Purpose

To establish an allergen management programme with the adequate controls to avoid allergen cross-contact and appropriately educate colleagues to be able to effectively manage the associated risks associated with allergens, to include cross-contact.

All allergens present in Central Production Units must be controlled to ensure that they do not contaminate product, where they are not listed on the ingredient declaration.

Allergens should not be seen in isolation as a group of allergens, but as individual allergens. The aim is not to just prevent allergen containing products from contaminating non-allergen containing products. But also, prevent allergen containing products from contaminating other allergen containing products. For example, a product containing milk, must be prevented from contaminating a product containing nuts and vice versa.

Where materials are unpackaged, a full allergen risk assessment is required to identify the controls. Where products are packaged, a reduced risk assessment can be completed, which focuses on the risks of damage and cross-contact due to spillages.

Allergens in scope

1. Cereals containing Gluten*	2. Celery
3. Crustaceans	4. Egg
5. Fish	6. Lupin
7. Milk	8. Molluscs
9. Mustard	10. Peanuts
11. Sesame	12. Soybeans
13. Sulphites	14. Tree Nuts

*In line with the Coeliac Society UK, Gluten containing grains are considered as; Barley, Bulgar Wheat, Couscous, Durum Wheat, Einkorn, Emmer (Faro), Khorasan wheat (Kamut), Pearl barley, Rye, Semolina, Spelt, Triticale, Wheat. Barley Malt Extract, and Oats.

Allergen mapping and risk assessment

A risk assessment is required to establish what controls are required. The risk assessment must be completed in stages, as follows:

- Materials and physical properties
- Recipe, process, and equipment steps

Materials

Opened materials must be risk assessed, including additives and processing aids to establish:

- If allergens are present in each material
- If there is a risk of cross-contact to each material, prior to delivery

The information required will be taken from material specifications and, where this level of detail is not supplied on the specification, a questionnaire should be sent to the supplier to complete.

Physical properties
The risk assessment must assess the physical state of the material, as certain materials are more likely to pose a higher risk of contamination that others:

- Powders are more likely to be airborne, contaminating materials in the area
- Sticky or fatty ingredients are more likely to adhere to surfaces, making cleaning more difficult
- Materials made up of particulates (such as nibbed nuts) can get lodged in equipment, making cleaning and removal more difficult

Recipe
Work in progress materials, rework and products must then be assessed, to determine:

- The presence of allergens in the recipe
- The risk of allergenic contamination from one recipe to another

Process steps
The final stage of the risk assessment is to assess the risk of cross-contamination from the process:

- From movement of colleagues involved in the process
- From the use of shared equipment
- From airborne movement or splashing of the materials
- The risk of allergenic cross-contact from one material to another

Controls

Where risks are identified, controls appropriate to the level of risk must be determined, documented and implemented.

The risk of cross-contact can be reduced through the use of the following techniques:

- Physical segregation of allergenic containing materials
- Systems to restrict the movement of airborne dust containing allergenic material
- The use of separate or additional protective overclothing when handling allergenic materials
- Effective cleaning
- Segregation of allergen containing materials through time, through the scheduling of production
- Effective waste handling, storage and disposal
- Spillage control
- Restrictions on food brought onto site by colleagues, visitors or contractors

Even where on-pack alibi warning labels are used, the above controls must be applied where they physically can be, as they represent established good allergen practices.

Validation

Validation should be carried out to demonstrate that the cleaning procedures work, and this should include worst-case cleaning trials. Worst-case based on the most difficult equipment to clean, the most difficult product to clean off the equipment, and the product with the highest content of the allergen in question.

- Worst-case swabbing of the processing equipment before cleaning, to prove the allergen is present
- Swabbing of the processing equipment after cleaning, to prove cleaning was effective
- Analysis of the product from the previous run, to prove that the allergen was present in the product
- Worst-case analysis of the product from the current run, to prove there's no trace allergen present (worst-case based on the first-off samples, which would have the greatest contamination pick-up)
- Sampling and testing following accredited laboratory methods, which are suitably sensitive

Rapid tests, ATP and lateral flow devices are acceptable to validate that cleaning activities are effective, but for ongoing verification, swabs and lab testing should be used to demonstrate the validated process can be verified ongoing.

The cleaning procedures must be revalidated where there is a change to the procedure, the materials used, and the equipment being cleaned. The required allergen cleaning procedure must also be considered, when specifying and purchasing new equipment.

