective separation processes are used by the grain processor (e.g. milling facilities for **oats** can be shared with **wheat**, **barley** etc.)? Is the allergen similar in size and colour as the cereal grain (i.e. difficult to clean and separate)? What is the form of the processed cereal (e.g. whole, split, grits, meal, flour)? What is the form of the cross contact (e.g. readily dispersible - powder/dust, or particulate - split, whole, seed, leaf, pod, grit, hull, pearl, kernel, coarse ground)? Is the cross contact similar in appearance to the cereal (i.e. difficult to clean and separate)? Examples of known cross contact: - • Buckwheat flour with **wheat** cross contact. • Maize flour with **wheat** and **soy** cross contact.

Table 2: Allergens associated with agricultural co-mingling

Food	Details
Nuts - tree nuts and ground nuts	What is the geographical origin of the **tree nut** or **peanut**? Have other countries, that are included in the supply chain, been considered? Are other **tree nuts** and/or **peanut** processed in the same facility? Does the primary and secondary processor have allergen controls within their facility? Is the cross contact similar in size and colour as the nut (i.e. difficult to clean and separate)? What is the form of the processed nut (e.g. whole, split, shelled, pieces, meal, flour, paste)? What is the form of the cross contact (e.g. readily dispersible - powder/dust, paste, or particulate - whole, split, pieces, meal)? Is the cross contact similar in appearance to the nut (i.e. difficult to clean and separate)? Examples of known cross contact: - • **Cashews** with **peanut** cross contact. • **Tree nuts** with other **tree nut** cross contact.
Oil Seeds (e.g. chia seed, hemp seed, linseed, mustard seed, poppy seed, quinoa seed, sesame seed, sunflower seed)	Are any **wheat**, **sesame** or **soy** crops grown in the same geographical region? What other crops are being (or can be) grown nearby? Examples of known cross contact: - • Chia seed with **soy** cross contact. • Hemp seed with **wheat** grain cross contact. • Hemp protein with **wheat** cross contact. • Mustard seed with **wheat** grain cross contact.
Spices (e.g. celery seed, coriander, cumin, dill, fennel, fenugreek, turmeric, etc.)	Are any **wheat**, **sesame** or **soy** crops grown in the same geographical region? What other crops are being (or can be) grown nearby? Is the allergen similar in size and colour as the spice/seed (i.e. difficult to clean and separate)? What is the form of the cross contact (e.g. readily dispersible - powder/dust, or particulate - split, whole, seed, leaf, pod, grit, hull, pearl, kernel, coarse ground)? Does the primary and secondary processor have allergen controls within their facility? Examples of known cross contact: - • Fennel seeds with **sesame** seed and **wheat** cross contact. • Dill seeds with **sesame** seed cross contact. • Cumin seeds with **wheat** and **peanut** cross contact. • Coriander seeds with **wheat** and **sesame** seed cross contact. • Fenugreek seeds with **sesame** seed cross contact. • Celery seeds with **wheat** cross contact. • Ground cumin with **wheat** and **peanut** cross contact.

Table 2: Allergens associated with agricultural co-mingling

Food	Details
Herbs (e.g. oregano, marjoram, rosemary, thyme, parsley, etc.)	Are any **wheat** crops grown in the same geographical region? What other crops are being (or can be) grown nearby? This includes cereals containing gluten including **wheat**, wild **wheat**, **barley**. Is the allergen similar, in size and colour, to the herb (i.e. difficult to clean and separate)? What is the form of the cross contact (e.g. readily dispersible - powder/dust, or particulate - split, whole, seed, leaf, pod, grit, hull, pearl, kernel, coarse ground)? What is the form of the herb? Examples of known cross contact: - • Oregano with **wheat** cross contact. • Marjoram with **wheat** cross contact.

2.2 Agriculture practices and allergen controls

During cultivation, primary processing, storage and transportation of commodity crops, there are several factors that can contribute to agricultural allergen co-mingling as described in Table 3. However, measures can be put in place that can help reduce the degree of this occurring. Table 4 describes where controls can be implemented and situations where there may not historically have been any controls identified.

Further information is available in the Codex Alimentarius Code of Practice on food allergen management for businesses (CXC 80-2020). This document provides allergen management guidance including measures to prevent cross contact during primary production, manufacturing, and retail and food service. Section III focuses on practices that reduce the likelihood of agricultural co-mingling during primary production.

