Guidelines on Allergen Advisory Labeling

(also known as Supplemental Allergy Statements or Precautionary Allergen Labelling, PAL)

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Document Purpose

Unintended allergen presence (UAP) occurs when a food allergen is introduced through cross-contact into a food that does not contain that allergen by design. Across the supply chain there may be various points of cross-contact that could result in UAP, including those related to agricultural practices, production processes, storage, and transportation. UAP can occur despite reasonable efforts being taken to prevent allergen cross-contact.

Current practices regarding the identification and communication of UAP are not harmonized across the supply chain. Allergen advisory labelling (also known as supplemental allergen statements, or precautionary allergen labelling, PAL) is used by food operators to communicate the potential for a risk to allergic consumers due to UAP. This Guideline is intended to assist with implementing common practice on what allergen information should be communicated between trading partners in supply chains, and how such information should be used to inform decisions on the labeling of UAP in finished products through PAL. Allergic consumers rely on accurate information on allergen presence to make decisions for any food they may consume, and the approach used by food operators needs to be consistent to provide the greatest benefit to consumer safety. The objective is communication of accurate information to enable consumers to make informed choices.

The intended audience for this Guideline is personnel within food businesses who are responsible for allergen management. This includes professionals responsible for finished product labeling and the food safety and quality roles that provide information necessary for labeling including product design, supplier management and production management.

Although the regulatory underpinning of allergen management is discussed, this Guideline is not intended to describe practices necessary for compliance with specific legislation. Furthermore, this Guidance is not intended to serve as a comprehensive guide for allergen management.

This Guideline provides the principles and steps in decision-making on whether PAL is appropriate to enable the following:

- Consistency across food businesses in decision-making on the application of PAL
- Harmonized application of allergen risk assessment tools and practices, including allergen quantitative risk assessment (QRA)

- Reduce the usage of PAL to situations where it is meaningful in terms of risk to allergic consumers, whilst not compromising consumer safety
- Promote a high level of consumer protection through the movement of reliable information across supply chains on the reasons for cross-contact occurrence and its characteristics.

Previously, some food industry stakeholders aligned around key criteria for consideration in allergy labelling (see Annex V for the Food Allergy Industry Alliance, FAIA 2001[5]). There is an opportunity to build upon these original criteria to better inform decisions on allergen labeling and specifically PAL. Since the original criteria, knowledge has been gained on topics related to the sourcing and production of food as well as advances in the clinical understanding of food allergies and scientific data supporting consumer safety through applied risk assessment models. As such, these guidelines include consideration of how food businesses can control allergens across supply chains, beyond just manufacturing, and incorporate recent advancements in the methods for risk assessment such as allergen quantitative risk assessment (QRA). Notably, developments in the approach to allergen risk assessment that enable informed conclusions on product safety, should be helpful in reducing unnecessary PAL that is based on practices of hazard identification only.

Background

Food allergy and risk assessment

An important role of the immune system is the surveillance of what is eaten to help prevent infection. Every person's immune system is different, due to both genetics and its adaptive nature. A key part of how the immune system functions is the recognition of proteins, which involves training on which proteins are innocuous and which signal the presence of a pathogen. Food is a major route of pathogen exposure, as such proteins within foods are processed by the immune system after ingestion and some proteins may lead to 'sensitization'. Sensitization is the process by which the immune system becomes primed to recognize when such proteins are eaten in the future, and through this mechanism, the potential to elicit a reaction may develop. Several types of cells are involved in the processing and recognition of food proteins which may ultimately lead to the production of antibodies against the part of the food protein that has been recognized. A specific type of antibody produced by the immune system is known as IgE, the physiological role of which is believed to be a response to parasitic infection, but it may erroneously be produced related to sensitization to other proteins present in foods. When IgE binds the protein which it has been produced to recognize, it can lead

to a rapid inflammatory response. It is for this reason that food allergy is sometimes known as 'IgE-mediated food allergy'.

There is a potential for the immune system to become erroneously sensitized and react to any protein in any food, however a limited number of foods are associated with the majority of food allergy, it is not fully understood why these foods are especially allergenic. These foods are commonly managed as the 'major' or 'priority' allergens including in a regulatory context. As discussed, it is the protein in these foods that can cause a reaction in consumers who are allergic to those foods. Ingredients derived from those foods that do not contain protein cannot cause an IgE-mediated food allergic reaction.

Although in theory allergic consumers could have the potential to experience reactions to very low amounts of allergenic protein that are eaten, in practice allergic consumers will only react objectively when exposed to allergen above a certain threshold amount, known as the 'eliciting dose' (ED). When an allergic consumer visits an allergy clinic they can have their ED assessed, and it is possible to gather this information from many allergic patients to create a chart of the amount of allergen and the proportion of the allergic consumers who experience a reaction. Using this approach, it is possible to select a point on the chart, such as the 'ED_{05}' (the amount of allergen that causes 5% of allergic consumers to experience a reaction), and use it to derive a 'reference dose' (RfD). Such RfDs incorporate conservatism in how they are calculated, and these data are reviewed based on the severity of reactions that the most sensitive consumers may still experience at and below the RfDs. The derivation of RfDs also considers the ability of analytical methods to detect allergens at these levels within food.

