



MARS

Allergen Management:
The Corporate Challenge

MARS Chocolate Europe

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Regulatory Affairs

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MARS | **Outline**

- **What is a food allergy ?**
- **What are the major food allergens ?**
- **Global allergen labelling status**
- **Allergen Control Plans**
- **Summary**



What is a food allergy ?

What is a food allergy ?

A true food allergy is a response where the body's **immune system** overreacts to the protein portion of a normal food



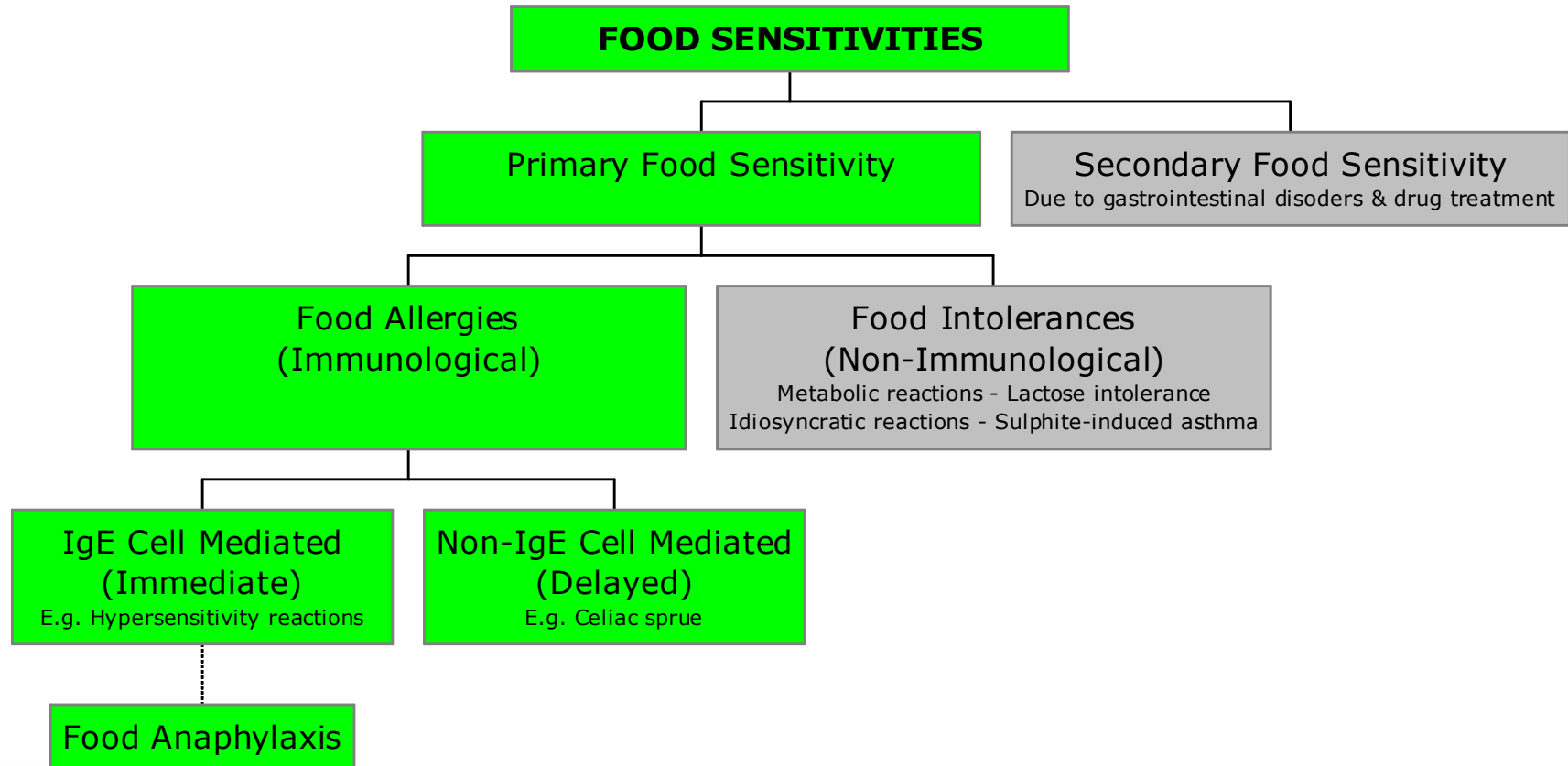
This may produce **unpleasant**, and sometimes **life-threatening symptoms**

