This presentation contains the Kraft Foods requirements for a proper allergen management at the production facilities. The supplier is responsible for implementing the requirements described on the following slides.
Agenda Topics

- Introduction
- Allergen Management System
  - Allergen risk Assessment
  - Allergen Management
    - SQE Allergens
    - Allergens and HACCP
    - Manufacturing control
    - Allergen testing, verification & validation

- Q&A
Kraft Foods Expectations

- Effective programme to manage allergens
- Allergen management programme based on risk-assessment (HACCP principles)
- Avoid the use of allergens where possible
- Cross-contact from ‘avoidable’ allergens strictly managed
- Cross-contact from ‘unavoidable’ allergens clearly communicated
- Effective allergen training programme – relevant to job responsibilities
Allergen Procedures

KRAFT FOODS SUPPLIER QUALITY EXPECTATIONS MANUAL

- Chapter 4, Section 4.6 – ALLERGEN MANAGEMENT

SUPPLIER AND EXTERNAL MANUFACTURER HACCP MANUAL

- Appendix C: Kraft Foods Food Allergen Category List
- Model CCP: REWORK HANDLING 75
- Model CCP: EQUIPMENT CLEANING FOR ALLERGEN REMOVAL (PRODUCT CHANGEOVER) 77
- Model CCP: PRODUCT FLUSHING FOR ALLERGEN REMOVAL (PRODUCT CHANGEOVER)

SUPPLIER QUALITY EXPECTATIONS MANUAL RESOURCE SUPPLEMENT

- SECTION N: ALLERGEN MANAGEMENT
Basis for identifying, evaluating and controlling food allergens

- risk assessment shall be carried out as part of HACCP Plan development to identify, review, and document allergens likely to be present
- process detailed in Kraft Foods Global, Inc. Supplier and External Manufacturer HACCP Manual
- assessment must consider all allergens on the Kraft Foods Allergen Category List (see Appendix C of the Kraft Foods Global, Inc. Supplier and External Manufacturer HACCP Manual) as well as any others identified in local regulations.
- assessment shall consider possible sources of allergens related to the formulation, process, and site-specific practices, including: raw materials/ingredients, rework addition and potential for cross-contact in manufacturing, storage or shipment practices.
- ensures that specific allergens are not inadvertently incorporated as an undeclared component of any product
Allergen Risk Assessment

• Avoidable allergens – managed by
  – Raw material storage & handling procedures, dedicated equipment, segregation, production sequencing, cleaning / flushing, rework management

• Unavoidable allergens
  • Allergens present through manufacturing cross-contact or carry-over product that cannot be avoided through product sequencing and cleaning due to technical limitations (e.g., nature of product, design of process) shall be properly identified and labelled

• Cross-contact information shall not be used as a substitute for an effective food allergen control program.
Example 1 – risks arising from agricultural contamination

- **Scenario:** Cocoa is grown in an area where peanuts are also commonly grown as a commodity crop
- **Risk & Hazard:** Jute sacks used to transport the harvested cocoa beans could also be used to transport peanuts. Peanut contamination in cocoa beans
- **Risk assessment:** Post harvest, cocoa beans go through numerous process steps including:
  - Sieving to remove agricultural debris
  - Roasting
  - Winnowing
  - Separation of cocoa butter, liquor and powder
- **Output from risk assessment:** Peanuts tend to be significantly smaller than cocoa beans. After processing steps the likelihood of peanut contamination minimal
- **Outcome = avoidable allergen; No need for cross-contact labeling**
Example 2 – risks from cross-contact in the factory

- **Scenario:** Factory that supplies dried fruit also processes hazelnuts

- **Risk & Hazard:** All ambient ingredients are located in the same storage area, but processed on dedicated equipment in separate parts of the factory. Risk of cross-contact during storage.