In the context of the UAP within a product due to agricultural comingling or cross-contact in the supply chain, a RfD can be used as a part of decision making on whether sufficient food safety risk exists to necessitate communication to consumers via PAL. Incorporating risk assessment into decision-making is important because there is a preponderance of PAL on food products, which in some cases may be unwarranted. The indiscriminate use of PAL contributes to an unnecessary lack of choice for allergic consumers and further promotes risk-taking behavior in a proportion of allergic consumers that ignore PAL on those products where it is warranted.

The process of Allergen Quantitative Risk Assessment (QRA) is a numerical comparison between a relevant RfD and consumer exposure to an allergen. Consumer exposure is itself a simple calculation using the amount of food consumed at an eating occasion and the amount of protein from the allergen within that food. However, allergen

exposure assessment (for use in QRA) should only inform a decision on PAL when the data available may not lead to an erroneous under-estimation. QRA can only be performed when suitable data are available on product consumption and the presence of protein from the allergen. It is for this reason, that allergen QRA demands a good understanding of the cause of cross-contact, so that the amount of cross-contact allergen can be estimated and verified.

Authority Expectations

The requirement to manage unintentionally present allergens, in order to protect the health of consumers, is enshrined within modern food safety systems. In the United States, food operators are required to comply with the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) for labeling and the Food Safety Modernization Act (FSMA) for preventive controls for allergens, including mitigation of allergen cross-contact. As elaborated in a 1996 FDA notice to food manufacturers[1] and reiterated in the 2024 Chapter 11 draft of the Hazard Analysis and Risk-Based Preventive Controls for Human Food[2]; PAL should not be used in lieu of adherence to current good manufacturing practices (cGMPs) or in lieu of the requirements for allergen cross-contact controls. This includes the evaluation of upstream suppliers such that they also are not using PAL in lieu of appropriate controls. Furthermore, it is stated that the use of PAL requires written justification, specifically why allergen cross-contact controls cannot ensure protection of food from allergen cross-contact.

The FAO/WHO Codex Alimentarius is an international body active in establishing common standards for food safety, and has played a central role on aspects of allergen management which are now enshrined in national regulations worldwide. The organization developed the original list of priority allergens and has recently updated that list together with a technical review on allergen risk assessment[3], including the derivation of suitable allergen RfDs. In order to assist food business in the implementation of such RfDs within allergen assessment, cross-stakeholder guidance has been developed and some trainings conducted[4].

At the time of writing there are national differences emerging in authority expectations on how allergen RfDs and allergen QRA may be used by food operators. For example, although the US FDA has not itself established allergen reference doses, the Agency does recognize that such reference doses are available and may be used by food operators as a part of scientifically valid assessments to facilitate decisions on appropriate food allergen controls, including voluntary labelling[3].

Principles & Decision-Making

Principles for decision-making on PAL

Once there is sufficient knowledge of supply chains and points of cross-contact are identified, risk to allergic consumers should be mitigated by one of the three following methods (presented in order of prioritization):

1 – Points of cross-contact should be controlled such that cross-contact potential is eliminated.

When a point(s) of cross-contact can only be minimized but not eliminated (there remains a chance of occurrence):

2 – It should be determined whether the point(s) of cross-contact is sufficiently controlled that an assessment of the magnitude of the risk presented by the cross-contact scenario demonstrates that health impact is minimized to an acceptable standard. This can be based on an understanding of established cross-contact scenarios* or allergen QRA (wherein predicted allergen exposure is compared to a relevant RfD) which should be documented.

In cases where health impact is not determined to be minimized to an acceptable standard:

3 - The potential presence of a priority allergen within a food should be communicated to consumers by the application of PAL.

Footnote:

* With many existing supply chains there is common knowledge of typical cross-contact scenarios. Further to this knowledge, there is considerable history regarding the magnitude or extent of cross-contact expected within supply chains. Allergen risk assessment should be based on the weight of all available evidence, including common knowledge and experience. This is particularly important due to the sporadic nature of many cross-contact situations and the limited ability of sampling and analytical testing to detect allergen presence. The potential co-mingling of commodity ingredients sourced through agricultural production is an oft-cited example for which there is potential for cross-contact and historical evidence typically supports safety for consumers considering the manner of use of these ingredients. However, case-by-case assessment remains necessary to determine whether any changes to historical practices in sourcing results in changes to the risk profile for the allergic consumer.