Cleaning verification

The validation must be used to determine verification activities for cleaning, for example, visual inspections and documented sign-off, inclusion in internal audits and the use of swabs or testing (such as Rapid tests, ATP, lateral flow devices or laboratory tests).
Where in-house testing is carried out for allergens, positive control testing must be carried out routinely, to confirm that it will detect the allergen if it's present in a real sample.

Claims

Where a 'free from' claim is made regarding the suitability of a food for allergy, intolerant or sensitivity sufferers, the process must be fully validated, to prove that stated claim can be achieved consistently. The validation must cover cleaning, and this must be completed over a number of production runs to prove that the results are consistent.

Verification of claims

The elements validated must then be used to form the routine verification activities. Verification activities for products with allergen claims should be more rigid, and at a greater frequency than products without these claims, due to the increased risk to the consumer. Where the verification activity fails, corrective action must be recorded and must include any product potentially affected. The failure must be assessed to root cause, to determine preventive actions. Verification of the materials must be monitored through a combination of testing and supplier verification methods.

On-pack warning labels

Where all possible controls have been implemented and a documented risk assessment demonstrates that there is still a a risk of cross-contact, a warning (for example a precautionary May Contains message) should be included on the label or in the specification of the product. The use of a precautionary allergen warning label is not a substitute for good hygiene and allergen practices. National legal labelling requirements must be used when using precautionary allergen warning statements and where these are used, the reference must be documented, with Primary Authority oversight and input required.

Purchasing controls

Allergenic materials must be listed on an approved allergen tracker, including non-edible materials such as lubricants and pest control chemicals. Colleagues must be trained to ensure that they do not purchase materials, other than those on the approved supplier list and allergen tracker, due to the risks involved. Where new materials are needed, the procurement of these materials must follow the necessary approval procedures, prior to purchase.

New product development

Where allergenic materials are brought onto site for product development, that are not on the approved allergen tracker, they must be controlled. Where allergenic materials are required for trials, they must be risk assessed through the product development process before they are approved to enter the Unit.

Physical segregation

Allergenic materials must be physically segregated from non-allergenic materials, through the application of dedicated storage areas or dedicated areas within a store area, and where possible dedicated equipment, tools and utensils.

Airborne risks

Where allergens are handled in the form of fine powders, the movement of airborne dust should be minimised by using physical barriers to separate areas, dedicated and designated handling areas, the use of closed containers and exhaust extraction. The location of air-conditioning or fans should be positioned to ensure these do not aid the distribution of airborne allergens.

Scheduling

Where recipes must be processed in the same area or on the same processing lines, the processing runs must be scheduled based on the allergen risk. All non-allergenic recipes should be produced before allergenic recipes, and then allergens introduced to the schedule, in such a way that it minimises the risk of allergen cross-contamination. Scheduling should be used to minimise the occurrence of changeovers between allergen containing and non-allergen containing recipes. Where possible, it's good practice to limit the use of allergens to the end of a shift or production week, followed by a deep clean.

Personal food

It may be necessary to restrict allergens on site. This includes food brought in by colleagues, by visitors and contractors.

Hygiene controls

Equipment and area cleaning procedures must be designed to reduce allergen contamination to acceptable levels. Cleaning equipment used to clean allergenic materials must be identifiable for the specific allergen use (colour-coded or labelled), single use, or effectively cleaned after use.

Spills

An allergen spill is defined as a spill that puts other materials at risk of cross-contact in the immediate vicinity. It is not a spill of materials where there is no cross-contact risk, for example, during normal production where the material around the spill is contained in the same recipe. Where an allergen spill occurs, a procedure must be in place to ensure that the contamination risk is contained and removed. All allergen spills must be recorded in a non-conforming product.

Waste
Waste which contains allergens should be removed so that the removal process doesn't become the source of allergen contamination in other areas of the factory.

Material intake
Allergenic materials must be listed on an approved allergen tracker, that's used at material intake - to ensure that materials are handled correctly.

Material storage
Allergenic materials should be segregated during storage, where practical. However, as a minimum the materials must be segregated where required by customers or where there's a risk of cross-contamination from spillage. Where materials are not segregated and are stored in packaging which is prone to breakage (such as paper sacks), these materials must be stored at ground level to reduce the risk of contamination if they get damaged.

Processing equipment
Where equipment (including tools and utensils) is solely dedicated for allergenic use, it must be colour-coded or suitably labelled, so that it is clearly identifiable.

Protective clothing
Protective clothing can be a source of allergen contamination; therefore, the use of separate PPC should be considered. Where it's used, it should be colour-coded so that it's easily identified – this indicates to others working in the area that an allergenic product is being handled.

Rework
Rework should only be reworked into the same product.

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