- **Risk assessment:** Hazelnuts are supplied vacuum packed and the factory has the following control measures in place:
  - Hazelnuts inspected upon receipt for damaged packaging
  - Hazelnuts are stored at ground level in a clearly labeled location
  - An allergen spillage kit and instructions are stored next to the hazelnuts
  - The site have dedicated utensils and tote bins for weighing hazelnuts
  - Dried fruit is always weighed before hazelnuts and the area cleaned after use.

- **Output from risk assessment:** The sites allergen control measures are sufficient to minimize the risk of cross-contact

- **Outcome = avoidable allergen; No need for cross-contact labeling**
Example 32 – risks from cross-contact from shared equipment

- **Scenario:** Factory that supplies popcorn also produce ‘sesame-snaps’ on same line (+ associated equipment)

- **Risk & Hazard:** Due to limitations with space and equipment, the supplier has no option but to manufacture popcorn and sesame-snaps on the same line. Risk of cross-contact during processing.

- **Risk assessment:** Popcorn is always produced before sesame snaps and the factory have the following control measures in place:
  - operatives wear color coded dedicated PPE when producing sesame-snaps
  - the line and associated equipment are always thoroughly cleaned after sesame production
  - all staff in the area have been trained in the sites allergen management programme
  - The site have dedicated utensils and tote bins for weighing sesame

- **Output from risk assessment:** Visual inspection of the line and equipment after thorough cleaning demonstrate sesame seeds still to be present

- **Outcome = Unavoidable allergen; cross-contact labeling required**
Food Safety and Quality Systems

Prerequisite (Basic Requirements)

Food Safety Assurance (HACCP)

Quality Assurance Systems

Cultural & Managerial Approaches

GMP/GHP

HACCP

QA/ISO

QM
An Integrated Quality Chain Approach
Focuses on Preventative Systems

Risk Categories

Chemical | Microbiology | Physical

Design | Procure | Convert* | Distribute | Trade | Consumer

Scope

- Design Safety Analysis
- Specifications
- HACCP
- Supplier QA
- Plant & Equipment Design/ Capability
- Contracts
- Selection/ Approval
- Material Monitoring
- Continuous Impr.
- Specifications
- HACCP
- Supplier QA
- Traceability
- Sanitation & Pest Control
- Complaint Mgmt
- Traceability
- Warehouse Controls
- Complaints
- Warehouse Control
- Specification
- Labeling
- Consumer Response
- Process Capabilities

Risk Prevention Programs

*Applies to internal & external plants
• Kraft Foods Supplier Quality Expectations Manual requires Suppliers to have a documented Hazard Analysis Critical Control Point (HACCP) plan in place for all products, manufactured for Kraft Foods.

• The HACCP system is a preventative approach to managing food safety and finally to reduce risk.

• Hazard Analysis and Risk assessment are the initial steps to develop a HACCP plan.

• During the Hazard Analysis the HACCP team should determine all potential biological, physical and chemical hazards that can exist in the raw materials and during the manufacturing stages of the product.

• Kraft Foods manages Allergens within the Chemical hazards.
Kraft separates between Allergens that cause a “true allergic reaction” which involves the immune system and basically constitutes an immune response to a foreign protein and a Food Intolerance which no involvement of the immune system.

- Allergens could cause severe, life-threatening reactions to sensitive individuals
- Food Intolerance reactions are generally less severe but have been associated in some instances with severe reactions.
  - Example: Sulfite induced Asthma
  - Example: Gluten intolerance
There is a relatively small group of substances that are known to cause severe life-threatening reactions.

Those with **global prevalence** are listed in the Kraft Foods Global Food Allergen Category List (appendix C of the HACCP manual).

Those with **regional occurrence** are listed above the Global Food Allergen Category List (appendix C).

The content of both lists are not expected to change significantly but addition / deletions could appear.

