



QM 2.8 Allergen Management

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2.8.1 Allergen Management (Mandatory)

2.8.1.1 The responsibility and methods used to control allergens and to prevent sources of allergens from contaminating products shall be documented and implemented. The allergen management program shall include:

- A risk analysis of those raw materials, ingredients, and processing aids, including food grade lubricants, that contain food allergens;
- An assessment of workplace-related food allergens that may originate from locker rooms, vending machines, lunchrooms, and visitors;
- A list of allergens that is applicable in the country of manufacture and the country(ies) of destination, if known;
- A list of allergens that is accessible to relevant staff;
- The control of hazards associated with allergens and incorporated into the food safety plan, and
- Management plans for control of the identified allergens.

Gluten Free Facility

The PFF factory is a Gluten Free facility, therefore, the only place where Gluten is permitted is the break room. There is NO purchasing, handling, or processing of ingredients containing Gluten (a protein found in wheat, rye, barley and similar grains). Specific information concerning Gluten Free practices and controls is found in PFF Gluten Management Policy (QM 2.8a).

Responsibilities

Position	Responsibility
Compliance Manager (SQF Practitioner)	Ultimate Responsibility for Allergen Management system Review of preprinted labels Perform Internal Audits of system Answer staff or customer inquires about allergens
Service (R&D)	Consider Allergen implications when selecting new ingredients and when doing new formulations
QC/Compliance	Conduct allergen/gluten testing
Production (Scheduler)	Schedule in a way to minimize Allergen cross contamination
Materials (Purchaser)	Purchase from suppliers with Allergen Control programs, and be aware of "may contains".
HACCP Team	Perform risk assessments of allergen containing raw materials, ingredients, packaging, processing aids, and food grade lubricants. Perform validation of food surface cleaning practice policy.
Mixing Supervisor Packing Supervisor	Oversee Allergen Cleans Review batch sheets for Allergens
Materials Department	Ensure Allergen Labeling occurs during receiving Ensure that "less or like above" is followed (do not stack allergens over materials that don't contain that allergen)
All Personnel	Adherence to this Allergen Management system Receive Allergen Management training Ask supervisors or Compliance Department if they are unsure of allergens contained in a material Report any instances of suspected allergen contamination



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Risk Analysis

During product realization, and during the annual review of the HACCP plan, a risk assessment is done by the HACCP team of all allergen-containing raw materials, ingredients, packaging, processing aids, and food grade lubricants. This risk analysis helps identify the potential for allergenic cross-contamination and applies the appropriate measures to control them. These measures are documented in the PFF Food Safety Plan.

Cleaning practices concerning food contact surfaces must also be validated as appropriate by the food safety team according to risk, legal requirements, and as sufficient to remove all potential allergens (including aerosols as appropriate) to prevent allergen cross-contamination.

Verification of Allergen Controls

The Allergen Management system must be reviewed by the Food Safety / HACCP Team at least annually and/or in the event of a non-conformance and updated if necessary. The Compliance Manager conducts allergen management system audits on-site at least annually. *Verification and Validation* of proper handling must be done through inspection of cleaning techniques, scheduling practices, accuracy of information in the tracking of allergens, and results from 3rd party labs who perform allergen testing **annually** on finished products.

Risk analysis must be followed by the implementation of procedures for validation and verification of effectiveness concerning cleaning and sanitation of areas and equipment in which allergens are handled.

Allergen Register

A register containing materials and their allergens is maintained by the Compliance Department. This register generates the allergen information on production batch sheets. Copies of Spec sheets from material manufactures disclosing allergen risks are maintained by the Compliance Department with assistance from the Materials Department.

Allergens found at PFF for Blending and Packaging	
	Dairy / Milk
Tree Nut (Almond, Cashew, Pecan)	Egg
Milling Line - No Allergens Used	
Allergens not found at PFF	
Wheat/Gluten	Peanut
Crustaceans	Fish
Sesame	



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Accessible to Staff

Personnel working with allergenic materials have access to the allergen register and are also informed by their batch paperwork of allergens present. Ingredients with allergens show those allergens on their identification label.

