

Allergen Recall Prevention



Foreword: This new allergen recall prevention guidance is a welcome addition to the suite of FDF information designed to help businesses understand their manufacturing responsibilities. It closely aligns with the FSA's priorities to better protect people, widen their choices, and support food businesses in achieving compliance.

More than two million people across the UK are affected by food hypersensitivity (food allergies, food intolerances and coeliac disease), with the most serious cases of food-induced anaphylaxis causing up to ten deaths annually. Food manufacturers need a robust system that covers the entire manufacturing operation to help identify and mitigate potential allergen issues, to ensure product safety for people with food allergies. It is crucial they understand the pitfalls that may lead to food safety incidents and how effective allergen management can help minimise the potential recall of products.

This guidance highlights important factors that should be considered when businesses assess allergen risks and also provides useful areas of focus when investigating the causes of allergen-related incidents to prevent future occurrences.

The FSA has a long-term ambition to improve the quality of life for people with food hypersensitivities. I encourage food businesses to read and use this FDF guidance to develop and maintain effective allergen risk management systems to help protect their customers".

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



Introduction

Incorrect or incomplete allergen information on food is extremely serious as it presents a high food safety risk to the allergic consumer. It also results in cost to business due to the need for product withdrawals and recalls. This guidance aims to help food manufacturers prevent, manage and investigate food allergen-related incidents or 'near-misses'.

This guidance supports food companies, particularly smaller ones, that make pre-packaged foods to identify the problem(s) that cause allergen incidents, determine appropriate actions to prevent their occurrence/re-occurrence and subsequently eliminate the need for future withdrawals or consumer recalls.

It provides a starting point for those companies who are not used to investigating allergen incidents, but this information is not exhaustive as each manufacturer has its own unique processes, suppliers and products. It is important food manufacturers consider this guide in the context of their own allergen risk assessments.

Food allergen incidents can occur for various reasons, but most recalls in the UK are caused by labelling or packaging errors and include:

- 1 Incorrectly or not declaring allergenic ingredients**
- 2 Mismatch of product to packaging**
- 3 Incorrect 'free-from' allergen claims**
- 4 Not declaring unintentional allergen presence – 'May contain'**

Each are examined in further detail within this guidance with key prevention considerations provided



Allergen Risk Management System

Food manufacturers need an allergen risk management system that covers all production stages. This needs to include assessments across the entire manufacturing operation (internal and external) to help identify and mitigate potential allergen issues, ensuring product safety for consumers with food allergies.

If a food incident occurs, it is best practice to investigate in order to identify its underlying causes. This can be undertaken by root cause analysis (RCA) using any of the established methods. Based on the outcomes, food businesses should then develop mitigation steps that prevent future incidents. It is important to establish a review period to assess the effectiveness of these steps in improving food allergen management.

Several methods are available to conduct root cause analysis (RCA). The two commonly used are:

1. Fish Bone (Ishikawa)

Identify all possible causes that contributed to the problem across several categories such as: People (training); Environment (layout); Method (instructions); Plant (infrastructure); Equipment (digital) & Material (Composition)

2. Five Whys

Ask a series of 'why' questions until the nature of the incident is uncovered and the actual root cause(s) is/are identified.

(Not limited to just five questions and can be used alongside the Fish bone method)



Continuously improve allergen management plans by applying findings from root cause investigations

1 Incorrectly or not declaring allergenic ingredients

When an intentionally used allergen is not declared or is incorrectly declared (e.g. not in English or not emphasised)

Where could this occur?

Multiple stages in the production process, such as: regulatory compliance (e.g. domestically manufactured or imported products), supplier or product specifications approval, product design, packaging design, label/artwork creation and printing, website information management.

Problems that can cause food allergen recalls:

Inadequate supplier approval, inadequate training and supervision, inadequate artwork design verification, ineffective communication (e.g. between marketing, technical and import teams), inadequate or failure of process and procedures (e.g. label verification, documentation inadequate quality checks), inadequate website/digital platform management, insufficient regulatory knowledge, and equipment malfunction.

