Allergen Management

June 23rd, 2015

Agenda Topics

- Introduction and Company Presentation 5 min
- Allergens 60 min
  - Allergens & HACCP
  - Allergen Risk Assessment
  - Manufacturing control
  - Allergen testing, verification & validation
- Questions 20 min

OUR DREAM: CREATE DELICIOUS MOMENTS OF JOY

We offer many of the world's favorite brands

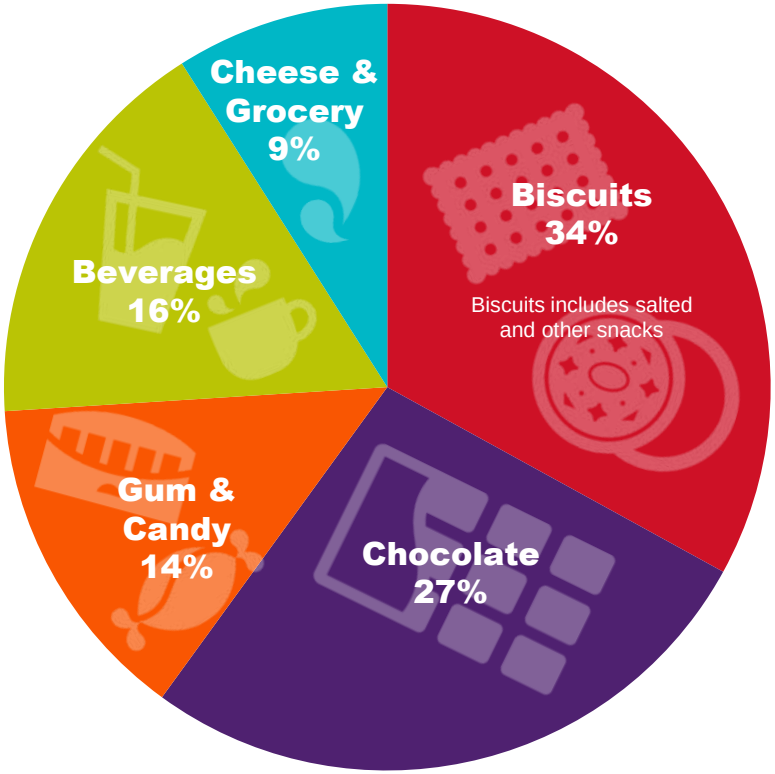
Mondelēz International
the power of big. and small.

Fast facts

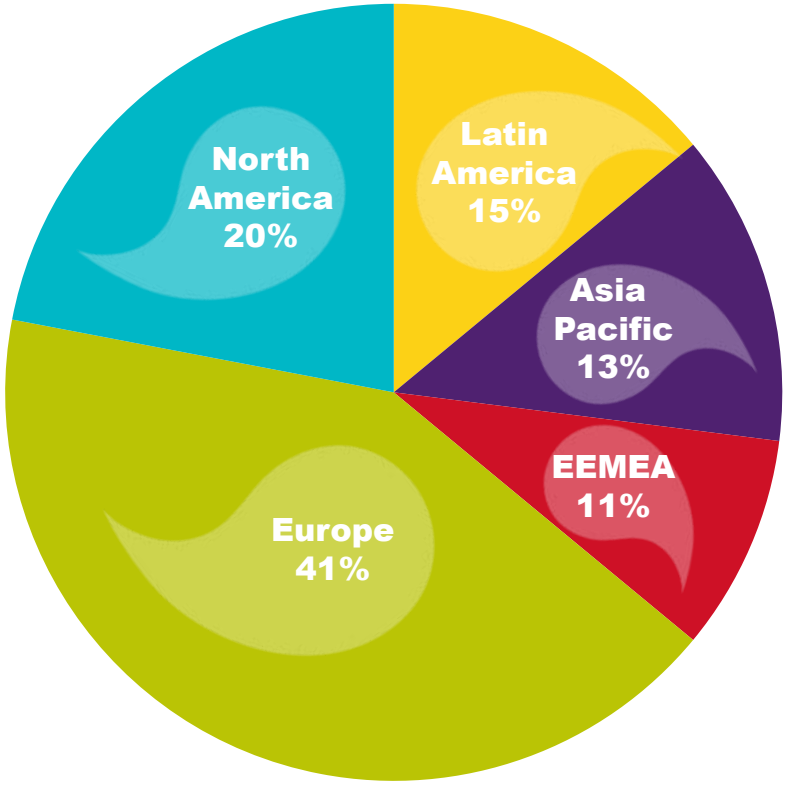
- net revenues of $34 billion in 2014
- global snacks powerhouse
- products marketed in 165 countries
- approximately 100,000 employees
- donated more than one billion servings of food since 1997