Allergen Hazards and Controls

Hazard(s) associated with allergens (commonly anaphylactic shock) have been considered in the HACCP Plan, and controls have been established as part of the Pre Requisite Program and label inspection.

2.8.1.2 Instructions shall be provided to all relevant staff involved in the receipt or handling of raw materials, work-in-progress, rework, or finished product on how to identify, handle, store, and segregate raw materials and products containing allergens.

PFF personnel receive training on the types of food that can cause allergic reactions which also includes a briefing on what allergens are, and what allergens are handled at PFF.

2.8.1.3 Provisions shall be made to clearly identify and segregate foods that contain allergens. Segregation procedures shall be implemented and continually monitored.

Allergen Identification and Segregation during Receipt, Storage, and Handling

The Compliance Manager and the Purchasing Supervisor work together to check raw materials and supplier information for the presence of allergens and label requirements. Together they must advise the Food Safety Team concerning potential raw material risks prior to use in manufacturing. This helps identify and control allergen hazards.

Purchases must only be made through approved suppliers and to approved specifications.

Suppliers are required to notify us prior to any changes regarding allergen status. This includes sending us an updated allergen matrix or allergen declaration, and an updated specification if allergens or new allergens are added to their facility or to shared lines that could impact our product.

Materials (ingredients, packaging materials, processing aids) containing allergens, list those allergens on their identification label(s). These allergens are also listed on the batch sheet.

Allergen Storage: Less or Like Above & Segregation

Allergen ingredient storage is limited to the allergen production room. Any batches being set up (majors / kitting and minors / pre-weighing) should have allergens added last and only added once the batch is brought into the allergen production room. These batches should not return to the main warehouse. The bin containing the allergen WIP will be stored in the allergen room.



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Any material stored below must contain all of the allergens stored above it. A material stored below may have all of those allergens and more, but not less.

Shelf	Permitted	Permitted	Not Permitted	Not Permitted
Top	No Allergen	No Allergen	Egg and Dairy	Egg
Middle	Egg	Egg	Egg	Tree Nut (no Egg)
Bottom	Egg and Dairy	Egg	No Allergen	Tree Nut

Storage of Finished Product (FIN)

FINs should be stored in their own area, but FINs containing allergens that are double packaged (inside a unit package inside a case packaging, or other bag in a box) may be stacked in any position (is exempt from Less or Like Above rules) due to the allergen being fully contained with negligible chance of cross contamination. FINs that are only unit wrapped or otherwise single barrier packaged, such as 25 or 50 lb bags, must follow Less or Like Above rules.

Storage of Packaging Materials (PKG)

Packaging supplies must be stored in their own area or on top storage racks (when segregation is not possible). Packaging may not have allergen containing ingredients, WIP or single packaged FINs stacked above them.

2.8.1.4 Where allergenic material may be intentionally or unintentionally present cleaning and sanitation of product contact surfaces between line changeovers shall be effective, appropriate to the risk and legal requirements, and sufficient to remove all potential target allergens from product contact surfaces, including aerosols as appropriate, to prevent cross-contact.

Separate handling and production equipment shall be provided, where satisfactory line hygiene and clean-up or segregation are not possible.

2.8.1.5 Based on risk assessment, procedures for validation and verification of the effectiveness of the cleaning and sanitation of areas and equipment in which allergens are used shall be documented and effectively implemented.

2.8.1.6 Where allergenic material may be present, product changeover procedures shall be documented and implemented to eliminate the risk of cross-contact.

Prevention of Contamination during Cleaning

Equipment / Line Cleaning

Whenever the batch before has allergens that this batch doesn't, a food safety clean is needed.

Batch 1	Batch 2	Food Safety Clean Needed?	Reason
Egg, Tree Nut	Egg	Yes	Batch 2 doesn't contain Tree Nuts, so a clean is required to remove that allergen
Dairy	Tree Nut	Yes	Batch 2 contains a different allergen (Tree



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			Nut) from Batch 1 (Dairy)
Egg	Egg, Tree Nut	No	Batch 2 contains all of the allergens that Batch 1 contained, therefore won't be contaminated
Egg	Egg	No	Batch 1 and Batch 2 contain the same allergens

Production (Mixing or Packing) Supervisors must review cleans to ensure they were done correctly. Scheduling should always be done in a way that minimizes allergen contamination risks. Minimizing allergen contamination also minimizes cleans required and leads to a more efficient schedule. Start production cycles with least allergen products, and end with the most allergen intensive.