These reactions typically occur **within minutes to two hours** after being exposed, sometimes increasing from mild to severe



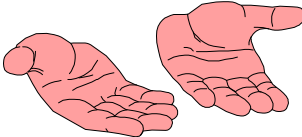
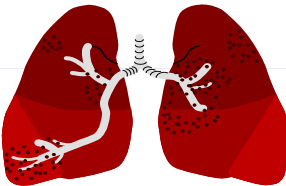
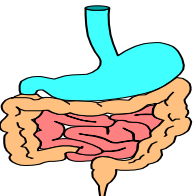
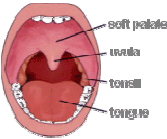
Allergic Reactions vs. Sensitivities

Allergic reactions are different from other food sensitivities or intolerances



Common Symptoms of an Allergic Reaction

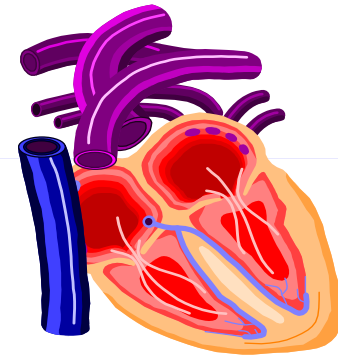
Different people have different sensitivities and resulting reactions range from mild to severe

<p>Cutaneous</p>		<ul style="list-style-type: none"> •Itching •Skin rashes (hives) •Pruritic rashes •Angioedema
<p>Respiratory</p>		<ul style="list-style-type: none"> •Asthma/rhinitis •Laryngeal edema •Swelling and puffiness, especially to mucus membranes
<p>Gastrointestinal</p>		<ul style="list-style-type: none"> •Diarrhoea •Abdominal cramps •Nausea •Vomiting
<p>Oropharyngeal</p>		<ul style="list-style-type: none"> •Oral allergy syndrome

Common Symptoms of an Allergic Reaction

Anaphylactic shock, the most severe type of anaphylaxis, occurs when an allergic response triggers a quick release from mast cells of large quantities of immunological mediators leading to:

- A sudden drop in blood pressure
- Broncho-constriction and difficulty in breathing
- Death in minutes if left untreated



Common symptoms of allergic reactions



How Much is Too Much ?

The **amount** of allergen required to elicit an allergic reaction differs from person to person

Threshold levels have not been identified
for most allergens



In one scientific study conducted to determine minimum amounts required for a reaction, as little as 100 μg (or 0.10 mg) of peanut protein could cause an allergic reaction in very sensitive individuals

There is currently no globally accepted allergen threshold level for most of the major allergens.

Regulatory authorities have used **5-10ppm** of allergenic protein as an action level for recall enforcement.

Leading scientists have selected **10ppm** as a level below which it is unlikely that one would have an adverse reaction.

Exceptions: Gluten = 20ppm **and** Sulphites = 10ppm



What are the top allergens ?