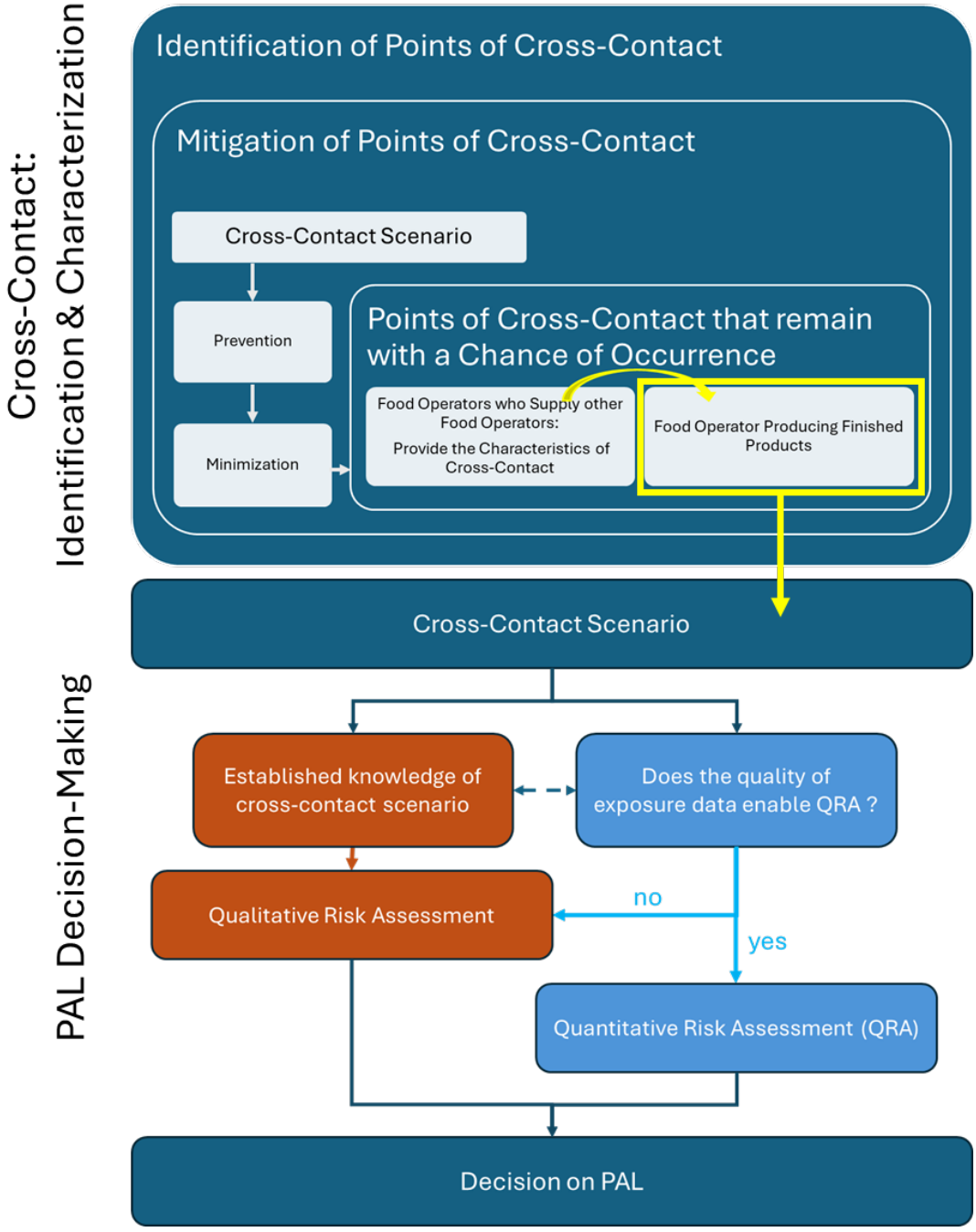
Framework for decision-making on PAL

The above Principles can be elaborated into a framework for decision-making on PAL, as shown in Figure 1. PAL should not be promulgated down a supply chain without justification. The reasons why the cross-contact could occur are a key input to understanding the potential for elimination or mitigation and for providing insight into the characteristics of the hazard profile. Theoretical points of cross-contact should not be assumed to result in UAP without evidence. Points of cross-contact should be identified, and those that have a chance of occurrence despite preventative measures should be characterized. The chance of occurrence identifies whether a potential point of cross-contact may actually lead to UAP. If the chance of occurrence is low, it should be considered whether mitigation measures can be applied such that there becomes effectively no chance of occurrence. If the chance of occurrence is unknown there should be an attempt to gather information to enable the assessment. Mitigation measures that effectively eliminate a chance of occurrence should be confirmed to be effective.

Cross-contact characterization provides data to inform both allergen risk assessment (including QRA when appropriate and possible) and appropriate controls necessary to validate and verify the risk. Information on the characteristics of cross-contact should be passed down the supply chain such that food operators producing finished products can reliably estimate risk when deciding on the need for PAL.

Decision-making on labeling should consider both established knowledge of the cross-contact scenario and whether the quality of available exposure data enables QRA. Established knowledge should be drawn from both experience of similar cross-contact scenarios and information on the specific scenario under assessment. QRA should only be performed if the available exposure data is coherent with an understanding of the cross-contact scenario and likely characteristics of UAP presence (note the dotted arrow in Figure 1). In the case that the quality of exposure data does not support QRA, the assessment should defer to the existing qualitative approach.

Figure 1: Framework for decision-making on PAL



Cross-Contact Identification & Characterization

Figure 1 provides a step-wise approach as follows:

- It is the responsibility of all food manufacturers (at all stages of the supply chain), to identify potential points of cross-contact within their operations.