* Source: Euromonitor market share

A global snacks powerhouse with net revenues of $34 billion in 2014

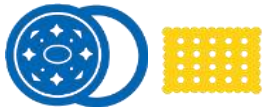


Nearly 75% of revenues in fast-growing snacks categories



80% of revenues come from outside North America

… with leading brands in each snacks category...


#1*


#1*

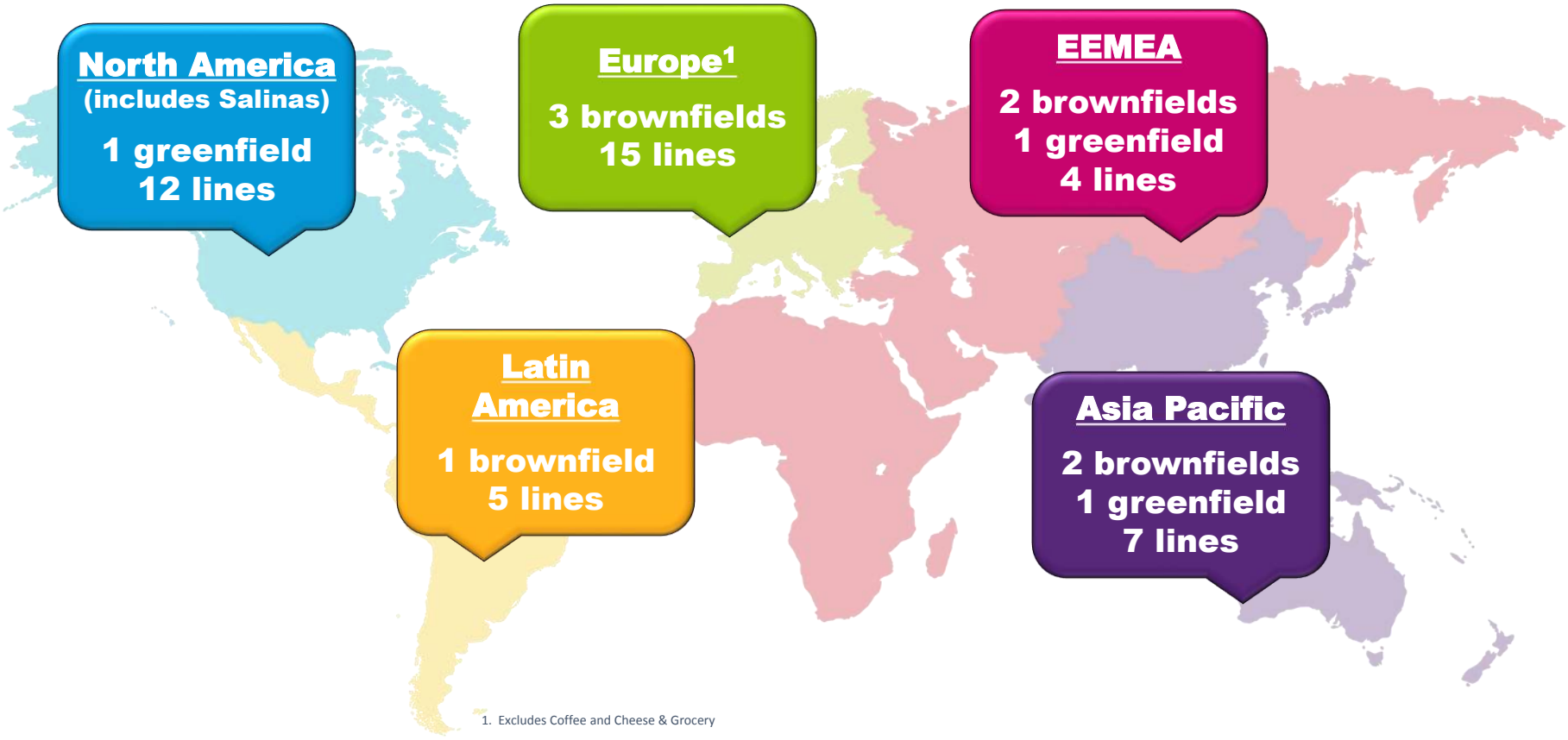

#1*


#2*

In 2014, our Power Brands, which represent over 60 percent of total net revenues, continued to drive our top line and grew at a rate nearly twice as fast as the total company.

* Category position. Source Euromonitor.

…supported with continued investments to fuel growth



1. Excludes Coffee and Cheese & Grocery

We continue to invest in our Power Brands, innovation platforms, technologies and infrastructure to drive strong growth over the long-term. Since 2012, we've invested $1.5 billion in new or existing manufacturing sites to better meet our growth needs.

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Allergen Risk Assessment & HACCP

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An Integrated Quality Chain Approach Focuses on Preventative Systems