MARS The 8 Most Common Food Allergens

SHELLFISH



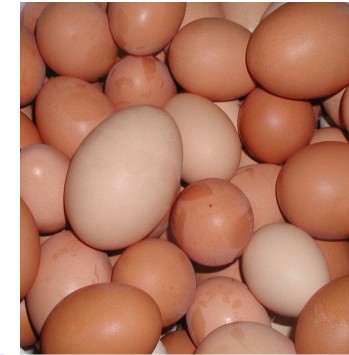
FISH



COWS MILK



EGGS



SOYA



WHEAT



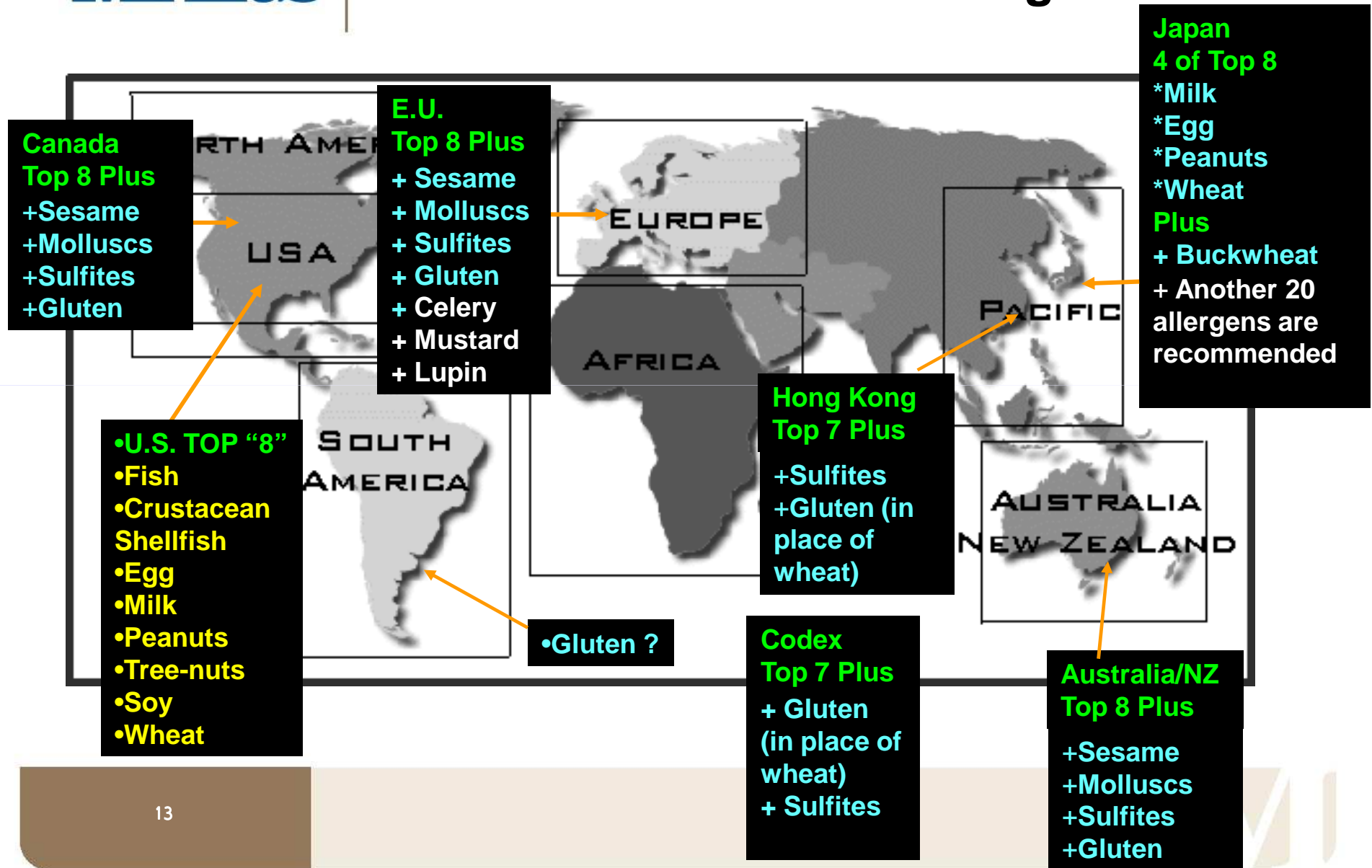
PEANUTS



TREE NUTS



International Food Allergen List



Comparison of Tree Nut Allergen Lists

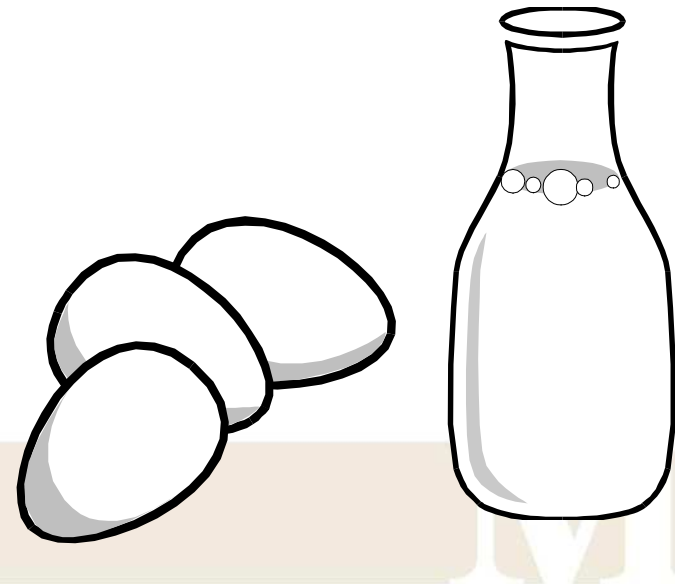
Canada	EU	US	ANZ
<ul style="list-style-type: none"> •Almonds •Brazil Nuts •Cashews •Hazelnuts •Macadamia •Pecans •Pine Nuts •Pistachios •Walnuts <p>•NB: Specifically Excludes Coconuts</p>	<ul style="list-style-type: none"> •Almonds •Brazil Nuts •Cashews •Hazelnuts •Macadamia •Pecans •Pistachios •Walnuts <p>•Queensland Nuts</p> <p>•NB: Does not include Pine Nuts</p>	<ul style="list-style-type: none"> •Almonds •Brazil Nuts •Cashews •Hazelnuts •Macadamia •Pecans •Pine Nuts •Pistachios •Walnuts <p>•Beech Nut</p> <p>•Butternut</p> <p>•Chestnut</p> <p>•Chinquapin</p> <p>•Coconut</p> <p>•Gingo Nut</p> <p>•Hickory</p> <p>•Lichee</p> <p>•Pili Nut</p> <p>•Shea Nut</p>	<ul style="list-style-type: none"> •Almonds •Brazil Nuts •Cashews •Hazelnuts •Macadamia •Pecans •Pine Nuts •Pistachios •Walnuts <p>•Hickory</p> <p>•Shea Nuts</p> <p>•NB: Specifically Excludes Coconuts</p>

Children: 6-8%

Adults: 2-4%



The majority of children have milk and/or egg allergies, and will tend to outgrow these allergies by the time they are 8 years old.