Exceptions listed in the Global Food allergen Category list are based on Scientifics and mentioned in the Appendix C of the HACCP manual.
## Allergens – HACCP Approach

<table>
<thead>
<tr>
<th>Category of Food Allergen</th>
<th>Positive List of Ingredients or Foods includes (but not limited to):</th>
<th>Examples of foods that often contain this material</th>
<th>Exemptions to the Category of Food Allergen</th>
</tr>
</thead>
<tbody>
<tr>
<td>Crustacean</td>
<td>e.g., Shrimp, crab, lobster, crawfish&lt;br&gt;Each species within this category, must be regarded as a separate allergen</td>
<td>Glucosamine Hydrochloride containing foods</td>
<td></td>
</tr>
<tr>
<td>Egg</td>
<td>e.g. Hen’s and other avian species&lt;br&gt;Ovalbumin, whole egg, egg yolk, egg white, lysozyme, hydrolyzed egg protein</td>
<td>Mayonnaise, meringue</td>
<td></td>
</tr>
<tr>
<td>Fish</td>
<td>e.g., Cod, Haddock, Flounder, Trout&lt;br&gt;Each species within this category, must be regarded as a separate allergen</td>
<td>Gelatin from fish.</td>
<td></td>
</tr>
<tr>
<td>Lupine/ Lupin</td>
<td>Lupine flour, lupini beans</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Milk</td>
<td>e.g., Cow’s, sheep's, goat's&lt;br&gt;Butter, buttermilk, casein, cheese, cottage cheese, curds, whey, lactoglobulin, lactose*&lt;br&gt;, malted milk, cream, sodium caseinate, sour cream, yoghurt, hydrolyzed milk protein&lt;br&gt;*Only if it contains protein</td>
<td>Margarines, milk chocolate, ice cream, custard, nougat pudding</td>
<td>Lactose and lactitol which contains no protein (specification must indicate process for protein removal)</td>
</tr>
<tr>
<td>Mollusk</td>
<td>e.g., Clams, oysters, mussels&lt;br&gt;Each species within this category, must be regarded as a separate allergen</td>
<td>Calcium Supplements</td>
<td></td>
</tr>
<tr>
<td>Peanut</td>
<td>Peanut butter, nut pieces, peanut flour, peanut protein, hydrolyzed peanut protein</td>
<td>Mixed nuts</td>
<td></td>
</tr>
</tbody>
</table>
### Allergens – HACCP Approach

<table>
<thead>
<tr>
<th>Category of Food Allergen</th>
<th>Positive List of Ingredients or Foods includes (but not limited to):</th>
<th>Examples of foods that often contain this material</th>
<th>Exemptions to the Category of Food Allergen</th>
</tr>
</thead>
<tbody>
<tr>
<td>Seeds:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sesame seeds</td>
<td>Sesame paste, Tahini paste</td>
<td>Hummus, biscuits, dressings and sauces</td>
<td></td>
</tr>
<tr>
<td>Soybean /Soya bean</td>
<td>Soya derived vegetable protein or textured vegetable protein, miso, tofu</td>
<td></td>
<td>Soy lecithin; tocopherol extracts (antioxidant used in flavours) purified by vacuum distillation or purified by other means as long as they are not a source of allergenic proteins. Acid hydrolyzed soy proteins greater than 62% Amino Nitrogen/Total Nitrogen (85% minimum degree of hydrolysis)</td>
</tr>
<tr>
<td>Tree nuts: Almond, Brazil Nut, Cashew, Hazelnut (Filbert), Macadamia Nut, Pine Nuts, Pistachio, Pecan, Walnut</td>
<td>Only those tree nuts identified. Each tree nut type within this category must be regarded as a separate allergen</td>
<td>Mixed nuts Some chocolates</td>
<td></td>
</tr>
<tr>
<td>Wheat</td>
<td>Wheat derived bran, wheat extracts, dextrin, meal, farina, graham flour, malt, flour, germ, gluten, starch including enzymatically/acid treated or chemically modified starches, semolina, hydrolyzed wheat protein</td>
<td>Breadcrumbs, crackers, bread, pasta</td>
<td>Wheat derived glucose, glucose syrup, dextrose, dextrose monohydrate, maltodextrin (all DEs), sugar alcohols, and caramelized glucose.</td>
</tr>
</tbody>
</table>
In addition to the allergens from the Global Food Allergen Category List the following substances have to be managed as allergens:

**Celery and Mustard**: only for Europe (including political EU, Nordic countries, Switzerland, Central Europe, Eastern Europe), Middle East and Africa

**Chestnut and Hickory**: only for Latin America (excluding products produced in Mexico for US)
**Ingredient allergen assessment**

(Form E1/E2 – Appendix D):

- Key source of allergens are the ingredients used in the plant.
- Purpose: To identify whether the product(s) being assessed can introduce undeclared allergens/sulfites into other products currently run on the manufacturing line OR – whether products currently run on the manufacturing line can introduce undeclared allergens / sulfites into the product(s) being assessed.
- Assessment done per manufacturing line.
- **Full assessment** consists of Forms E1 and E2.

Note: The content of the forms is required; however, the format of the forms is optional.
## Ingredient allergen assessment E1: Example in Kraft Format (Appendix D)

<table>
<thead>
<tr>
<th></th>
<th>A</th>
<th>B</th>
<th>C</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>List all ingredients (as per Food Allergen Category List and Regional Allergens, if applicable. See Appendix C.)</td>
<td>List identified allergens/sulfites of ingredients</td>
<td>List identified ingredients containing carryover allergens/sulfites from supplier per allergen profile of Raw Material Spec.</td>
</tr>
<tr>
<td></td>
<td>-&gt; containing allergens and/or sulfites (&gt;10ppm in final formula)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>-&gt; containing carryover allergens and/or sulfites (&gt;10ppm in final formula) per allergen profile.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>-&gt; List any processing aids that may come in contact with product contact surfaces or product itself that contains allergens or sulfites &lt;10ppm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Raw milk</td>
<td>Milk</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td>Salmon</td>
<td>Fish</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td>Soya flour</td>
<td>Soya</td>
<td>None</td>
<td></td>
</tr>
</tbody>
</table>
## Ingredient allergen assessment E2: Example in Kraft Format (Appendix D)

<table>
<thead>
<tr>
<th>List all finished products produced on the manufacturing line including use of common equipment e.g. rework tanks, fillers etc.</th>
<th>Are all identified allergens listed in Form E-1 labeled on the package of the finished product (this should be done for each finished product listed in the first column of this form)?</th>
<th>If “No” identify control mechanism(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>YES</strong> (list allergens)</td>
<td><strong>NO</strong> (list allergens)</td>
<td>(_ - CCP) (_ - PP )</td>
</tr>
<tr>
<td>Plain Cream cheese</td>
<td>Milk</td>
<td>Fish, Soya</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vegetable Blend Cream Cheese</td>
<td>Milk, Soya (from Soya flour)</td>
<td>Fish</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Salmon Flavored Cream Cheese</td>
<td>Milk, Fish</td>
<td>Soya</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Allergens – HACCP Approach

Allergen zoning MAP - Recommendation

• Purpose: To assess allergen (where applicable) cross-contamination potential between processing areas and identify prerequisite programs to manage and prevent cross-contamination.

• Usage of Plant layout

• In situations where different lines and/or area profiles exist, perform a risk assessment and indentify appropriate controls. It’s recommended to use an assessment similar to an allergen control checklist
Allergens – HACCP Approach

Allergen zoning MAP – Example where an allergen control checklist would be recommended

Contains or May Contain : Milk,
Contains or May Contain : Milk, Wheat, Soya, Hazelnuts, Peanuts, Cereal
Contains or May Contain : Milk, Wheat, Soya, Hazelnuts
Manufacturing Controls

Hierarchy of Controls
Precautionary Labelling should only be used as a last resort when the risk for contamination is uncontrollable, sporadic and documented (cleaning controls, test results, substantiated consumer reaction)

1) Avoid the introduction of an allergen into a facility that does not already contain the allergen.