Risk Categories

Chemical | Microbiology | Physical

Scope

Design → Procure → Convert* → Distribute → Trade → Consumer

Risk Prevention Programs

Design	Procure	Convert*	Distribute	Trade	Consumer
• 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 • Process Capability & Control	• Traceability • Warehouse Controls	• Complaints • Warehouse Control	• Specification • Labelling • Consumer Response • Process Capabilities

**Applies to internal & external plants*

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Allergens – HACCP Approach

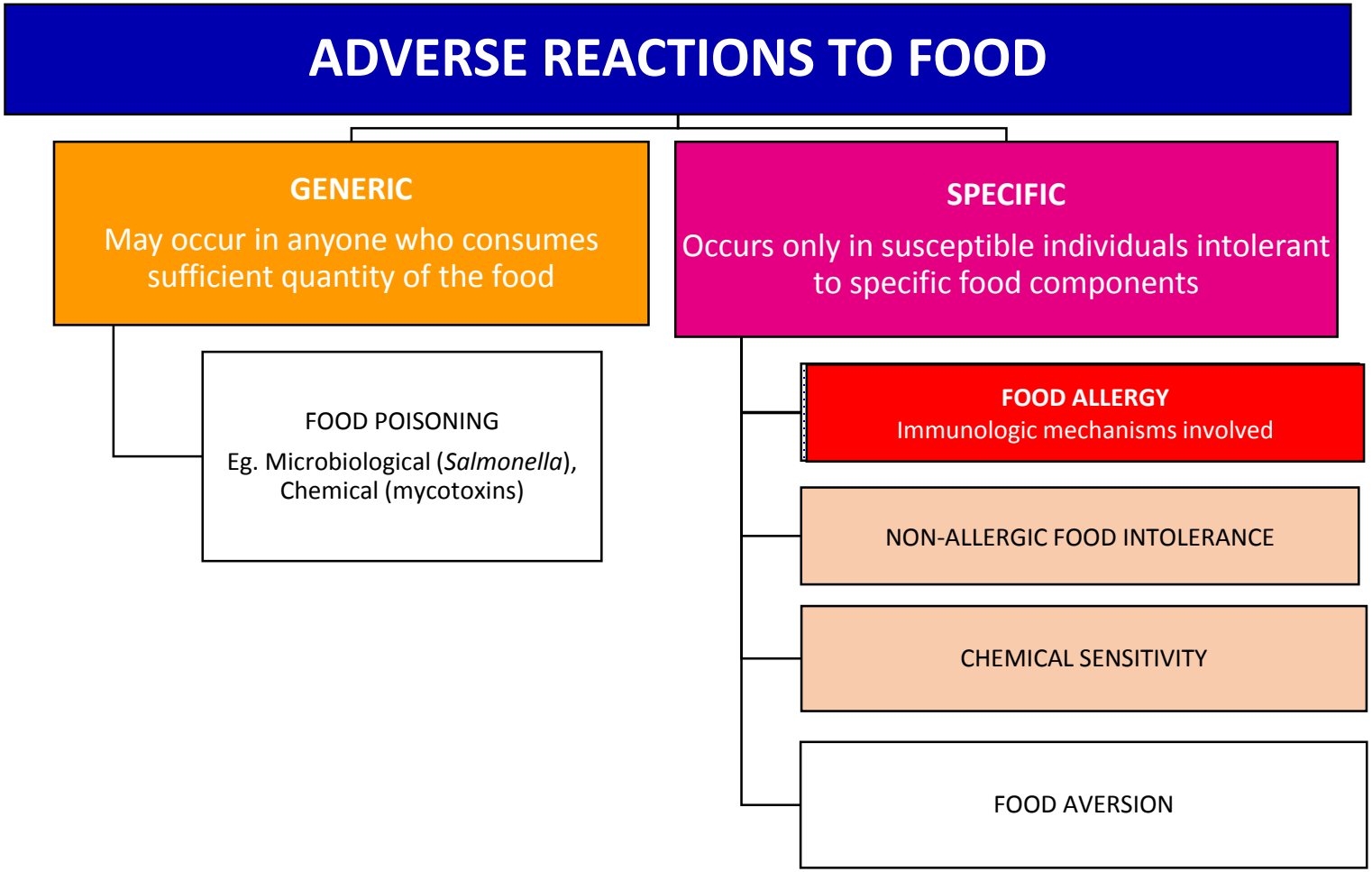
- Mondelēz International Supplier Quality Expectations Manual requires Suppliers to have a documented Hazard Analysis Critical Control Point (HACCP) plan in place for all products, manufactured for Mondelēz International.
- The HACCP system is a preventative approach to managing food safety and finally 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 exists in the raw materials and during the manufacturing stages of the product.
- Mondelēz International manages **Allergens** and substances causing **Intolerance/Sensitivity** within the **Chemical hazards**