Prevalence of Food Allergies and Anaphylaxis



- Prevalence of food allergy depends on genetic factors, age, dietary habits, environment, etc.
- Experts agree that allergies in developed countries are becoming more common, including food allergy.
- Doubling of peanut allergy children in past 10 years
- Up to 6% of preschool children have a food allergy. Many outgrow this, but not allergy to peanut.
- Most food allergy fatalities occur in teens/young adults who also have asthma. Peanuts/tree nuts involved in most cases.

The background features large, light-brown, stylized letters spelling 'NAMA'. The letters are bold and have rounded, slightly irregular edges. The 'N' and 'M' are particularly prominent, with the 'A' being smaller and positioned between them. The letters are set against a white background.

Allergen Labeling Regulations

Intentional (Recipe) Ingredients

EU Legislation – declarable allergens

There are 14 food allergens which are declarable under EU law.

Peanuts

Tree Nuts

Milk (& derivatives of)

Egg (& derivatives of)

Fish

Molluscs

Crustacea

Soya

Cereals containing gluten

(wheat, oats, rye, barley,
spelt)

Now includes:

Celery

Lupin

Mustard

Sesame

Sulphite

Options for labeling recipe ingredients:

1. **List as the common name within the ingredient listing.**

Examples: “wheat flour”, “milk fat” , egg albumin, soy lecithin, etc.