2) Total dedication and segregation of equipment (lines, utensils,...) where possible

3) Extensive, well-documented cleaning and inspection procedures to prevent allergen cross-contact or carryover.

4) If the risk still present a precautionary label statement should be used. Carry over levels shall be minimised.
## Manufacturing Controls

### Sources of Issues and Risk Levels at a Manufacturing Site

<table>
<thead>
<tr>
<th>Area of Concern</th>
<th>Potential Issue</th>
<th>Perceived Risk Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Labelling</td>
<td>Undeclared allergens</td>
<td>High</td>
</tr>
<tr>
<td>Rework, WIP, LMI</td>
<td>Cross contact/Carry Over</td>
<td>High</td>
</tr>
<tr>
<td>Training</td>
<td>Skills &amp; Awareness</td>
<td>High</td>
</tr>
<tr>
<td>Raw Materials</td>
<td>Undeclared allergens</td>
<td>High</td>
</tr>
<tr>
<td>Change Over Regimes</td>
<td>Allergen carry over</td>
<td>High</td>
</tr>
<tr>
<td>Hygienic Design</td>
<td>Cross contact/Carry Over</td>
<td>Medium</td>
</tr>
<tr>
<td>Shared Equipment &amp; Tools</td>
<td>Cross contact/Carry Over</td>
<td>Medium</td>
</tr>
<tr>
<td>Receiving &amp; Storage</td>
<td>Cross contact/Carry Over</td>
<td>Medium</td>
</tr>
<tr>
<td>Adjacent Line Situation</td>
<td>Cross contact</td>
<td>Medium</td>
</tr>
<tr>
<td>Traffic Patterns</td>
<td>Cross contact</td>
<td>Low</td>
</tr>
</tbody>
</table>
**Manufacturing Controls**

<table>
<thead>
<tr>
<th>Area of Concern</th>
<th>Potential Issue</th>
<th>Perceived Risk Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Labelling</td>
<td>Undeclared allergens</td>
<td>High</td>
</tr>
</tbody>
</table>

**Control Measures**

- **Labeling application:** In case finished product with different allergen profiles have similar appearing labels on the same line:
  - Risk of wrong label application high
  - Documented management required to assure right label application (CCP).
- Verification of proper label application on primary package and/or carton
- Automated detection system (e.g. bar code reader) recommended, if the risk is high.
- Manual visual review of proper label application (checklist) should be considered a prerequisite program.
Manufacturing Controls
## Manufacturing Controls

<table>
<thead>
<tr>
<th>Area of Concern</th>
<th>Potential Issue</th>
<th>Perceived Risk Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rework, Work in Progress (WIP), Locally Manufactured Ingredient (LMI)</td>
<td>Cross contact/Carry Over</td>
<td>High</td>
</tr>
</tbody>
</table>

### Control Measures

- **Rework handling:** Incorporate allergen containing rework only into the same and/or appropriately labelled product (rework matrix recommended)
- **Proper segregation, identification (labelling), and use of allergen containing rework, WIP and LMI**
- **Origin and ingredients of each unit (pallet, drum, tote, ...) to be documented in inventory records.**
Manufacturing Controls
<table>
<thead>
<tr>
<th>Area of Concern</th>
<th>Potential Issue</th>
<th>Perceived Risk Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Training</td>
<td>Skills &amp; Awareness</td>
<td>High</td>
</tr>
</tbody>
</table>

**Control Measures**

- Allergen awareness training should be provided to all new food handling employees during orientation.

- In depth allergen training should be provided so that all involved personnel is equipped with essential information and skills relative to their job responsibilities, and the site allergen risk profile. This includes:
  - Identifying ingredients and products that contain allergens.
  - Knowing the process steps where unlabelled allergens could be introduced to the product inadvertently.
  - Understanding the control methods applied on site.