Table 3: Situations contributing to allergen agricultural co-mingling

Situation	Details
Accumulation / markets / trading	Crop aggregators liaise with farmers to sell crops on their behalf. Accumulations of crops from various farms can be stored together and presented at markets. Knowledge of farming practices in relation to allergens may not be available. In some cases, differing mandatory allergen requirements may exist between the crop source, and destination country. Markets and traders should have an understanding of the export and import country allergen requirement to ensure allergen presence is communicated throughout the supply chain.
Adjacent crop fields	The growing environment (e.g. neighboring fields and farms) should be considered when reviewing the potential for allergen cross contact. The adventitious presence of an allergen may be from drift or crop migration. Growers should understand the history of the growing area.
Crop rotation	This is the practice of cultivating different crops in a specific growing area during alternate seasons. Rotational crops are selected to restore nutrients in soil, help manage weed and pest activity. Allergen co-mingling may occur due to the exposure to physical remains of previous crops, without sufficient removal, prior to replanting. Growers should understand the history of the growing area (e.g. in some regions garlic is crop rotated with peanut crops).
Farming equipment	Maintenance of farming equipment helps to minimise potential for allergen cross contact. Adequate cleaning of, for example, planting, harvesting and weeding equipment, should be sufficient to prevent carry-over of plant debris from previous crops into the next crop. Farming Equipment may be used across several commodities/growers as shared equipment or leased as joint farming equipment. Farms with various crops may use the same sowing and harvesting equipment without a sufficient cleaning step that prevents allergen co-mingling. Smaller farming communities may share farming equipment without knowledge of what the equipment was previously used for or without a sufficient cleaning step that helps mitigate allergen co-mingling. Training programs should be in place with adequate awareness of identified risks and allergen management practices.
Cleaning crops	Cleaning crops after harvest can help reduce the presence of cross contact allergens. Sifting equipment, size sorters, and colour sorters, may help clean and separate allergens. Growers should know the size and colour of the allergen to assess the effectiveness of mechanical sorting and cleaning. Note: Determination and separation of some commodities from allergen commodities may not be possible due to the similarity of colour and size. There are also multiple tolerances for extraneous matter of seeds and grains within various commodity standards for unprocessed commodities around the world that permit higher tolerances of foreign seed and grain. Refer to section on Permission foreign grain in this table. This may allow for higher levels of allergen presence particularly in lower graded commodities[1].

Table 3: Situations contributing to allergen agricultural co-mingling

Situation	Details
Particulates	Most agricultural crops are in particulate form (leaf, seed, grain, pulse, pod, nut). Particulates can remain in whole or split form during harvesting and storage. Often particulates of allergen crops have a similar colour or size to non-allergen crops making it difficult to identify, separate or clean.
Permissible foreign grain	Food commodity standards vary from country to country. Established standards allow for permissible foreign objects in unprocessed seeds and grains at different levels. The same commodity group may have different tolerances between countries or jurisdictions. Extraneous matter which includes foreign seeds and grains can be permitted from 1-3% by Codex or upward of 5-8% in the USA or Canada depending on the graded product. This may allow for a higher level of allergen presence particularly in lower graded commodities[1]. As such, it should be noted that agricultural cross contact, even when well controlled, in many instances may be present to some level[1].
Primary processing \ primary processors	Primary processors perform the initial processing step on crops and commodities (e.g. air drying, shelling, hand sorting). Knowledge of the primary processing environment should be considered for the potential for allergen cross contact. Allergen cross contact can occur when processing steps are located close to other commodities which are allergens or are part of uncontrolled conditions. Primary processors who dry crops or commodities should have measures in place that prevent or minimise co-mingling where possible with allergens (e.g. physical barriers). Storage containers or packaging should be clean. Bag reuse should be avoided when it previously stored an allergen. Storage of the filled containers should be in line with allergen management practices where allergens are clearly labelled to reduce the likelihood of cross contact due to unintentional mixing. Training programs should be in place to address allergen controls such as the implementation of physical separation barriers, clearly labeled areas and the management of tools (e.g. containers, hanging materials).
Secondary processing	Where secondary processing is performed an understanding of the raw commodity origin before secondary processing should be known. For example, in some instances a commodity may be sent to another country for further processing, when this occurs, depending on the county of origin labelling laws, the country of origin for the product may change. In such cases the true origin of the commodity may not be known or communicated in supplier documentation.