2. **In parentheses following the name of the ingredient.**

Examples: "lecithin (soy)," "casein (milk)," "whey (milk)", "flavour (peanut)" when protein is present.

3. **Immediately after or next to the list of ingredients in a "contains" statement.**

Example: "Contains Wheat, Milk, and Soy."

- Requires label to disclose these allergenic ingredients in **commonly understood terms**
- Considered for food ingredients that **contain protein** derived from a major food allergen
- **Includes all minor ingredients** → incidental additives, flavors, processing aids, etc.

The background features large, light-brown, stylized letters 'NAMA' in a serif font. The letters are semi-transparent, allowing the text to be visible through them. The 'N' and 'M' have a distinctive shape with a pointed top and a rounded bottom. The 'A' is also stylized with a pointed top and a rounded bottom. The 'M' is the largest and most prominent letter, with a central vertical stroke that tapers to a point at the top.

Allergen Labeling Regulations

Labeling of allergen cross contact

Allergen Advisory or Precautionary Labeling

- **Situation:**

- Applied to products when, despite due diligence in cleaning, you are unable to eliminate all cross contact of the allergen from one product to another product.

- **Goal:**

- To help inform food allergic consumers
 - Avoid eating products carrying these statements.

- **Examples:**

- May Contain <allergen>
- Made on same equipment as <allergen>
- Manufactured in the same facility as <allergen>

Allergen Advisory/Precautionary Labeling

- **Labeling Status:**

- There is some industry and regulatory guidance on this type of labeling in a few markets, however, there are **no regulations** covering this type of labeling.

- **Current Challenges:**

- No one set of criteria for applying this kind of labeling.
- Food allergic consumers are frustrated (lack of food choices) and are taking more chances in eating products.

- **Recommendation:**

- Well defined guidelines for consistent application of allergen advisory statements, taking into account:
 - Non-Zero Thresholds (dose)
 - Probability (likelihood of occurrence)
 - One common allergen statement ?



The background features a large, stylized logo for NAMA. The letters 'N', 'A', and 'M' are rendered in a light beige color with rounded, blocky shapes. The 'N' and 'M' have a distinctive shape with a pointed top and a rounded bottom. The 'A' is a simple, wide, blocky letter. The logo is centered on the page.

Allergen Control Plans

Elements of an Effective Allergen Control Plan

- Fundamentals
- Product Design
- Supplier Control Programs
- Segregation of Allergenic Foods
- Prevention of Cross Contact
- Label/Packaging Review
- Validated Allergen Cleaning Program



Allergen Control Plan - Fundamentals



- Form a cross functional allergen control team
- Conduct a risk assessment to determine the choice of allergen management procedures
 - Allergen process flow diagram
 - Critical control points
- Develop allergen control plan specific to each processing facility
- Provide allergen training for employees on a regular basis

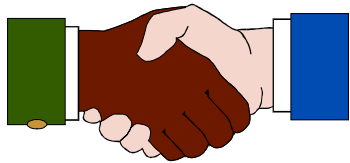


Allergen Control Plan – Product Design

- Only add allergenic ingredients to new products when they make a real difference in taste or functionality
- Question ingredient suppliers on the necessity of allergens in their recipe
- Create a process to review allergens in new products with the manufacturing facility prior to ordering ingredients.



Allergen Control Plan – Suppliers



- Allergen Management begins with **raw materials**
- Suppliers should have a **documented allergen control plan**
- Require letters from suppliers to guarantee that ingredients do not contain undeclared allergens
- **Audit** your suppliers on a regular basis
- Require suppliers to have **validated sanitation cleaning procedures in place**

Allergen Control Plan – Segregation of allergenic foods

- **Receiving**

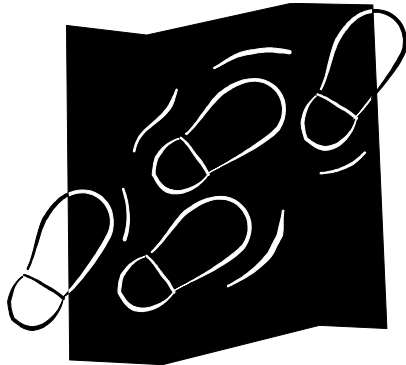
- Review labels of incoming raw materials
- Identify allergen on the labels of raws (name, colours, etc.)
- Dedicated or shared transportation vehicles ?