Allergens – HACCP Approach

SQE (Supplier Quality Expectation) Requirements for Allergen:

- Effective programme to evaluate, identify and control food allergens
- Allergen management programme based on risk-assessment (HACCP principles)
- Where possible:
  a) Avoid the use of allergens
  b) Design allergens out
- Cross-contact from ‘avoidable’ allergens strictly managed
- Adequate management of rework containing allergens (like into like)
- Cross-contact from ‘unavoidable’ allergens clearly communicated
- Effective allergen training programme – relevant to job responsibilities

Allergens – HACCP Approach



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Allergens – HACCP Approach

- Mondelēz International separates between Allergens that cause a “true allergic reaction” which involves the immune system and basically constitutes an immune response to a protein **and** a Food Intolerance or Sensitivity with no involvement of the immune system.
- Allergens could cause severe, life-threatening reactions to sensitive individuals
- Food Intolerance reactions are generally less severe (not fatal)- Example: Gluten intolerance caused by cereals other than wheat
- Food Sensitivity has symptoms similar to allergy and are reactions to chemical element of food
  Example: Sulfite
- Food aversion: Psychological condition (don’t like it)

Allergens – HACCP Approach

Within the group of allergens Mondelez Int. distinguish between

- Those with global prevalence. They are called “Global Allergens” and listed in the Mondelēz International Global Food Allergen Category List (appendix C of the HACCP manual)
- Those with regional occurrence. They are listed above the Global Food Allergen Category List (appendix C) and called “Regional Allergens”

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

Global Allergen List

Category of Food Allergen	Positive List of Ingredients or Foods includes (but not limited to):	Examples of foods that often contain this material	Exemptions to the Category of Food Allergen
Crustacean	e.g., Shrimp, crab, lobster, crawfish Each species within this category, must be regarded as a separate allergen	Glucosamine Hydrochloride containing foods	
Egg	e.g. Hen's and other avian species Ovalbumin, whole egg, egg yolk, egg white, lysozyme, hydrolyzed egg protein	Mayonnaise, meringue	
Fish	e.g., Cod, Haddock, Flounder, Trout Each species within this category, must be regarded as a separate allergen		Gelatin from fish used as a carrier for vitamin or carotenoid preparations Gelatin from fish used as a fining agent in wine, beer and cider.
Lupine/ Lupin	Lupine flour, lupini beans		

Allergens – HACCP Approach

Global Allergen List (cont.)