Table 3: Situations contributing to allergen agricultural co-mingling

Situation	Details
Storage	Storage facilities with multiple commodities should ensure physical segregation of commodities with known allergen risk. Storage facilities and vessels used for multiple commodities should be appropriately cleaned and inspected. Storage containers should be suitably designed to facilitate adequate cleaning and inspection. Allergen cross contact should be minimised by managing the flow of raw materials, the storage, and the processing steps within the facility. Storage bags should be clean and bag reuse should be avoided when it previously stored an allergen. Storage of the filled bags should be in line with allergen management practices where allergens are stored on lower shelves to reduce the likelihood of cross contact due to spillage. Training programs should be in place to address allergen controls such as the separation and movement of allergens around storage areas, cleaning of storage containers, the requirement of single use jute bags between commodities, and addressing allergen spillages.
Transportation	There are a variety of transportation vehicles depending on the commodity and size of the operation. Controls and processes need to be appropriate for the transportation mode (e.g. bulk tanker, rail transport, shipping container, trucks, carts, trolleys). Often these vehicles are shared, hired, and used across multiple users. Depending on the cleaning practices, cross contact is likely unless the vessel is dedicated to the one type of crop. Transport vehicles/containers should be appropriately emptied of the previous commodity, cleaned, and inspected before use to ensure there is no residue or carry-over from the previous commodity. Liners (e.g. cardboard sheeting of containers) used should be single use only. Transport vehicles/containers should be suitably designed to facilitate adequate cleaning and inspection. Loose crops and commodities should be transported separately or alternatively adequately separated by capping and wrapping with pallet covers to prevent spillage. Stacking of bagged commodities should be in line with allergen management practices where allergens are stored in a manner to reduce the likelihood of cross contact due to spillage. Spillages of allergens should be cleaned up as soon as possible to minimise subsequent allergen cross contact. Training programs should be in place to address allergen controls such as the separation of allergens, the cleaning between commodities transported and addressing allergen spillages.

Table 4: Practices used to mitigate allergen co-mingling

Table 4 describes practices that can be implemented to control and reduce the extent of allergen agricultural co-mingling within crops and commodities.

Practice	Details
Contracted farms	These are farms where agreements have been made controlling the choices of crop rotations that may contribute to allergen concerns and include suitable cleaning practices of farming equipment. The use of contracted farms provides a deeper knowledge and understanding of the farming practices by the procurer.
Backward Integration practices	Backward or vertical integration is the relationship between the farmer or farming community and the FBOs. The farming community is supported by the FBO sharing knowledge and providing guidance about selection of seeds, fertilization, pest control advice, crop rotation, soil, and water management. This arrangement can help provide training and education for allergen cross contact controls. Backward Integration provides a deeper knowledge, greater control, traceability and understanding of the farming practices for the FBO.

Case Study 1: Crop rotation practices can impact upon ingredient allergen status

The dawn of a new challenge for the food industry

In 2014, the presence of low levels of peanut in garlic powder was detected through testing of garlic sold within the USA. Further testing, at that time, showed peanut concentrations in garlic powder ranging from 10 parts per million (ppm) to over 200 ppm[2]. Testing in the EU in 2016 also found positive results. It seemed consistent that the garlic, which showed positive presence of peanut, was in powdered or flake form, was souced from China. Today, most of the world's garlic is grown in China, some in India, and the remainder throughout the world including the United States and the EU[3].

The investigation begins

The food industry, traders, importers, spice agents and analysts acted quickly to establish how peanut could be present in dried garlic. It was found that the most likely reason was due to the regular practice for growers in China to cultivate peanuts and garlic in tandem, or to crop rotate garlic with peanut. Crop rotation is a standard agricultural practice, important for sustainable farming and nourishing soils. In these fields, both peanuts and garlic are grown below ground and therefore some residual peanut plants may be harvested along with garlic. There is also the likelihood of sharing the same equipment for harvesting, and facilities for sun drying, transport and storage. The complexity of the supply chain is shown by the significant amount of garlic cultivation in China. There are over two million farms and more than 1000 dehydrators supporting the garlic supply chain.

Industry guidance

When purchasing dehydrated garlic, or ingredients that contain dehydrated garlic, ask the supplier to provide information about peanut cross contact. The supplier can refer to the guidance in the section on dehydrated garlic in Table 2 of this Guide to form part of their investigation.

Three points to consider if peanut is present in the garlic due to cross contact:

- Sourcing garlic from geographical origins which do not crop rotate with peanut could eliminate the risk of peanut cross contact.
- Whether the raw material supplier's peanut allergen controls eliminate, reduce or quantify the risk of peanut cross contact.
- Conducting a risk assessment to determine the concentration of peanut cross contact present in the food for sale. The *Food Industry Guide to the Voluntary Incidental Trace Allergen Labelling (VITAL®) Program* (which is freely available on the Allergen Bureau website) provides guidance on cross contact allergen risk assessment.

