

FDF Guidance on Change Management of Allergen Information

“ Foreword

I am very pleased to welcome this new allergen labelling guidance from the FDF. People with food hypersensitivity need good information about the food they buy to keep themselves safe. It's therefore vital that businesses are able to apply allergen labels accurately and consistently. This guidance provides important advice on the application of precautionary allergen, or 'may contain' labels. The FSA's research has shown that people with food hypersensitivity and food businesses are concerned about how 'may contain' labels are used and this guidance should provide clarification. This is very important to help people with a food hypersensitivity who may not always scrutinise food information on products they purchase regularly and trust. The FSA takes seriously its responsibility to protect the interests of people with a food hypersensitivity. Helping businesses to get their labelling right is an important part of this work and I encourage businesses to use this guidance as part of their allergen management processes.

Susan Jebb OBE, Chair, Food Standards Agency (FSA)



MANUFACTURERS: Only use allergens essential to a recipe

This guidance outlines the actions a food business operator (FBO) should consider when managing changes that impact the allergen labelling on pre-packaged products. Key best practice considerations include the use of additional communications and the importance of information sharing across the whole supply chain.

It is best practice to only use allergenic ingredients essential to a product's recipe. FBOs should inform consumers of any change in allergen information and encourage consumers with food allergies to always check labels. Many manufacturers choose to alert consumers to allergen information changes on the front of pack (e.g. 'New recipe' or 'Allergen Update') to immediately inform allergic consumers about a change in a product's allergen profile.



Allergen profile changes may result from the following:

- 1. Intentional allergen presence:** the addition or removal of an **allergenic ingredient** due to product reformulation, new ingredients including additives, flavourings, processing aids and changes in supply chain (this is a non-exhaustive list).
- 2. Unintentional allergen presence:** farm to fork changes in **cross-contact risk** and controls and are not part of the recipe e.g. contamination arising from supplier, equipment, production environment (this is a non-exhaustive list).

The information on the following pages provides guidance on the steps that should be considered in each scenario. These are not presented in a specific order however should be incorporated into each FBO's food safety management procedures as appropriate.

Allergen labelling and risk communication Any pre-packaged food and drink product which contains any of the 14 regulated food allergens must declare these within the ingredients list in an emphasised format (e.g. bold). It is a manufacturer's responsibility to conduct a proper risk assessment and inform consumers where there is an unavoidable risk of unintentional allergen presence by the use of precautionary allergen labelling (e.g. 'may contain ...' statement).

Allergen risk assessment FBOs should conduct risk assessments to determine the potential allergenic risks in their manufacturing environments, and this should include a rigorous assessment of ingredients, processes, and supply chain. Change management processes should then establish the steps needed to be taken when the allergen profile of a product changes. The considerations listed below should be reflected upon and used as a guide to evaluate and, where necessary, redesign existing processes.

1. Intentional allergen presence

A deliberate presence of an **allergenic ingredient** is where allergens are intentionally used as part of the recipe or product formulation. It may be necessary to reformulate an existing product and change its recipe, which can add or remove an allergenic ingredient. Whilst the addition of an allergenic ingredient carries a higher risk, it is important that both addition and removal of an allergenic ingredient requires careful consideration. The process of managing allergenic ingredient addition or removal should include conducting an allergen risk assessment, identifying control measures and implementing a plan to effectively inform customers and final consumers.

A. Addition of allergenic ingredient in existing recipe

- Identify the issue, describe the reason for the change, conduct allergen risk assessment and establish required changes
- Conduct a label change review: allergen(s) to be declared and emphasised in the ingredients list
- Where appropriate, consider how final consumers are to be informed of the new allergen(s), label change and over what time period
- Optional label communication examples: 'New recipe' front of pack alert including a signpost of either: 'see back of pack' or 'see ingredients list' / 'Allergy Update' front of pack alert including a signpost of either: 'see back of pack' or 'see ingredients list' / 'New allergen information' front of pack alert including a signpost of either: 'see back of pack' or 'see ingredients list'. Continued use of the alert to be reviewed after 6-12 months (depending on product shelf life)
- Update product data on all brand websites including associated nutritional websites/apps and customer services/care line training based on the new allergen(s)
- Develop a process of informing customers, such as other food businesses buying for use in their operations, about the impact of the added allergen(s) (e.g. label change and over what time period)
- Consider the product turnover at customer and impact of packaging stocks
- Assess impact on barcode / Global Trade Item Number (GTIN) - new GTIN needed. Update internal reference codes and product change codes for B2B (business to business) as necessary
- Consider informing relevant allergy charities of added allergen(s) who can directly alert those consumers they are in contact with who, are most at risk