Category of Food Allergen	Positive List of Ingredients or Foods includes (but not limited to):	Examples of foods that often contain this material	Exemptions to the Category of Food Allergen
Milk	e.g., Cow's, sheep's, goat's Butter, buttermilk, casein, cheese, cottage cheese, curds, whey, lactoglobulin, lactose*, malted milk, cream, sodium caseinate, sour cream, yoghurt, hydrolyzed milk protein **Only if it contains protein*	Margarines, milk chocolate, ice cream, custard, nougat pudding	Lactose and lactitol which contains no protein (specification must indicate process for protein removal) Alcoholic distillates derived (including ethyl alcohol) from whey
Mollusk / Mollusc	e.g., Clams, oysters, mussels Each species within this category, must be regarded as a separate allergen	Calcium Supplements	
Peanut	Peanut butter, nut pieces, peanut flour, peanut protein, hydrolyzed peanut protein	Mixed nuts	
Seeds: Sesame seeds	Sesame paste, Tahini paste	Hummus, biscuits, dressings and sauces	

Allergens – HACCP Approach

Global Allergen List (cont.)

Category of Food Allergen	Positive List of Ingredients or Foods includes (but not limited to):	Examples of foods that often contain this material	Exemptions to the Category of Food Allergen
Soybean /Soya bean / Soy	Soya derived vegetable protein or textured vegetable protein, miso, tofu		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) Phytosterol or phytosterol esters derived from soy
Tree nuts: Almond Brazil Nut Cashew Hazelnut (Filbert) Macadamia Nut Pine Nuts Pistachio Pecan Walnut	Only those tree nuts identified. Each tree nut type within this category must be regarded as a separate allergen	Mixed nuts Some chocolates	Alcoholic distillates including ethyl alcohol of agricultural origin dervived from treenuts
Wheat	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, spelt, Khorasan wheat, Kamut	Breadcrumbs, crackers, bread, pasta	Wheat derived glucose, glucose syrup, dextrose, dextrose monohydrate, maltodextrin (all DEs), sugar alcohols, and caramelized glucose. Alcoholic distillates including ethyl alcohol of agricultural origin derived from wheat Vinegars (including spirit vinegar) derived from wheat

Allergens – HACCP Approach

In addition to the allergens from the Global Food Allergen Category List the following substances have to be managed as allergens, also called “Regional Allergens”

Celery and Mustard: only for Europe (including political EU, Nordic countries, Switzerland, Central Europe,

Eastern Europe), Middle East and Africa

Stages of an Allergen HACCP Risk Analysis

Forms: Appendix D

1. Identify all allergens present on site	Fill form E1 and Form C, use RM specification as key source of information
2. Identify potential opportunities for cross-contact within own operations	Start to fill Form E2 and Form D but leave the management open (allergen cleaning or labelling), Perform allergen mapping Form J
3. HACCP assessment confirms: Addition of a new allergen to a line or different allergen lines and/or area profiles exist (Form J)	Fill the Allergen Checklist to evaluate allergen management
4. Update Form E2 and D with the final allergen management agreed after the assessment (allergen cleaning or –labelling)	Finalize Form D and E 2 on the management, update all relevant HACCP and plant documents (Form G, plant procedures, plant control sheets..)
5. Perform an assessment if labelling is critical	If yes: Introduction of automated label verification for allergen control (if applicable) or visual label control.

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Note: The content of the forms is required; however, the format of the forms is optional

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 identify appropriate controls.