- **Storage**

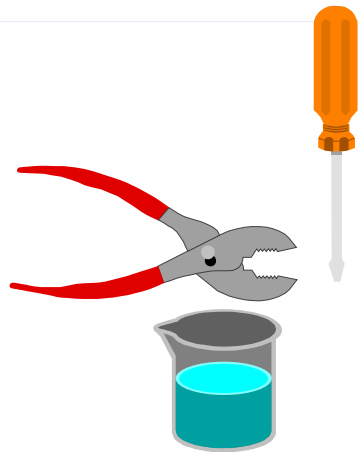


- Store allergenic ingredients separately from non-allergenic ingredients to prevent cross contact
- Use dedicated pallets or bins
- Use documented clean up procedures for spills

Allergen Control Plan – Minimise or Prevent Cross Contact

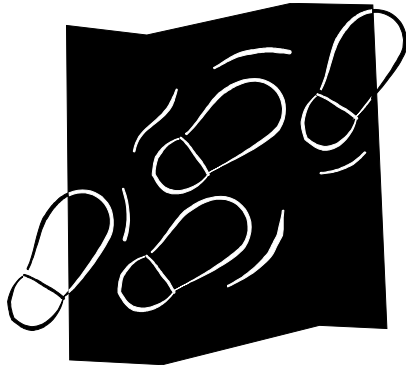


- Wherever possible dedicate separate production areas for allergenic and non-allergenic ingredients (equipment, air handling systems, tools, utensils, etc.)
- If segregation is not possible then consider strategies to minimise allergen cross contact:

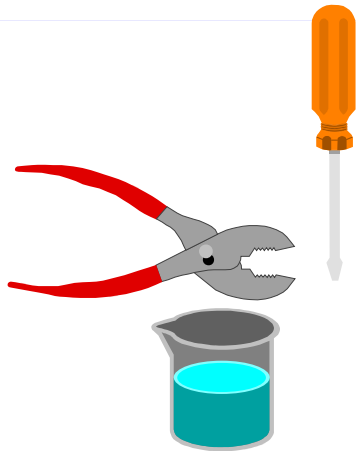


- Schedule longer runs of allergenic products in order to minimise changeovers
- Add allergenic materials as late in the process (when possible)
- Design traffic patterns and airflow to minimise cross contact
- Restrict personnel who work with allergenic products from coming in contact with non-allergenic products

Allergen Control Plan – Minimise or Prevent Cross Contact



- Whenever allergenic and non-allergenic products are made in close proximity, put **barriers** in place to minimise cross contact
- Design equipment for **easy cleaning and accessibility**



- Consider **wet-cleaning** of equipment when possible. When not possible, consider other cleaning procedures to minimise cross contact, e.g., flushing, etc.

Allergen Control Plan – Label Review

- Understand and follow government legislation on allergen labeling regulations.
- Allergen advisory statements should **NOT** be used in place of GMP
- Monitor, document and verify the correct label at all changeovers as they occur.
- Discard all out-of-date labels.



Allergen Control Plan – Validated Allergen Cleaning

- Have well-defined and validated cleaning procedures
- Keep detailed records for cleaning, validation and verification
- Ensure compliance with cleaning procedures via internal/external audits

- Food allergies affect a small percent of most populations but can potentially result in life-threatening reactions.
- Major allergens have been defined in numerous markets.
- Accurate allergen labeling is critical to help consumers make an informed choice
- We need data to support allergen threshold levels which are key to developing regulatory action levels for labeling and more consistent labeling across the industry
- It is critical to have effective allergen management in place for each of your manufacturing facilities & with your ingredient suppliers



Thank You