- When a point of cross-contact has been identified, the reason for the cross-contact should be understood so that it can be prevented if reasonably possible.
- If the cross-contact cannot be prevented, it should be mitigated as much as possible and the cross-contact scenario documented, such that the information is available to downstream customers, or to enable a risk assessment by a finished food manufacturer. The cross-contact scenario consists of a summary of the following:
    a) The reason for the cross-contact (the physical way in which the cross-contact can occur),
    b) the chance of occurrence, and mitigation measures applied
    c) the characteristics of UAP including its concentration, form and distribution within the affected product
    - **Annex II** provides an example template of how information can be communicated across supply chains. Ingredient suppliers are encouraged to provide information within existing documents such as the technical data sheet for the ingredient. However, information can also be collected via survey, which if necessary can be complemented with additional questions case by case.
    - Concerning point b). food operators should have sufficient training that points of cross-contact that do not have a chance of occurrence are not communicated across the supply chain and to consumers. In practice, the concept of 'chance of occurrence' is linked to the frequency of cross-contact and uncertainty on whether UAP may ever occur. In the evaluation of whether a cross-contact has a 'chance of occurrence', food operators should differentiate between cross-contacts that are theoretical, likely to be infrequent, and with no evidence that it may happen, and those for which evidence is available or can be obtained that cross-contact leads to UAP.
    - If sufficient information is not available on the characteristics of cross-contact (for example alongside an indication from an ingredient supplier that there is a cross-contact and potential for UAP), it is not possible to perform a QRA, therefore a qualitative approach is required.
    - To facilitate a refined allergen risk assessment, exposure to UAP through all points of cross-contact should be considered. Exposure estimates should not underpredict and should include data from ‘reasonable worst case’ assumptions of cross-contact within production systems and when available data from analytical testing. The sensitivity, quality, and reliability of data should be considered in a risk assessment (see below 'understanding the quality of data').
    - On an on-going basis Good Manufacturing Practices, and where appropriate sampling and testing, should be applied to ensure that there is not a change in the chance of occurrence or characteristics of cross-contact for a previously

assessed point of cross-contact and associated UAP. Any such change necessitates a re-evaluation.

- The identification of cross-contact risks and their characterization should be recorded as a part of the labeling decision, an example template is provided in A**nnex III**.

PAL Decision Criteria

- When points of cross-contact have been assessed and determined to be able to be effectively controlled, PAL should not be applied. Precautionary allergen labeling should only be applied when cross-contact is plausible and following risk assessment it is determined that the magnitude of cross-contact is not minimized to an acceptable standard.

- When there is a chance of occurrence of cross-contact:
  - In the following situations PAL should not be applied:
    - there is established knowledge of the cross-contact scenario such that the magnitude of cross-contact is known to be managed such that health impact is minimized to an acceptable standard
      or
    - the quality of data on characteristics of cross-contact and consumption are sufficient to support an exposure assessment, and such exposure is below the relevant RfD
      or
    - the cross-contact scenario is sufficiently understood that it is possible to support a '*demonstrable over-estimate*' of exposure and such exposure is below the relevant RfD.
  - In the following situations PAL should be applied:
    - there is no established knowledge of the cross-contact scenario and
    - the quality of available data on characteristics of cross-contact and consumption does not support an exposure assessment or demonstrable over-estimate
      or
    - the quality of data on characteristics of cross-contact and consumption supports an exposure assessment (for comparison to allergen RfD) and the outcome of QRA concludes that the magnitude of cross-contact is not minimized to an acceptable standard.

In all cases, decision making on PAL should be captured, including the available evidence, see **Annex III**

Understanding the Quality of Data

To enable a QRA, it is necessary to understand the quality of the available data. Information is needed on the Characteristics of Cross-Contact and consumption of the affected food to enable an assessment of the exposure experienced by consumers to UAP (for comparison to a RfD). The type of data that may be available and how to use them within an exposure assessment are described in available guidance[4].

Allergen QRA cannot be used as a part of decision-making on PAL unless there is knowledge on the quality of the available data. It is important to understand whether the data available reflects the actual situation of cross-contact. The objective of this knowledge is to ensure that the exposure assessment follows the principle of 'reasonable worst case'. This means that allergen exposure is not underestimated but is also not beyond realism in terms of overestimation.

In practice this means that based on the cross-contact scenario and available data, there is assurance that the amount of allergen a consumer may be exposed is not greater than the exposure estimate. This is based on information on how the cross-contact occurs, so knowledge of how much allergen could enter an affected product, supported by any analytical data which may be available, in addition to the quantity of that product which may be consumed. These parameters should be feasible, so realistic given the cross-contact scenario, but represent a realistic worst case in terms of the amount of allergen that may be present and consumed. In this way if the output from a QRA is that the risk to allergic consumers is acceptable, there is confidence in this conclusion.

It should be noted, that in situations where there is doubt on the accuracy of the data on the characteristics of cross-contact, it is possible to perform a 'demonstrable worst-case' over-estimate of exposure for use in QRA. Demonstrable over-estimates of exposure are possible when there is theoretical knowledge of the amount of UAP that could feasibly have occurred and provide assurance that actual consumer exposure is not higher. Guidance is available on performing exposure assessments as a part of QRA[4].

Roles of Food Operators

Table1: Quick Reference on the Roles of Food Operators

	Suppliers of Foods that are not finished foods	Finished Food Operators
Required Activity	➢ Consider globally-relevant priority allergens and allergens of relevance to the relevant jurisdiction. ➢ Evaluate supply chain for points of cross-contact, the potential sources of UAP. ➢ Verify there is a real chance of occurrence of cross-contact (that it is not a hypothetical possibility only). ➢ Collect and document data: the cross-contact scenario, the reason for cross-contact, preventative measures, frequency and characteristics of cross-contact.	➢ The decision on whether to apply PAL to a finished food product should follow a documented risk-based logic, including: • The decision on the appropriate method of risk assessment, the conduct and outcome of that assessment, and the decision on whether PAL is appropriate based on that outcome.
Required Communication	➢ Provide information such that customers can be confident that all priority allergens for the market of supply of the ingredient, and intended market of sale of the finished product if such information is provided by the customer, have been considered within the assessment process. ➢ Where information is not available or has high uncertainty, this should be stated.	➢ The presence of PAL should communicate a tangible allergen risk that cannot reasonably be otherwise controlled. ➢ Provide information such that consumers can be confident that products have been through an assessment process that covers the full supply chain. As such, there should be assurance that information that is communicated on UAP, via PAL in the case of finished foods for consumers, is an outcome of that process. ➢ There should be a record of decision-making logic on the application of PAL, which should include how knowledge on the characteristics of cross-contact and food consumption informed the decision. This should include information from the full supply chain (upstream, co-manufacturers and in-house operations).