Case Study 2: Supply chains can be complex and need to be fully understood

Responding to a new allergen cross contact discovery

During December 2019 and January 2020, pesto products manufactured in Italy were recalled across Europe and the UK due to the presence of undeclared peanut. Investigations indicated that the source of the peanut was from cashew ingredients in the form of meal, flour and pieces and it was thought these ingredients originated from Vietnam. In Australia, recalls were instigated for imported pesto products, followed by other products after proactive analysis for peanut in cashew ingredients was carried out. The food industry acted quickly and collaboratively with consumer groups, analytical laboratories, retailers, and regulators, to gain a better understanding of the nature of the issue.

The investigation begins

Many of the recalled foods were produced in different countries, so it was quickly agreed that the source of the peanut was not where the finished goods were manufactured. Analysis did not provide much insight as it did not show a consistent presence of peanut in the foods. Initially, there was a strong indication that the exposure to peanut occurred due to the bags used to transport the cashews from India and the Ivory Coast to Vietnam where the majority of the cashews are processed. This was uncertain, however, so it was necessary for industry to track back, share knowledge, work together and understand the supply chain to identify the point of exposure.

Supply chains can be complex

Cashews are grown in many geographical regions worldwide, including Vietnam, India, West Africa, and South America[4]. Most of the whole cashews (the nut within its shell) are then transported to Vietnam for processing.

In cashew processing, the first step is to remove the shell, which is a critical step because the shell is toxic. The shell separation process involves roasting and steaming at high temperatures, and once the shell is removed there is further roasting to remove any residual oils (which may also contain toxins) and peel from the nut. It was concluded that if the unprocessed cashew nuts were exposed to peanut residue from shared bags used during transportation, it is unlikely that peanut residue would remain after the shell, oil and peel separation steps, and any peanut residue present would be much lower than the levels detected in the recalled foods.

The roasted cashews are then graded. The bigger whole nuts are separated from the smaller whole nuts and from the pieces and all are bagged. At this stage, the original shipping bags cannot be reused so as to avoid contamination of the shell toxins.

Whole cashews are considered a premium product and once bagged, are distributed across the world demanding a higher price. During this investigation, analysis in Australia did not detect any peanut residue on whole cashews so the focus was directed to the smaller nuts and pieces.

The smaller whole cashews and pieces can undergo further processing. Some are bagged and distributed to suppliers, but most go on to various processors in the supply chain for additional roasting/nibbing/chopping. The complexity of the supply chain is shown at this point where in Vietnam alone, there are approximately one thousand (large, medium, and small) cashew processing sites. The potential that some of these sites are also processing other tree nuts and peanuts is high. It is likely that some supplier approval systems have not encompassed the complexity of this step.

Investigation is continuing

It is most likely that the source of the peanut contamination occurred during the secondary processing steps. This aligns with detecting peanut residues in the more finely ground cashew materials and may also explain why analysis did not show peanut consistently present in the foods. Investigation is continuing, however, this case study shows that for commodity ingredients, any secondary processing steps can inherently increase the allergen cross contact risk if allergen management practices are not well understood or implemented. As part of the raw material approval process, the supply chain needs to be fully understood to be confident of the allergen status of ingredients.

Case Study 3:
When a cause and effect may not always seem to correlate

Primary processors, storage and silo dust

In addition to the traditional use of maize flour, it is often used as an alternate to wheat-based grains. When previously declared gluten free maize crops (at the EU threshold of <20ppm) tested positive for gluten levels more than >20ppm, investigations uncovered increasing numbers of wheat production occurring in areas previously known for growing maize. The change / introduction of the new crop was driven by changes in commodity prices.

A concerted effort was made by producers to clean and sort the maize with extra physical and colour sorting applications, however gluten detection at unacceptable levels was still observed. After trial-and-error, producers found that the introduction of a vigorous brushing and aspiration process at the raw material stage reduced gluten to acceptable levels. Producers concluded that the challenge in removing gluten was a result of the grain dust collecting in storage silos year after year. Grain dust can be practicably invisible, static and incredibly challenging to clean from elevators and silos.