Line Segregation	
There are separate rooms which contain bins, augers, and drop stations for allergen and non allergen materials.	
Material Type	Room to Use
ING with allergens WIP with allergens	Allergen Dump Station only Allergen Tote Dumper and Auger Filler only
ING with no allergens WIP with no allergens	Non Allergen Dump Station only Non Allergen Tote Dumper and Auger Filler only

All production food contact tools (utensils, scoops, buckets, and brushes) must be labeled and segregated according to their allergen use as much as possible. Employees working in the allergen room will wear a blue coat when instructed.

During batch preparation, operator(s) must use disposable paper or plastic bags for preparing dry ingredients (primarily during pre-weigh). Each label must be specific to the identified allergen on the premises.

Any new or used equipment coming into the facility must go through the commissioning process with approval from the Compliance and Maintenance Departments.

Any used, aftermarket, refurbished, or rehabilitated equipment will require prior approval from Kitchen with Confidence. Pure Functional Foods will notify Kitchens with Confidence prior to installation of equipment at CFFsupport@menutrinfo.com.

2.8.1.7 The product identification system (refer to 2.6.1.1) shall make provision for clear identification and labeling, in accordance with the regulatory requirements of those products produced on production lines and equipment on which foods containing allergens are manufactured.

2.8.1.8 The product trace system (refer to 2.6.2) shall take into consideration the conditions under which allergen-containing foods are manufactured and ensure full traceback of all ingredients and processing aids used.



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Identification and Trace Concerning Allergenic Ingredients

Mixing product batch sheets clearly record what materials and lots were used, and show what allergens are contained within the batch. WIP Lot code shows what bin the product was made in.

Finished Material product batch sheets show what WIP and other materials were used, and the FIN Lot code tells which production line was used.

2.8.1.9 The site shall document and implement methods to control the accuracy of finished product labels (or consumer information where applicable) and assure work-in progress and finished product are true to label with regard to allergens. Measures may include label approvals at receipt, label reconciliations during production, destruction of obsolete labels, verification of labels on finished products as appropriate, and product change over procedures.

The Compliance Department (typically the Compliance Manager) and R&D reviews all labels and pre-printed materials (any material bearing an ingredient statement and/or allergen declaration) at receiving (QA inspection) and applies the identification label to the materials.

A pre-printed materials register with an example of each lot is also maintained for reference.

The batch sheets list all the materials required along with their allergen and certification status, the allergen and certification status of the part being made, and has an arming code preventing the mis-selection of parts.

Any destruction of obsolete pre-printed packaging is overseen by the Compliance Department. (See also *Waste Management for this topic*)

2.8.1.10 Re-working of product (refer to 2.4.6) containing food allergens shall be conducted under conditions that ensure product safety and integrity are maintained. Re-worked products containing allergens shall be clearly identified and traceable.

Rework

Rework of products containing allergens must be conducted according to the same allergen control criteria and methods as stated in this policy. Product safety and integrity must be maintained during rework and reworked products must be clearly identifiable and traceable. Scheduling rework must be done by properly taking into account any allergens present in any previous batches and the batch scheduled for rework on lines and machinery.

2.8.1.11 Sites that do not handle allergenic materials or produce allergenic products shall document, implement and maintain an allergen management program addressing at a minimum the mitigation of introduced or unintended allergens through supplier, contract manufacturer, site personnel, and visitor activities.



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There are food dispensing machines in the facility, located at the main employee entrance foyer. Employees go through allergen training which includes hand washing when leaving the cafeteria and before entering production areas. Allergen signs and hand washing signs are posted in the employee cafeteria and in the entrance foyer as well as a sign reminding people where eating is allowed.

All contractors and visitors are escorted when they are in the building. The escorts are responsible for making sure that contractors, suppliers, and visitors are following all food safety programs while they are in the facility.

Suppliers are required to go through the supplier approval process which includes requiring an allergen program or statement be provided.