Annex I: *Definitions and Abbreviations*

- ***'Allergen reference dose' (RfD):***

an amount of total protein from an allergen expressed in mg that is considered as tolerable for a population of allergic consumers when eaten at or below this amount. Reference doses should be science-based, published, and recognized (for example within the Codex Alimentarius).

- ***'Agreed limit of acceptability'*** *(in the context of allergen quantitative risk assessment)**:***

refers to whether consumer exposure to an allergen is greater or less than the allergen reference dose and therefore whether risk management measures are appropriate such as the application if PAL.

- ***'Chance of occurrence'*** *(of cross-contact)**:***

Describes whether or not a point of cross-contact may actually lead to unintended allergen presence.
Notes: this is a phrase used in allergen risk assessment instead of the concept of 'likelihood' common to HACCP-type risk assessments (which was designed to compare between different types of risks across a supply chain). The concept of 'likelihood' causes confusion when applied to allergen risk assessments, as it combines both the frequency of occurrence and the chance of occurrence. For this reason, allergen risk assessments separate these terms (see Annex for further explanation).

- ***'Characteristics of cross-contact'***:

the criteria that describe the physical attributes of cross-contact:

  - concentration
  - form & distribution
  - frequency

- ***'Cross-contact':***

the situation whereby a priority allergen unintentionally becomes a part of another food that does not contain that allergen. prepared.

- **'Cross-contact scenario'**:

the physical events that occur at that point of cross-contact to result in UAP, including the estimated chance of occurrence including frequency. Fully evaluated cross-contact scenarios include a description of mitigation measures and the characteristics of UAP.

- '***Demonstrable over-estimate***'

Refers to situations wherein the cross-contact scenario is sufficiently understood that the physical parameters that lead to UAP can be over-estimated with certainty. For example, the maximum amount of product from preceding production that could theoretically have entered the subsequent production run.

- ***'Elimination' / 'eliminated'*** *(of cross-contact)**:***

this is when a point of potential cross-contact will not result in the occurrence of cross-contact. This may either be because the point of cross-contact under evaluation was theoretical only and investigation has shown it does not have a chance of occurrence or because control measures have been successfully applied to a point of cross-contact.

- ***'Point(s) of cross-contact':***

a location where cross-contact can occur within a supply chain. Points of cross-contact between foods can happen due to agricultural practices or at any stage as foods are

- ***'Precautionary allergen labelling (PAL)':***

a risk management tool to communicate the potential unintentional presence of allergen within a food to customers and ultimately the consumer.

- ***'Reasonable worst case'*** (in the context of allergen exposure assessment)

the use of data on allergen occurrence, concentration, and consumption such that there is assurance that the estimated exposure is not less than that which would be foreseeable to occur (i.e. exposure is not under-estimated). An example would be assuming a high amount of food consumption, as per available technical guidance (ref). However any over-estimation should not be unrealistic, the exposure should be feasible given the cross-contact scenario under investigation.

- **Unintended allergen presence (UAP):**

the presence (or potential presence) of an allergen within a foodstuff that has not been intentionally used as a part of the preparation of the foodstuff (i.e., not an ingredient or processing aid). Note, UAP is the physical presence of cross-contact allergen within a food, this is subsequent to the 'point of cross-contact' which is how allergen may enter the food and 'cross-contact' which is the act of cross-contact occurring.

Annex II: *Communicating cross-contact information across supply chains.*

Suppliers of foods that are not finished products (such as ingredients, composites, semi-finished foods) should provide for their customers information on cross-contacts that may result in UAP in the supplied material.

Preferably this information should be made available pro-actively, the preferred method of communication is via technical information for the supplied material. However, it is common practice for trading partners to exchange questionnaires that include questions related to allergen presence.

Allergen information via technical information sheets.

Recommended format for customer communication on cross-contact information within technical information sheets:

Cross-Contact Scenario

Description of the reason for the cross-contact
Description of the mitigation measures, and remaining chance of occurrence
Source and description of data provided

Characteristics of Cross-Contact

Form and distribution of UAP	**Frequency of UAP**	**Concentration of UAP due to cross-contact**
Description including whether the UAP is: ➢ Amorphous ➢ Particulate & ➢ Homogeneous ➢ Heterogeneous	Description including whether the UAP is likely to have: ➢ Isolated presence ➢ intermittent presence ➢ regular presence	Description of the concentration of UAP, and how the data has been obtained: ➢ Estimate only ➢ Analytical point data ➢ Analytical data range Note, concentration is normally expressed as mg/kg protein. In the case of particulates the size/weight and number should be provided.
Description of the certainty of the above information, based on supporting evidence, does the information have: ➢ Acceptable uncertainty ➢ Medium uncertainty ➢ High uncertainty		

Allergen information via ingredient questionnaire.