As commodity prices are impacted by economic and environmental drivers, often growers and producers respond by changing their crops. Depending on the crop choices, this may have an impact on allergen status. Introducing additional levels of cleaning is not always useful (or practicable) especially when the grains are a similar size and colour, and this may be compounded by an acceptance threshold of zero detection. These challenges are not isolated to commodities such as wheat flour and maize flour in Europe but have been noted in other commodities such as certain spices from India, which have been exposed to mustard and soy dust contamination.

4. RISK RATING, SAMPLING AND TESTING

A FBO can determine the level of risk that may be associated with a material, using a risk rating matrix, supported by sampling and analysis. This approach can assist organisations in their risk review, and also inform any additional allergen management procedures which may be required in the facility.

The Raw Material Risk Matrix Questionnaire assigns a risk rating after completing a set of questions aimed in assessing the level of risk that may exist in areas such as, but not limited to, the geographical region the commodity is grown, known crop rotational practices, controls which may be in place to mitigate or reduce allergen cross contact during the harvesting, storage, transport and during any downstream value-add processes which may occur. The level of risk assigned, either low, medium or high, is then used to determine the number of samples required for analysis to assist in verifying the presence and prevalence of cross contact in the incoming material.

The following information provides details on the application of the ingredient risk questionnaire, sampling considerations and analytical testing recommendations.

4.1 Ingredient Risk Questionnaire

The Raw Material Risk Matrix Questionnaire has 20 questions, covering the physical nature of the material, complexity of the supply chain, crop rotation, trading, processing and includes questions pertaining to known cross contact risks and allergen controls. The questionnaire is most suited to the below types of agricultural commodities:

- As listed in Table 2 of this document
- Those which have undergone value adding processes and / or blending

The questionnaire is less suitable for highly refined / processed ingredients (i.e. citric acid). Refer to Table 1 in Unexpected Allergens in Foods guidance document for further information on allergen risks for such ingredients.

The questionnaire is intended to be used in the below scenarios:

- To aid the allergen risk assessment when procuring ingredients which contain agricultural commodities and raw materials which contain agricultural ingredients
- To determine allergen prevalence and potential to manage allergen concentration in the raw material
- When there is suspected food fraud / adulteration and to determine if there is an unknown / unexpected risk
- For specification and product claim review
- To determine routine sample numbers for surveillance testing
- For initial assessment of the raw material / ingredient for use
- To evaluate new suppliers / new ingredients / or when root cause analysis is required for unexpected issues
- To inform the VITAL risk assessment and labelling outcome

4.2 Questionnaire Risk Rating Outcome

A material assessed using the Raw Material Risk Matrix Questionnaire, will receive a risk rating of either low, medium, or high. The risk rating outcome determines the number of minimum samples that are recommended from each consignment to verify the presence and prevalence of the cross contact. Prevalence is assessed by reviewing analytical results, obtained over several samples and batches. In some circumstances the additional use of visual assessment is also recommended. Refer to Appendix 1 for the rationale that underpins the selection of the above sample numbers for each risk rating.

Risk Rating	Number of Samples
Low	5
Medium	Minimum 10. Square root of consignment (if above 100 units)
High	Minimum 15. 10 % of consignment (if above 150 units)

4.3 Sample collection

Samples selection should consider the nature of how cross contact may occur in the material and acknowledges that, in many instances, cross contact will be heterogenous (unevenly distributed).

The nature in which sampling occurs in manufacturing environments traditionally relies on historical data and assumes that contamination generally occurs homogenously. In the case of agricultural cross contact, in many circumstances, unless secondary processing has occurred to change the form of the material, allergen presence is usually heterogenous. As such, the use of random sample collection is encouraged.

Selecting samples at random provides an equal chance that samples will be chosen throughout the lot being assessed[5]. A representative, unbiased sample is critical. This can be achieved manually, or a random number generated can be used (i.e. Microsoft Excel has this capability). It should be noted that composite sampling is not recommended, refer section 4.6 for further information.

Example 1: Random sample selection

50 boxes are delivered from the one batch code to your facility. The questionnaire risk rating outcome is "low", therefore, 5 samples are required to be collected. Traditionally the facility would collect 1 sample every 10th box to achieve this requirement.

In the case of sample collection for agricultural cross contact, it is recommended that 5 random samples are collected from the consignment. A random number generator is used, and the below boxes were chosen at random for sampling – 4, 17, 19, 35 and 43.

Where a bulk commodity requires assessment (silos, tankers), or the questionnaire has identified that material may have a particulate cross contact risk, in addition to sample collection for laboratory analysis, it is recommended that visual foreign grain analysis is used to support the determination of the presence and prevalence of foreign allergenic grains.