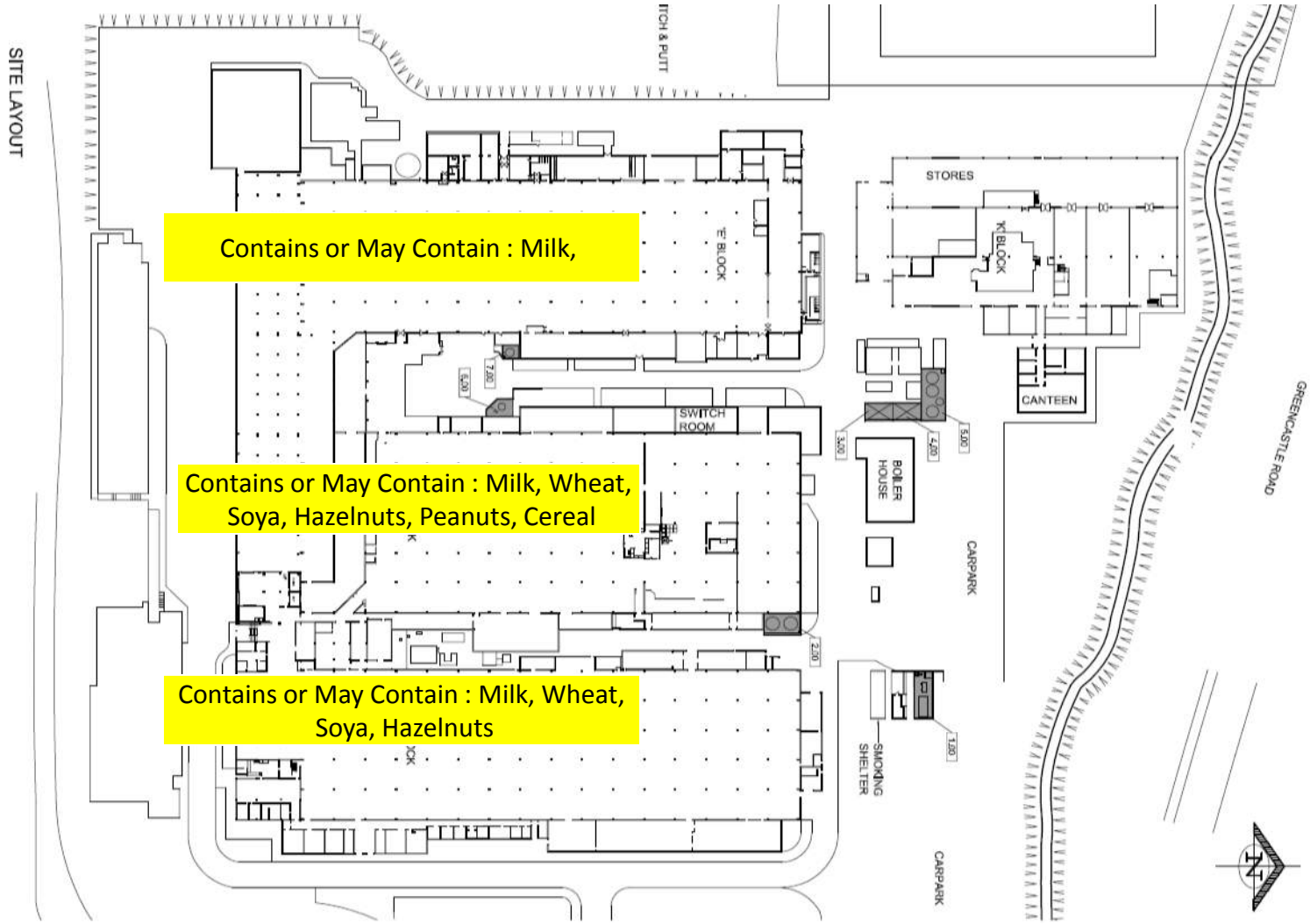
  It’s recommended to use an assessment similar to an allergen control checklist

Example of a allergen control checklist: FDE Table 2A Critical elements for HACCP Risk Analysis and Risk Management

Adobe Acrobat Document

Allergens – HACCP Approach

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



Allergen Risk Assessment Case study

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Allergen Risk Assessment

Basis for identifying, evaluating and controlling food allergens

- A risk assessment shall be carried out as part of HACCP Plan development to identify, review, and document allergens likely to be present
- The process detailed in Mondelēz International Global, Inc. Supplier and External Manufacturer HACCP Manual
- The assessment must consider all allergens on the *Mondelēz International Allergen Category List (see Appendix C of the Mondelēz International Global, Inc. Supplier and External Manufacturer HACCP Manual)* as well as any others identified in local regulations.
- The 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.
- It ensures that specific allergens are not inadvertently incorporated as an undeclared component of any product

Allergen Risk Assessment

Mondelēz International acknowledge that you cannot provide 100% guarantee that materials supplied are 100% 'allergen-free'

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.