- Evaluation and verification of employee’s allergen knowledge / skills shall be carried out annually and refresher training provided where required.
## Manufacturing Controls

<table>
<thead>
<tr>
<th>Area of Concern</th>
<th>Potential Issue</th>
<th>Perceived Risk Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Raw Materials</td>
<td>Undeclared allergens</td>
<td>High</td>
</tr>
</tbody>
</table>

**Control Measures**

- Ensure that all supplier information are available and full describe the allergen status.
- Change notification process shall be in place
- Questionnaires & Audits
## Manufacturing Controls

### Control Measures

- **Product change over:** Removal of allergen containing materials prior to a production of non-allergen containing product via cleaning/flushing (CCP).
- **Packaging change over:** Removal of all labeled packaging material from the line/packaging equipment and the immediate production area.
- **Product Sequencing:** When possible an allergen-containing product must never be followed by a product that does not contain an allergen.
- **Verification** (after each change over) and **validation** (at minimum every 2 years).

### Table: Area of Concern

<table>
<thead>
<tr>
<th>Area of Concern</th>
<th>Potential Issue</th>
<th>Perceived Risk Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Change Over Regimes</td>
<td>Allergen carry over</td>
<td>High</td>
</tr>
<tr>
<td>• Cleaning</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Flushing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Sequencing</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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*Note: This content is based on the partial image and raw text provided. The full document contains additional information not captured in the image.*
## Manufacturing Controls

### Control Measures, cont'd

- **Allergen cleaning**: remove *visible* product/residue from all product contact surfaces and above exposed product zones.
- **Documented visual inspection** after cleaning. For CIP: verify all validated cleaning parameters (time, temperature, flow, concentration of detergents) are met.
- **Flushing**: Quality clean before and validated quantity of flushing material (inert non-allergic materials or product)
- **Use of vacuum cleaning** rather than air hoses/compressed air.
- **Dedicated cleaning tools / cleaning tools program.**

<table>
<thead>
<tr>
<th>Area of Concern</th>
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<th>Perceived Risk Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Change Over Regimes</td>
<td>Allergen carry over</td>
<td>high</td>
</tr>
<tr>
<td>- Cleaning</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Flushing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Sequencing</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## Area of Concern

<table>
<thead>
<tr>
<th>Area of Concern</th>
<th>Potential Issue</th>
<th>Perceived Risk Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hygienic Design (Factory and Equipment)</td>
<td>Cross contact/Carry Over</td>
<td>Medium</td>
</tr>
</tbody>
</table>

### Control Measures

- Hygienic design to allow for appropriate GMP’s, change over regimes and inspection programs
- Ensures cleanability of all assets.
- Includes factory layout (physical segregation)
- Easy to access and dismantle equipment
- No crossovers of open production lines, e.g. conveyor belts
- Shielding, partitions, covers and catch pans to protect exposed unpacked product
- Air handling units /dust extraction system might be necessary
- Uncleanable parts of shared equipment disposable or dedicated (e.g. cloth belts, sleeves, filling pipes)
- Review process for new installations or upgrades.
- Training & Awareness!
Manufacturing Controls
# Manufacturing Controls

<table>
<thead>
<tr>
<th>Area of Concern</th>
<th>Potential Issue</th>
<th>Perceived Risk Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shared Equipment &amp; Tools</td>
<td>Cross contact/Carry Over</td>
<td>Medium</td>
</tr>
</tbody>
</table>

**Control Measures**

- Includes totes, bins, containers, tanks, tankers, rework systems, cleaning tools, maintenance tools
- Written cleaning/change over procedures with verification and validation program in place.
- Shared tools shall be colour coded/labelled OR included in the allergen cleaning program.
## Manufacturing Controls