Where businesses may have established sampling procedures for collecting bulk samples for other screening requirements (for example: mycotoxin, Genetically Modified Organisms (GMO), foreign grains) existing sample collection methods may be a useful reference as many of the standards and guidance documents for these types of analysis also recommend random sample collection.

Devices used for sampling should be suitable to aid in the collection of a representative sample. Depending on the size of the container under assessment, devices used may consist of, scoops for stream sampling, probes/triers (manual or mechanical) and automatic samplers[11].

For the collection of samples from static lots (i.e. bags and bulk containers), it is recommended facilities employ the use of sample probes/triers. These types of sampling devices allow for the collection of the sample from the entire depth or width of the bag, allowing a cross section of the contents to be collected simultaneously. Sample probe/trier selection is dependent on the grain/seed size of the commodity requiring sampling[6]. Examples of the different types of sampling triers can be found in Appendix 2.

It is recommended that sampling practices employ the same rigor as that used to collect microbiological samples, using aseptic techniques to minimise environmental impacts that could compromise the integrity of the sample requiring analysis.

Example 2: Bag in Box / 1 tonne bulk bag delivery:

Using Example 1 as a basis for this example, 5 random samples are required for review. Boxes / bags numbers 4, 17, 19, 35 and 43 have been chosen for collection. Using an appropriate sampling device (i.e. probe sampling device, scoop) collect a sample from the container being assessed.

Example 3: Collection of samples from bulk deliveries (i.e. tankers, rail cars)

5 random samples are required for review; however, samples are required to be collected from commodities received in bulk containers.

Sample collection, depending on the commodity and the processes already in place, may occur using an automated sampling device. In this case, where possible, sample collection for allergen analysis can also occur through this process. In cases where this may be a closed system, it is acknowledged that the sample collected and used for analysis may be from a composite sample collected from the load. Where possible, this is not recommended.

Alternatively, it is recommended that samples are taken from an accessible location (i.e. during off-loading) and taken periodically throughout the off-loading process.

4.4 Sample Volume

Sample volume is dependent on the way a the material is received into a facility (e.g. bag in box, bulk bags, tankers). Generally, it is recommended that a minimum of 100 – 200 grams be collected for each sample. However, where bulk commodities are concerned with no secondary processing, larger volumes (500g to 1kg) may be appropriate. Where businesses may have established sampling procedures for collecting samples from bulk deliveries for other screening requirements (mycotoxin, GMO, foreign grains) similar methods for sample collection and sample size may also by applied.

4.5 Sample Frequency

Sample frequency is dependent on several variables such as, the risks identified through the completion of supplier and raw material questionnaires, delivery frequency, volumes received and historical data. Similar to other food safety control measures, sampling frequency should be reviewed when circumstances change and not be considered static.

The frequency of sampling is a business decision, which can be influenced by:

- The risk rating, history of the supplier, and can be adjusted to a higher frequency should the risk or the supply chain change
- The introduction of a new supplier or a new raw material, may result in a higher sampling frequency initially and reduced once data supports the risk, or;
- When a statistically valid sampling plan may be required to determine the potential of controls and / or to set limits or specifications for allergen cross contact

4.6 Allergen Analysis Recommendations

When choosing a method for allergen analysis, it is critical that there is a clear understanding of the analytical outcomes and the appropriate application of laboratory results for each allergen detection scenario. There are many factors that can affect the accuracy of analytical testing. More specific guidance on the food allergen analysis can be found on the Allergen Bureau Food Allergen Analysis website.

When sampling, avoid composite samples for allergen analysis. Compositing samples occurs when several samples are combined into a single unit. Testing a composite sample may dilute the allergen concentration and the reported value may not represent the level in each individual sample. This is of importance when assessing incoming ingredients for compliance purposes, for example, the absence of an allergen, as stated by the supplier (i.e. gluten free, dairy free)[10].