Key prevention considerations: to avoid incorrect allergen declarations

- Establish and maintain a process for approving ingredient specifications with suppliers and consistently follow up.
- Conduct verification checks to ensure ingredients and packaging match the expected allergen profile.
- Implement a supplier management system that includes agreements for suppliers to notify of any changes in ingredient/allergen profiles, with periodic reconfirmation.
- Develop a detailed, multi-step process for artwork creation and management, requiring formal approvals against established standards.
- Accurately transfer ingredient lists from product specifications to artwork, recipes, and bills of materials, ensuring allergens are correctly emphasised in ingredient list (e.g. casein (milk)) and in the correct language (i.e. English)
- Maintain an accurate, controlled specifications database with version history, serving as the single source of data for artworks, recipes, and technical documentation.
- Regularly review allergen risk assessments, including thorough label and packaging checks to ensure allergen declarations are correctly emphasised.
- Establish a continuous allergen management training program to ensure all personnel clearly understand processes and a process to check this understanding.
- Stay updated with regulatory changes and ensure compliance with the latest allergen labelling requirements and official guidance.
- Where possible, use technology to automate allergen ingredient tracking and declaration processes, reducing the risk of human error (e.g. barcode scanning).
- Establish a management process to control, with appropriate allergen labelling, the import of products from multiple manufacturing sites (e.g. domestic and internationally manufactured).

**Check allergen information on all
raw materials and ingredients**

2 Mismatch of product to packaging (mispacks)

When the packaging doesn't accurately represent the product inside (e.g. product in wrong packaging or use of wrong label)

Where could this occur?

Multiple stages in the production process, such as: packaging design approval, storage, selection and allocation of packaging (e.g. film or labels), packaging transfer to production line, selection and packing of product, labelling.

Problems that can cause food allergen recalls:

Lack of proper training and supervision, labelling and artwork complexity (e.g. similarity in design, use of multiple labels), insufficient quality checks (e.g. robust label checks), labelling equipment or machine issues (e.g. breakdown, uncalibrated, outdated/ malfunctioning software), and inadequate standardised processes (e.g. storage and segregation, packaging allocation, line clearance).

Key prevention considerations: to avoid mispacks

- Ensure a well-organised storage system, with physical separation, clear identification labelling and secure transport to the production line, for all raw materials and packaging.
- Integrate within the production site's allergen management procedures a segregation process for allergens.
- Establish a selection process with verification checks for product recipes and packaging identification (e.g. use of codes to issue stock).
- Have a robust line clearance procedure to remove previous product and packaging from production lines before starting a new product.
- Carry out visual label verification checks during packaging changes to ensure continuous compliance. Where possible use automated or digital solutions, such as scanners or barcodes, to enhance accuracy and efficiency.
- Include allergen risk analysis for rework or 'add-back' activities to ensure consistency and safety.
- Conduct scheduled internal housekeeping reviews or audits to maintain high standards.
- Provide ongoing training and briefings on updated allergen procedures for all relevant personnel.
- Confirm that outsourced printers have systems to consistently update to the latest 'approved' artwork.
- Consider a system of removal of old artwork designs so that they are not available to be used by accident.
- Effectively manage digital information, including the use of barcode scanning systems, to confirm the correct labels or correct packaging are issued and applied.
- Maintain a library of retained products to verify packaging used in case of complaints and for potential testing.
- Develop quarantine and disposal procedures for outdated packaging to prevent its reintroduction into the production area.
- Have a process of document control to ensure the use of the current artwork and specifications, and the retirement of outdated versions.

Mispacks are very high risk to allergic consumers as they can hide the presence of allergenic ingredients

3 Incorrect 'free-from' allergen claims

When a 'free-from' allergen claim declared on a product is incorrect due to it containing that allergen as an ingredient or via unintended presence (e.g. may contain)

Where could this occur?

Multiple stages in the production process, such as: regulatory compliance, recipe development, supplier risk assessments, approval stages, product specifications, product design, label/artwork creation, printing and website information management.

Problems that can cause food allergen recalls:

Inadequate risk assessment, invalidated production process, inadequate allergen testing, poor allergen management practices; inadequate cleaning, faulty product recipe control, process control failures (e.g. equipment/ machine failure, poor label management)

Key prevention considerations: to avoid incorrect allergen absence claims

- Establish a thorough process for checking, approving, and monitoring ingredient specifications with suppliers for both deliberate and unintentional allergen presence.
- Verify that all ingredients used in production match the criteria for declaring a 'free-from' claim.
- Implement a process with multiple checks for artwork creation and formal final approval to ensure accurate 'free-from' claims.
- Inspect and confirm that prepacked foods are correctly labelled with accurate allergen information.
- Regularly allergen test product samples to substantiate 'free-from' claims.
- Conduct regular training sessions on updated procedures for all production and packaging personnel.
- Cross-reference ingredient lists with product recipes to ensure accurate 'free-from' allergen labelling.
- Periodically review suppliers to verify their allergen management practices and the integrity of their 'free-from' ingredients.
- Implement traceability systems to track ingredients from source to final product, ensuring the integrity of 'free-from' claims.