It is common practice for customers purchasing ingredients to require the vendor to complete an 'ingredient questionnaire'. As there is limited information that can be incorporated into such questionnaires, a format is proposed whereby key data is captured via questionnaire, which can be supplemented if requested by the customer with additional information.

Example of a questionnaire format to gather qualitative and quantitative information on allergen presence from suppliers.

	Qualitative Information						**Quantitative Information**	
Allergen	Presence Direct add or cross-contact	Labeling Exempt from labeling	Labeled as cross-contact	Source of allergen	Source of cross-contact Cross-contact due to shared production line	Other sources of cross-contact, e.g. co-mingling, storage, transport, present at same site	Form & Distribution	Concentration of protein from allergen (+size of particulates if present)
Example: in the case of supplied ingrdient peanut butter: Nut almond	Cross-contact	no	yes	Almond paste	yes	none	Amorphous, homogeneous	1.5 – 150 mg/kg

Supplementary information that should be made available to supply chain customers upon request.

Parameter	To be provided
Cross-contact scenario (route)	How cross-contact can happen resulting in UAP
Preventative measures	Evidence of controls (for example cleaning of shared line)
Chance of occurrence	What circumstances result in UAP (what fails / cannot be controlled)
Frequency	Likelihood of presence in any delivery
Source of data provided	Source of any quantitative data provided, including whether analytical testing has been performed, frequency of testing, method LoQ and uncertainty.

Annex III: *Example Template for PAL decision-making for a finished food product*

Record of decision-making for PAL (identification of product, production locations, assessment date)	
Step 1: identification of points of cross-contact	
Upstream (supplied materials)	Information from suppliers (available via ingredient technical sheets or questionnaires)
In-house	Information on points of CC
Step 2 : characterization of cross-contacts	
Cross-contacts that have a chance of occurrence (and thereby lead to UAP)	➢ Reason for the cross-contact(s) ➢ Preventative measures that have been applied and why there remains a chance of occurrence ➢ Likelihood of UAP occurring (frequency)
In the case of each identified cross-contact that has a 'chance of occurrence' perform the following steps	
Characteristics of cross-contact ➢ Form & distribution of CC within affected product ➢ Concentration of CC within affected product	Summarize available information including how it was obtained (source of data)
Step 3: PAL decision-making	
Step 3a: decision on the method of risk assessment	
Are the available data on the characteristics of cross-contact sufficient to support QRA ?	Determine whether available data is representative and of sufficient quality. This should include whether information from the 'cross-contact scenario' enables either a 'reasonable worst-case' exposure estimation or a demonstrable over-estimation of exposure
Food consumption	Quantity of the affected food that may be consumed per eating occasion
Is it appropriate & possible (based on data) to perform QRA ?	Yes – goto step 3b No – decision-making is limited to qualitative approach, record outcome in step 4
Step 3b: QRA conduct and outcome	
QRA conduct	Summarize QRA inputs, calculation, result
QRA outcome	Is risk to allergic consumers managed such that health impact is minimized to an acceptable standard (exposure greater or less than the relevant RfD) ?
Step 4: Conclusion	
Labeling decision	Whether or not PAL should be applied for specified allergen for the product (indicate whether qualitative approach was used and under what circumstances the assessment would need to be reviewed)

Annex IV: *Examples of PAL Decision-Making*

Information communicated from supplier via technical data sheet
Ingredient: smooth peanut butter paste
Cross-Contact: almond paste

Cross-Contact Scenario	
Description of the reason for the cross-contact	Shared production lines, peanut butter and almond paste.
Description of the mitigation measures, and remaining chance of occurrence	Wet cleaning does not remove residues and creates micro concern, equipment tear-down and clean is performed monthly. Despite push through and discard of subsequent product, residue of previous production can remain in subsequent product. Push through and discard of first 2 mins of subsequent production.
Source and description of data provided	During the production runs that happen before and after every equipment tear-down and clean, verification of residual carry-over is undertaken, immediately after change-over and every 10 mins until 2 hours subsequent production. Gradual reduction in concentration is measured as the subsequent production run progresses.

Characteristics of Cross-Contact		
Form and distribution of UAP	**Frequency of UAP**	**Concentration of UAP due to cross-contact**
Description including whether the UAP is: **Amorphous and homogeneous**	Description including whether the UAP is likely to have: **Intermittent**	Description of the concentration of UAP, and how the data has been obtained: **Data range 1.5 to 150 mg/kg almond protein within peanut butter**
Description of the certainty of the above information, based on supporting evidence, does the information have: **Acceptable uncertainty**		

Record of labeling decision-making:

Record of decision-making for PAL cereal bar brand product x243 SKU yz123, sunny town site, 15 Oct 2025	
Step 1: identification of points of cross-contact	
Upstream (supplied materials)	Technical data sheet (attached), almond within peanut butter
In-house	none
Step 2 : characterization of cross-contacts	
Cross-contacts that have a chance of occurrence (and thereby lead to UAP)	See attached supplier information, technical data sheet
In the case of each identified cross-contact that has a 'chance of occurrence' perform the following steps	
Characteristics of cross-contact	Peanut butter is used as a drizzle on top of cereal bar, so equally spread across the bar, each bar is sized as