Consider the following when performing analysis:

- Samples should be tested individually where possible
- The use of rapid methods, such as Lateral Flow Devices (LFD) are not recommended as these methods are unable to quantify the allergenic protein content, required to support the validation process and VITAL risk assessment
- Currently ELISA (Enzyme Linked Immunosorbent Assay) is considered the most robust method available for allergen protein analysis. Other established methods for allergen analysis may be used where ELISA methods are not available (i.e. celery, sulphites)
- Other methods such as PCR may be suitable. Where PCR may be used, it is recommended that quantitative real time PCR is used

Example 4:

A commodity is screened for the presence of peanut by the producer. Routine analysis occurs on composite samples, using LFD. All historical surveillance testing shows no cross contact with peanut. In response to an emerging issue, customers further down the supply chain detected peanut protein in the commodity. Peanut was detected using the ELISA method from single, non-composited samples, from a large sample size. Although the prevalence of the detection was sporadic, the probability of positive detections was increased by assessing a larger number of samples, tested individually. This example demonstrates how sampling (single verses composite) can lead to differing outcomes in test results, influencing the understanding of the actual level of risk which may exist.

- Discuss with the laboratory if matrix suitability analysis needs to be performed for the material undergoing analysis, in some cases the matrix may result in either false positive or false negative results

Example 5:

A manufacturer determines that sesame analysis is required on chia seeds. The supplier of the chia seeds advises that ELISA is not a suitable method due to cross reactivity and PCR is the most appropriate method. The manufacturer contacts the laboratory to ascertain if they have reviewed the chia matrix as suitable for the kit under their scope of accreditation. They are advised that no cross reactivity is observed, and matrix suitability has been performed. This example demonstrates that a deeper understanding may be required to understand the differences in the methods available on the market and determine which ones may be more suitable for certain matrices. It is recommended that you contact your laboratory provider. Laboratory accreditation information can be obtained from ILAC (International Laboratory Accreditation Cooperation). For more information on food analysis refer to the Allergen Bureau information on Food Allergen Analysis.

Taking multiple representative samples, randomly, increases that likelihood of establishing the presence of the allergen when present heterogeneously (in particulate form). The application of a standardized approach to sample collection and how many samples are collected, assists FBO to establish the level of allergen risk which may exist.

4.7 Intended use of the analytical outcome

Similar to other risk assessments conducted in the food industry, the outcome of any risk assessment and/or control measures which are in place, should be verified. Verification ensures that the risk assessment outcome is as expected, that implemented controls are effective, and provides evidence to support the outcomes and allows for data trending to monitor for change.

The analytical outcome based on the number of samples analysed according to the risk rating can be used to:

1. Inform allergen management with regard to the control of allergen cross contact
   - The prevalence of detection in the number of samples analysed provides the FBO information on the type of allergen management controls that may be required in the facility to control the incoming risk. For example, greater controls may be required for material segregation, where the material is used on shared equipment, production scheduling and cleaning may need to be reviewed and it may allow the business to review alternative suppliers
2. Inform the VITAL risk assessment for the material
   - For example, where information may not be available from the supplier, or the material undergoes further processing, analytical results may be useful in the VITAL risk assessment
3. Inform other assessment (such as visual assessment) to further support and gain understanding in the prevalence of allergen presence in the material being assessed

Example 6:

If a particulate risk is identified in an ingredient and there is no further processing to change the form of the allergen, this would transfer through into the VITAL risk assessment as a 'Particulate' cross contact allergen, resulting in an Action Level 2 outcome and require Precautionary Allergen Labelling.

A particulate as defined in the Allergen Bureau Food Industry Guide to the VITAL Program document as a material that: does not mix homogeneously with other parts of the food and/or may consist of, or is likely to aggregate into an entity which contains equal to or greater than the Reference Dose.

It should be noted that depending on the presence and prevalence of detection in the number of samples analysed, the findings may impact the facilities allergen management program and the way in which the material is handled in the facility.

Example 7:

In many instances an inital particulate cross contact risk identified may be exposed to further processing to change the form of the allergen to readily dispersible. For example, the agricultural commodity may be milled or ground, such in the case of grains and spices.

Food allergen analysis may assist to determine the presence and prevalence of the cross contact allergen. It may also aid in providing data on the natural variability of the detectable concentration (ppm) of the allergen. The natural variation, combined with the prevalence of detection, can assist businesses in assessing the likely maximum level of cross contact present and further assist in the VITAL risk assessment evaluation.

In this scenario, although the cross contact allergen may appear to be homogenous in nature in the further processed commodity, it is important to note that it still meets the definition of a cross contact allergen in the VITAL Program – the cross contact is unavoidable and sporadic in nature.

However, it would not be considered industry best practice if results from the analysis were used by a FBO to inform a labelling decision without conducting a quantitative risk assessment. For example: if a particulate risk is identified, however allergen presence is not detected in the number of samples assessed, this does not mean that the risk no longer exists, and that the risk should not be communicated further in the supply chain. In fact, it would be considered industry best practice to communicate any level of risk that may exist to ensure that the supply chain is well informed and can use this information to inform downstream users in their own risk assessment and allergen management procedures.