False or unsubstantiated 'free-from' allergen claims are a high risk to allergic consumers, as they are relied upon for making safe food choices

4 Not declaring unintentional allergen presence

When a non-deliberately added allergen has been incorporated into a product and not declared on the label (e.g. 'may contain')

Where could this occur?

Multiple stages in the production process, such as: regulatory compliance, supplier and raw material approval stage, storage, risk assessments, cleaning, preparation and processing (e.g. weighing), assembly of the product, product packing, labelling and product despatch.

Problems that can cause food allergen recalls:

Inadequate supplier verification, inadequate risk assessment, poor label management; Lack of proper allergen training; process control failures (e.g. equipment/ machine failure), ineffective quality control (e.g. segregation, cleaning).

Key prevention considerations: to avoid incorrect unintentional allergen presence communications

- Establish a clear process for verifying the allergen profile/status of all ingredients, including compound ingredients, processing aids and additives.
- Incorporate questionnaires to assess potential allergen cross-contact risks at your supplier's site, especially if there is a precautionary allergen labelling (PAL) statement (e.g. 'may contain').
- Implement a supplier approval process that includes allergen risk assessment, establish continuous monitoring and ensure suppliers notify you immediately of any changes to the allergen profile of ingredients and raw materials.
- Maintain effective segregation strategies to minimise the risk of allergen cross-contact, such as dedicated storage for allergenic ingredients.
- Plan production to prevent the risk of allergen cross-contact (e.g. group similar allergen-containing products) and implement verified hygiene protocols between different allergen batches.
- Communicate the production plan to all relevant personnel, with visual aids where necessary.
- Where possible, use colour-coded containers, tags or separate utensils for ingredient identification and traceability during weighing.
- Have a procedure in place to effectively manage allergen ingredient spillages.
- Understand the cleaning requirements for equipment to ensure the complete removal of allergenic material, whether through CIP (Clean-in-Place) or full strip-down methods.
- Implement validation and conduct verification processes for cleaning to confirm the complete removal of allergens.
- Regularly clean the tools used for cleaning to prevent cross-contact.
- Where possible, consider the use of color-coded cleaning tools, overalls, aprons and gloves to minimise cross-contact and highlight allergen handling areas or separate cleaning tools.
- Partner and work with accredited laboratories to discuss allergen testing needs and to ensure reliability.
- Implement a process of review and regular training on site policies and allergen handling procedures, and schedule equipment maintenance to uphold safety standards.

Work with your suppliers to understand the allergen cross-contact risk of all ingredients

Resources

[FSA/FSS Guidance on Food Traceability, Withdrawals & Recalls within the UK Food Industry](#)

This aims to help UK food businesses comply with laws, manage food safety incidents ([including incident reporting](#)) and ensure effective traceability, withdrawals, and recalls.

[FSA/FSS An Introduction to Root Cause Analysis Course](#)

This helps food businesses understand the theory and practice of root cause analysis, and how its use and reporting could reduce the number of recurring food safety incidents.

[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 Food Allergy and Intolerance Training](#)

This interactive training has been developed by the Food Standards Agency (FSA) for Local Authorities' enforcement officers. However, it might also be of interest to food industry organisations and businesses, consumers and others who would like to learn more about food allergies and how to handle allergens safely.

[FDf Guidance on Allergen Label Change Management](#)

This guidance outlines the actions a food business operator (FBO) should consider when managing changes that impact the allergen labelling on pre-packaged products.

[FDf Guidance on 'Allergen'-Free and Vegan Claims](#)

This 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](#)

This UK best practice guidance aims to provide advice on how to label food products that include cereals containing gluten 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.

[Allergen Bureau Allergen Risk Review Website](#)

This is a freely available interactive factory map that shows where allergen risks can occur in different areas of a food manufacturing facility.

[FDf allergens toolkit \(FDf members' only\)](#)
[FDf membership – reasons to join](#)