➢ Form & distribution of CC within affected product ➢ Concentration of CC within affected product	an individual portion at 38 g but are packaged in pairs. Each bar contains not more than 5g peanut butter (with up to 150 mg/kg almond protein).
Step 3: PAL decision-making	
Step 3a: decision on the method of risk assessment	
Are the available data on the characteristics of cross-contact sufficient to support QRA ?	Acceptable quality data available
Food consumption	For labeling purpose a portion is one bar, however they are packaged in pairs and so it is assumed that a consumption event would be 2 bars, 76 g
Is it appropriate & possible (based on data) to perform QRA ?	Yes
Step 3b: QRA conduct and outcome	
QRA conduct	Worst case 150 mg/kg almond protein within peanut butter which is used as drizzle on a cereal bar at not more than 5g per bar. Equals 0.75 mg almond protein per cereal bar. Assume that 2 cereal bars may be eaten at a consumption event, equals 1.5 mg almond protein. RfD for almond[(3)] = 1 mg RfD is exceeded.
QRA outcome	The health impact is not minimized to an acceptable standard
Step 4: Conclusion	
Labeling decision	PAL should be applied 'may contain almond' Note, although serving size of 1 bar meets the acceptable standard for exposure to almond protein, it should be assumed that 2 bars may be eaten in which case exposure would not meet the acceptable standard for allergic consumers.

Annex V: *Previous Food Industry Guidance: Food Allergy Issues Alliance, Food Allergen Labeling Guidelines. 2001*

Food Allergy Issues Alliance

FOOD ALLERGEN LABELING GUIDELINES

Introduction

The Food Allergy Issues Alliance is a group of food trade associations and other interested organizations that convene to discuss issues related to food allergy. During 2000 and 2001, the Food Allergy Issues Alliance has been discussing numerous options related to labeling of Major Food Allergens (defined in Section A of this document), focusing on those options that would not require new regulations.

Food allergies affect an estimated six to seven million persons in the United States. Some of these sensitized consumers can develop serious or life-threatening allergic reactions if exposed to the causative proteins. Currently, there is no cure for food allergies. The only successful method to manage food allergies is to avoid foods containing the causative proteins. Food processors must be diligent in informing food allergic consumers about the presence of Major Food Allergens in their products. This information, which is communicated on food labels, is intended to help food allergic consumers make a clear decision about whether or not a food is appropriate for them to eat.

The food industry has taken numerous steps over the past several years to address the needs of food allergic consumers, including changes to manufacturing processes to reduce the potential for cross contact with Major Food Allergens. The food industry recognizes that under existing good manufacturing practice (GMP) regulations, reasonable precautions must be taken to prevent cross contact with major allergenic proteins. In instances when cross contact cannot be avoided, even when complying with GMPs, food and ingredient manufacturers use labeling that informs the food allergic consumer of the possible presence of allergens in the food.

Food manufacturers label the ingredients in their products in accordance with existing regulatory requirements. The Food Allergy Issues Alliance recognizes, however, that consistency in labeling of food allergens could further address the needs of food allergic consumers, and has developed these Food Allergen Labeling Guidelines to address those needs. Eighteen food, consumer and health organizations, and one scientific advisor have signed on to the Food Allergen Labeling Guidelines.

The Food Allergen Labeling Guidelines:

A. Identify the Major Food Allergens.

B. Advocate the use of terms commonly understood by consumers (i.e., "plain English"[1]) for Major Food Allergens within, or in immediate proximity to, the ingredient declaration, to provide clear communication with the food allergic consumer.

C. Call for manufacturers to disclose the presence of Major Food Allergens when they are an intentional part of the food, regardless of source. Thus, Major Food Allergens would be disclosed regardless of the fact they may otherwise be exempted from declaration (e.g., as part of a flavor, or as an incidental additive or processing aid).

D. Establish guidelines for conditions when the use of supplemental allergen statements is appropriate.

All companies in the food industry are encouraged to adopt and adhere to the following labeling guidelines for Major Food Allergens.

A. Major Food Allergens

The Food Allergen Labeling Guidelines focus on the Major Food Allergens, which have been estimated to cause more than 90% of all food allergic reactions. For the purposes of this program, the Major Food Allergens are defined[2] as the allergenic proteins from:

1. Crustaceans (such as crab, crayfish, lobster, and shrimp)
2. Eggs;
3. Fish;
4. Milk;
5. Peanuts;
6. Soy;
7. Tree nuts (almonds, Brazil nuts, cashews, chestnuts, filberts/hazelnuts, macadamia nuts, pecans, pine nuts, pistachios, and walnuts); and,

[1] The Food Allergy Issues Alliance recognizes "plain English" as a simple term of art for terms commonly understood by consumers. However, "plain English" is not appropriate terminology to reference the names of Major Food Allergens with respect to bilingual or multi-lingual food labels.

[2] FAO. 1995. Report of the FAO Technical Consultation on Food Allergies. Rome: Food and Agriculture Organization.

8. Wheat.

Additional food allergens may be added to this list of Major Food Allergens as their public health importance becomes recognized.

An ingredient that is derived from a Major Food Allergen is not subject to these guidelines when it does not contain the causative allergenic protein. By way of example, highly refined peanut and soybean oils would not be subject to these labeling guidelines to the extent that the allergenic proteins are not present in the oils.

B. Use of Ingredient Terms Commonly Understood by Consumers

Ingredient terms commonly understood by consumers for the Major Food Allergens in the product should appear within, or in immediate proximity to, the ingredient declaration of the food label. Examples of acceptable ingredient terms commonly understood by consumers of Major Food Allergens include, "eggs," "fish," "milk," "peanuts," "shrimp," "soy," "walnut," or "wheat."