4.8 Ongoing monitoring

As with all risk assessment processes, ongoing monitoring and verification activities are recommended based on the outcomes of the initial risk assessment of the raw material/ingredient under review. The frequency of ongoing monitoring as already described in the document, is a business decision. However, frequency can be based on the outcome of the risk assessment, any analytical data collected to support the management of the allergens in the facility, if there is a change to the supply chain, or in the event that an unexpected allergen detection occurs in a finished product or if a consumer complaint is received regarding an adverse reaction.

APPENDIX 1: SAMPLING RATIONALE

Several international standards applicable to sampling for agricultural risks (i.e. aflatoxins, GMO), sampling for specific commodities, as well as general sampling standards were reviewed to inform the number of samples that are required on completion of this Raw Material Risk Matrix Questionnaire and the level of risk determined.

It was evident from the review, that there was no current standard available which was appropriate to reference and reflect the number of samples that might be required to determine an allergen cross contact risk. The majority of risk based sampling plans are designed to provide guidance on either the number of samples that are required generally from a batch, such as those based on Acceptable Quality Level (AQL) approaches[9], or the number the samples that are required to be tested dependent on the number of units in a consignment, more notably seen in standards appliable to assessing commodity defects, for example EN ISO 948:2009 Spices and Condiments Sampling[8].

It should also be noted that sampling plans which are based on the number of units in a consignment, tend to result in a decrease of samples collected from the batch as the number of units increases. In almost all cases sampling plans also assume that any contaminant will be homogeneous, which will in many instances not be the case with agricultural cross contact. Depending upon where in the supply chain analysis is conducted and the level of value-adding which may occur, allergen cross contact could be either heterogenous or homogeneous in nature.

As such, the working group have used the supporting standards listed in the table below to determine the number of samples required dependent on the level of risk determined from the Raw Material Risk Matrix Questionnaire. Each question is weighted based on the working groups experience, historical data and the level of known risk that exist with several questions. The Raw Material Risk Matrix Questionnaire risk rating outcomes have been verified by several Allergen Bureau member companies, by comparison to existing company risk assessment processes.

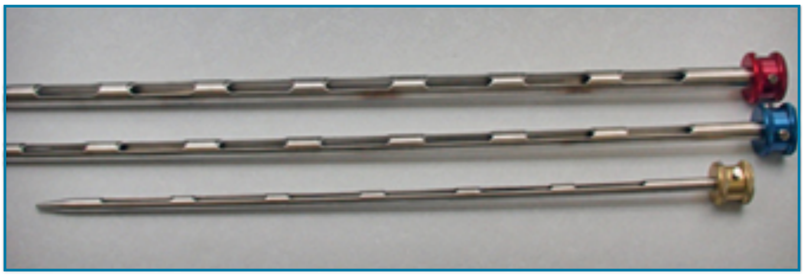
The sample number required is intended to increase based on the risk and has been chosen for its applicability irrespective of the lot size, allowing for the sample number to be determined by using square root or percentage calculations, whilst providing a minimum number of samples required to ensure that enough representative samples are taken from the lot size being assessed.

Risk Rating	Number of Samples	Supporting Standards
Low	5	EN ISO 948:2009 Spices and condiments Sampling[8]
Medium	Minimum 10. Square root of consignment (if above 100 units)	USFDA Investigations Operations Manual 2020 Chapter 4 – Sampling section 4.3.7.2 Random Sampling[12] EN ISO 948:2009 Spices and condiments Sampling[8] DS/CEN/TS 15568 2007 Foodstuffs – Methods of analysis for the detection of GMO and derived products – Sampling strategies, Section 7[7]
High	Minimum 15. 10 % of consignment (if above 150 units)	Codex CAC/GL 50- 2004, Table 8, page 34 based on the ICMFS Micro sampling guides[9] EN ISO 948:2009 Spices and condiments Sampling[8] DS/CEN/TS 15568 2007 Foodstuffs – Methods of analysis for the detection of GMO and derived products – Sampling strategies, Section 7[7]

APPENDIX 2: EXAMPLE SAMPLING DEVICES

Examples of Sampling Probes/Triers, sourced from the Canadian Grain Commission Sampling Systems Handbook and Approval Guide, Manual sampling[6].

Double Sleeve Trier



Nobble Trier

5. ENDNOTES

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