<table>
<thead>
<tr>
<th>Area of Concern</th>
<th>Potential Issue</th>
<th>Perceived Risk Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Receiving &amp; Storage</td>
<td>Cross contact/Carry Over</td>
<td>Medium</td>
</tr>
</tbody>
</table>

### Control Measures

- Identification and labelling of materials upon receipt
- Segregation
  - Area visibly designated
  - Allergen containing materials stored below non-allergens
  - No open allergen ingredient storage
- Dedicated weighing, transfer systems and tools OR appropriate cleaning program
- Includes single containers (pails, bags, drums, etc)
- Spillage procedure required.
Manufacturing Controls
### Area of Concern

<table>
<thead>
<tr>
<th>Area of Concern</th>
<th>Potential Issue</th>
<th>Perceived Risk Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adjacent Line Situation</td>
<td>Cross contact (dust, people, spillage, utensils)</td>
<td>Medium</td>
</tr>
</tbody>
</table>

**Control Measures**

- Avoid contamination of/from adjacent lines during cleaning and production (covers, curtains, no compressed air, etc.).
- Dedicated line staff as needed
- Consider distance between lines, when assessing risk
- Contamination risk of people and dust often overestimated, but needs to be validated
Manufacturing Controls
Manufacturing Controls

<table>
<thead>
<tr>
<th>Area of Concern</th>
<th>Potential Issue</th>
<th>Perceived Risk Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Traffic Patterns</td>
<td>Cross contact</td>
<td>Low</td>
</tr>
</tbody>
</table>

**Control Measures**

- Limit movement of people, materials, equipment, vehicles and maintenance tools between segregated areas and dedicated equipment.
- May require change of workwear when moving from an allergen to a non-allergen area (dusty environment).
- Enhanced GMPs should be implemented.
Contains or May Contain: Milk, Wheat, Soya, Hazelnuts, Peanuts, Cereal

Contains or May Contain: Milk, Wheat, Soya, Hazelnuts
Allergen Validation

- Training
- Supply chain assessment
- Validation
- HACCP principals
- Informed Labelling
- Uniformity of Practice (GMP)
- Prerequisite Programmes
Allergen Validation

- Two Step Approach

  1st Step: Physical Validation of an Allergen Change Over
  - Identifies the protocol to validate that current sanitation procedures are sufficient to prevent allergen carryover on lines where allergens and non-allergens products are produced.
  - After cleaning, a tear down inspection of the equipment must be performed to ensure that there is no product left on internal surface. Special attention to valves, pumps, filler and other potentially difficult to clean areas

- 2nd Step: Analytical Validation of Allergens Using Allergen Test Kits (ELISA)
  - This method describes analytical validation, if test kits are available. Prior to any analytical validation a physical validation of each line must be completed.
Designing a Cleaning Validation Program

- Allergen mapping
- Risk-assessment
- Select samples on a ‘worst-case’ scenario basis
- Select an appropriate ‘target’ allergen
- Conduct validation:
  - 1. Visual Inspection
  - 2. Sampling & Testing
- Cross-validate method for verification
Risk Assessment Considerations

- Physicochemical nature of the allergen
- Associated protein level
- Heterogeneous or homogeneous
- Concentration in recipe
- Potential for aerosol / dust generation
- Existing barriers to restrict spread of allergen
- Level of processing allergenic material undergone
- Configuration of equipment and ease of cleaning
Rule of thumb – “If you can’t see it and you can’t easily reach it, you can’t clean it”

Target difficult to clean areas

- Rough or pitted surfaces (worn conveyer belts)
- Welds, bends or anywhere where product could hang up
- Select areas with direct physical contact with the product

Types of sample

- surface swabs
- Purge sample (dry systems)
- Rinsate (CIP)
- Settle plates / air monitoring
- Finished product
Criteria

- Clinically relevant
- Validated methodology
- Resistant to processing
- Difficult to remove (tenacious)

Where products contain multiple allergens or a validated method does not exist:

- Nominate a target allergen on the basis of its physiochemical properties and / or the matrix in which they were carried (tenacious & hence difficult to clean e.g. high fat)
• Results only as good as samples submitted
• Sampling plan linked to risk analysis to maximise probability of detecting contamination (if present)
• Plan must consider:
  – Physical nature of contaminant
  – Level of processing undergone
  – Amount of protein
  – Type of production environment
Representative sample size reliability

Sample size
Training for operatives taking samples
Analytical Techniques

- **Lab-based**

- **Factory-spot tests**
  - Rapid lateral flow devices
  - Non-specific protein tests
    - ATP bioluminescence
    - Coomassie
Validation is vital - Wide range of devices commercially available
Analytical Techniques

• Lab-based
  – Protein based techniques:
    • Enzyme linked immunosorbent assay (ELISA)
  – DNA techniques
    • Polymerase chain Reaction (PCR)
  – Separation methods
    • Liquid chromatography-mass spectrometry (LC-MS)
ELISA – Kraft Method of Choice

- Kits specific for allergenic proteins
- Clinically relevant (proven to cause reaction)
- Quantitative within a standard range
ELISA

• **Advantages**
  – Improved sensitivity and selectivity (low mg/kg)
  – Developed in house improved extraction techniques
  – Larger range of commercial kits available
  – Fast generation of results

• **Disadvantages**
  – Matrix interference (+ve/-ve /synergic)
  – Decreased sensitivity to modified proteins (thermal, mechanical and enzymatic)
  – Inter-kit variability (different targets)
  – Kits not available for all allergens
## Limits of Reporting

<table>
<thead>
<tr>
<th>Allergen</th>
<th>ELISA mg/kg (ppm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Casein</td>
<td>2.5</td>
</tr>
<tr>
<td>BLG</td>
<td>5</td>
</tr>
<tr>
<td>Egg</td>
<td>2</td>
</tr>
<tr>
<td>Gluten</td>
<td>10</td>
</tr>
<tr>
<td>Peanut</td>
<td>1</td>
</tr>
<tr>
<td>Hazelnut</td>
<td>5</td>
</tr>
</tbody>
</table>
What Does The Result Mean?

- Result reported as Not Detected
  - what is the limit of detection?
- Result reported as 10 mg/kg almond
  - almond protein / total almond?
- Result reported as < 2.5 mg/kg almond
  - not detected above the reporting limit
- Result reported as >15 mg/kg casein
  - more casein than the top standard
Lab Validation

- In-house method validation is essential
- Verify kit manufacturers claims
- Matrix validation
- Method validation to ISO17025 standard (UKAS)
- Extend external accreditation AOAC
- Inter-lab ring-trials (FAPAS)
Kraft Foods position is NOT to delegate risk to consumers and to decrease food choice. Thus cross contact labelling ("may contain") shall be the last resource only.

Risk management does NOT mean seeking for zero risks, but minimizing the risks.

As chemical a contamination risk allergens shall be managed through GMP, prerequisite programs and HACCP.

For evaluating allergen risks there is no template for controls. Each situation may require specific solutions to manage the risks.

Verification, validation and monitoring is key.

Analytical testing provides data to support assessments and validation, but does NOT replace assessments.
The Kraft Foods Supplier Quality web site is designed to facilitate the communication between Kraft Foods and our suppliers.

Here you will find all of the Quality Requirements and Guidelines for Suppliers to Kraft Foods, as well as the slides used in our Supplier Forums.

**The web site includes:**

- Supplier Quality and Food Safety Contractual Requirements
- Supplier Forum presentations
- Quality Support Material
- Contact email address
- eLearning modules

**Browser Address:** [http://brands.kraftfoods.com/kraftsupplier/](http://brands.kraftfoods.com/kraftsupplier/)
Visit the Kraft Foods Supplier Quality and Food Safety web site at:
http://brands.kraftfoods.com/kraftsupplier/