The ingredient terms commonly understood by consumers should be disclosed by following the label declaration options presented in Section C of these guidelines.

C. Label Declaration of Major Food Allergens

A food that contains a protein of a Major Food Allergen should be labeled in a manner that informs the consumer of the allergen's presence, regardless of its source. Ingredient declarations, which appear on the information panels of food labels, are the primary vehicle for communicating information about food allergens to the at-risk population. Information on Major Food Allergens should appear within, or in immediate proximity to, ingredient declarations.[3]

A Major Food Allergen should be disclosed even where a labeling exemption might otherwise apply (e.g., as a component of a flavor). Food processors should request from their suppliers, and those suppliers should provide, information about the presence of Major Food Allergens in all food ingredients, such as flavors. Food processors should carry this information forward to the ingredient declarations on labels of foods that use those ingredients.

[3] Some foods that are introduced unlabeled into interstate commerce for final labeling or further processing at a different location (21 CFR 101.100(d)) should include information on the presence of Major Food Allergens in the labeling that accompanies such shipments.

The ingredient terms commonly understood by consumers for Major Food Allergens should be disclosed on the information panel, within, or in immediate proximity to, the ingredient declaration, by using one or more of the following methods:

1) The use of a statement, such as "Contains _____," with the blank filled in with the ingredient term commonly understood by consumers for Major Food Allergens (*e.g.,* Contains soy and milk). This statement may be prefixed by an allergy information statement phrase (e.g., Allergy information: Contains soy and milk"). This statement should be placed at the end of, or in immediate proximity to, the ingredient declaration.

2) The use of an asterisk or other reference mark next to the ingredient name or class name that refers the consumer to a statement that identifies the ingredient term commonly understood by consumers for Major Food Allergens. This statement should be placed at the end of, or in immediate proximity to, the ingredient declaration. For products that contain two or more ingredients that contain the same Major Food Allergen, the same asterisk or other reference mark should be placed after each relevant ingredient in the product. For example, "casein*, whey*, semolina†, natural flavor†" would appear in the ingredient declaration, referring the consumer to a statement such as "*milk, †wheat" following the ingredient declaration.

3) The use within the ingredient declaration of a parenthetical statement following the ingredient name or class name that identifies allergens that are present in the ingredient (e.g., natural flavor (peanuts and soy), whey (milk)).

4) The use within the ingredient declaration of a name that identifies the presence of the allergen such as "natural walnut flavor," or "natural peanut flavor."

5) The use of bolding or other highlighting within the ingredient declaration or in allergy information statements in immediate proximity to the ingredient declaration.

Food companies also should follow FDA's current guidance[4] regarding the labeling of "incidental additives" that contain or are themselves a Major Food Allergen, by declaring the Major Food Allergen in the ingredient list of the food.

[4] June 10, 1996, FDA Allergy Warning Letter, is attached as Appendix A. April 2001 Compliance Policy Guide, Sec. 555.250 "Statement of Policy for Labeling and Preventing Cross-contact of Common Food Allergens," is attached as Appendix B.

D. Supplemental Allergen Statements

Food processors that prepare foods potentially exposed to inadvertent contact with Major Food Allergens acknowledge that labeling is not a substitute for good manufacturing practices (GMP).

Supplemental allergen statements should be used judiciously only when all four of the following criteria are met:

1) The presence of a Major Food Allergen is documented through visual examination or analytical testing of the processing line, equipment, ingredient or product, or other means;

2) The risk of presence of a Major Food Allergen is unavoidable even when current GMPs are followed;

3) A Major Food Allergen is present in some, but not all, of the product; and,

4) The presence of a Major Food Allergen is potentially hazardous.

If some, but not all, of these criteria are met, food and ingredient manufacturers should consider food allergen control and/or labeling strategies other than supplemental allergen statements.

When all four of these criteria are satisfied, the supplemental allergen statement should be placed in close proximity to the ingredient declaration. When using an ingredient that utilizes a supplemental allergen statement, the food processor should carry that supplemental allergen statement forward to the label of its food only when these four criteria are met. Any supplemental allergen statement should be as accurate and conspicuous as possible, to help allergic consumers make a clear decision about whether or not the food is appropriate for them to eat. Any supplemental allergen statement should be placed at the end of, or in immediate proximity to, the ingredient declaration.

Food processors should strive to label the same product consistently, even if it is produced in different locations or in different package sizes. Such label consistency would be useful to food allergic consumers.

May 22, 2001

References

1 - FDA Allergy Warning Letter June 10, 1996, NOTICE TO MANUFACTURERS, Label Declaration of Allergenic Substances in Foods
2 - Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry. Chapter 11: Food Allergen Program. https://www.fda.gov/media/172318/download
3 - Ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens. https://www.who.int/groups/ad-hoc-joint-fao-who-expert-consultation-on-risk-assessment-of-food-allergens
4 - Practical Guidance on the Application of Food Allergen Quantitative Risk Assessment (QRA). ILSI Europe. https://ilsi.eu/publication/practical-guidance-on-the-application-of-food-allergen-quantitative-risk-assessment-qra/
5 - Food Allergy Issues Alliance, Food Allergen Labeling Guidelines. 2001. Industry trade association document. Provided in Annex V