B. Removal of allergenic ingredient from existing recipe

- Identify the issue, describe the reason for the change, conduct allergen risk assessment and establish required changes
- Conduct a label change review: remove allergen declaration and emphasis from the ingredients list
- Where appropriate, consider how final consumers are to be informed of the removed allergen(s), label change and over what time period
- Optional label communication examples: 'New recipe' front of pack alert including a signpost of either: 'see back of pack' or 'see ingredients list' / 'Allergen information changed' front of pack alert including a signpost of either: 'see back of pack' or 'see ingredients list'. Continued use of the alert to be reviewed after 6-12 months (depending on product shelf life)
- Update product data on all brand websites including associated nutritional websites/apps and customer services/care line training based on the removed allergen(s)
- Consider a process of updating customers, such as other food businesses buying for use in their operations, about the impact of the removed allergen(s) (e.g. label change and over what time period)
- Consider the product turnover at customer and impact of packaging stocks
- Assess impact on barcode / Global Trade Item Number (GTIN) - no change expected
- Consider informing relevant allergy charities of removed allergen(s) (i.e. more consumer choice)

MANUFACTURERS: The addition of an allergenic ingredient carries a higher risk to consumers

2. Unintentional allergen presence

A non-deliberate allergen presence in food due to a **cross-contact risk** where contamination could occur anywhere from farm to fork. It may be necessary to change the precautionary allergen labelling (PAL) statement (e.g. 'may contain') on an existing product label as result of a change in cross-contact risk. PAL statements are currently voluntary, and its absence does not mean a food product is 'Free-From' an allergenic ingredient. The use of PAL should be based on a risk assessment that demonstrates a risk of allergen cross-contact that cannot be sufficiently controlled.

Precautionary allergen labelling (PAL) – 'may contain [allergen]'

- **PAL is an unavoidable cross-contact risk** PAL statements should only be used where a risk of allergen cross-contact is identified that cannot be sufficiently controlled (e.g. by segregation or cleaning)
- **PAL is NOT a disclaimer to avoid legal food safety management responsibilities**
- **The absence of a PAL statement does NOT mean the same as a substantiated 'Free-From' claim**

A. Addition of PAL

- Describe the reason for the change, conduct allergen risk assessment and establish required changes
- Required label change: add new PAL statement on label once authorised
- Where appropriate describe how final consumers are to be informed of the labelling change and over what time period
- Optional label communication example: 'Allergy Update' front of pack alert including the signpost: 'see back of pack'. Continued use of the alert to be reviewed after 6-12 months (depending on product shelf life)
- Update all brand websites and associated nutritional websites and customer services/care line training with any changes based on new PAL
- Develop a process of informing how customers (e.g. other food businesses buying for use in their operations) are to be informed of the labelling change and over what time period
- Consider the product turnover at customer and impact of packaging stocks
- Assess and consider impact on barcode / Global Trade Item Number (GTIN) – new GTIN needed
- Update internal reference codes and product change codes for B2B as necessary
- Consider informing relevant allergy charities about added PAL who can directly alert those consumers they are in contact with who, are most at risk

B. Removal of PAL

- Describe the reason for the change, conduct allergen risk assessment and establish required changes
- Required label change: remove the PAL statement from existing label once authorised
- Where appropriate, describe how final consumers are to be informed of the labelling change and over what time period
- Optional label communication example: 'Allergen information changed' front of pack alert. including a signpost: 'see back of pack'. Continued use of the alert to be reviewed after 6-12 months (depending on product shelf life)
- Update of all brand websites and associated nutritional websites and customer services/care line training with any changes based on the removed PAL
- Develop a process of informing how customers (e.g. other food businesses buying for use in their operations) are to be informed of the labelling change and over what time period
- Consider the product turnover at customer and impact of packaging stocks
- Assess and consider impact on barcode / Global Trade Item Number (GTIN) – no change expected
- Consider informing relevant allergy charities about removed PAL (i.e. more consumer choice)

Additional resources



FSA Technical Guidance on Food Allergen Labelling and Information Requirements

This updated publication aims to help food businesses follow national allergen labelling requirements and helps authorised food officers enforce these measures.



FSA Precautionary Allergen Labelling Guidance

This guidance for small food businesses advises on the use of precautionary allergen labelling, such as 'may contain'.



FSA Precautionary Allergen Labelling Checklist

A checklist to help businesses understand when and how to apply precautionary allergen labelling to food products.



FDF Guidance on 'Allergen'-Free and Vegan Claims

It may be necessary to have PAL on a vegan product. This FDF guidance aims to dispel any misunderstanding that a vegan claim automatically means a food product is safe and suitable for an allergic consumer. Food businesses should follow a rigorous risk assessment of the ingredients, process, and environment of the products entire supply chain.



FDF/BRC Guidance on 'Free-From' Allergen Claims

A growing number of food business operators are making "free-from" allergen or "allergen-free" claims for their food products. This guidance advises food business operators on the appropriate use of "free-from" claims in relation to food allergens.



FDF Gluten Labelling Guidance: Best Practice for Prepacked Foods which Include or Exclude Cereals Containing Gluten

This UK best practice guidance aims to provide advice to food business operators, irrespective of size, on how to label food products that include cereals containing; alongside the claims that can be made relating to the absence or reduced presence of gluten (e.g. gluten-free).



Allergen Bureau Unexpected Allergens in Food Guide

This guide provides the food industry with a list of foods, ingredients and raw materials that may unexpectedly contain allergens, and a list of questions food business operators can ask their suppliers which support the allergen risk review process.

FDF allergens toolkit (FDF members' only)

FDF membership – reasons to join