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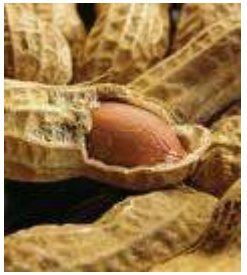
Allergen Risk Assessment – Scenario 1



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 therefore processing steps significantly reduce the risk of peanut contamination
- **Outcome = avoidable allergen**; No CCL

Allergen Risk Assessment – Scenario 2

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 CCL**

Allergen Risk Assessment – Scenario 3

Example 2 – 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 program
  - The site have dedicated utensils and tote bins for weighing sesame
  - Output from risk assessment: Visual inspection of the line and equipment after through cleaning demonstrate sesame seeds still to be present
- **Outcome = Unavoidable allergen; CCL required**

Manufacturing Controls

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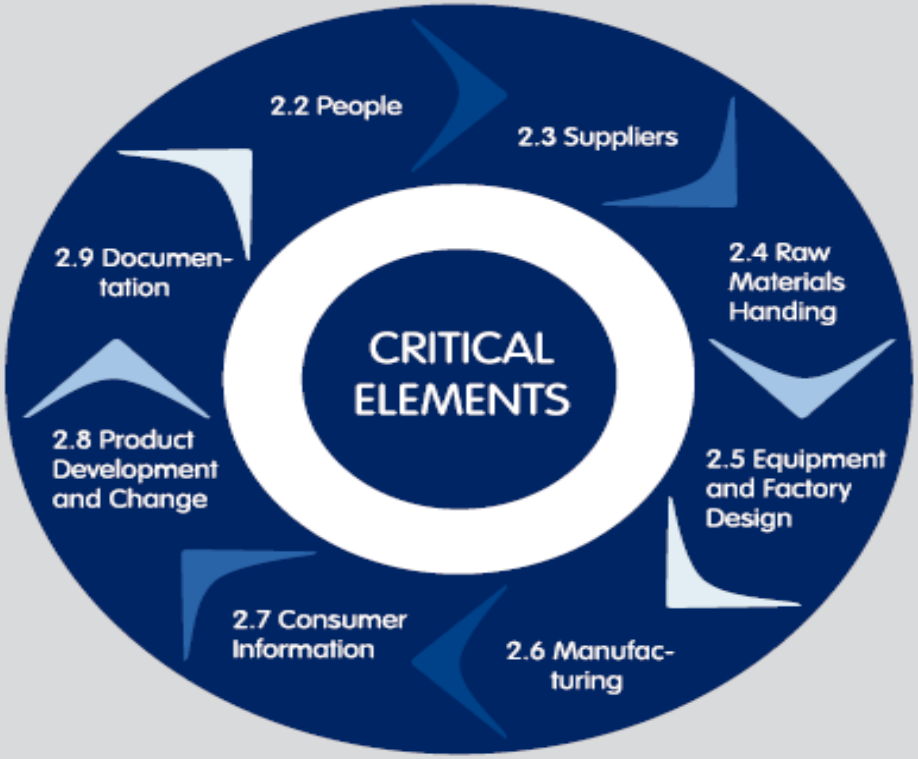
Allergens – HACCP Approach

Elements to Manage the Risk -FDE guideline

Allergen management is an integral part of existing food safety management systems

Fig. 1: Critical elements in allergen risk management



Manufacturing Controls

What is Needed to Manage Allergens in a Manufacturing Facility Plant

- Allergen Risk Analysis and Management
- Allergen Controls
- Allergen Validation and Verification (change over regimes)

Manufacturing Controls

Hierarchy of Controls

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.

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)

Manufacturing Controls

Allergen Change Over …or Precautionary Labelling?

A complete situation assessment should be done on site

- To verify current allergen controls.
- When new allergen containing products are being introduced.
- To evaluate the impact of any changes to existing products (recipe, process)
- of the impact of changes to processes.

Use of a checklist recommended

- Check critical criteria for compliance
- Move from ‘zero risk’ to ‘acceptable risk level’ based approach.
- Acknowledge that cannot completely eradicate allergens in food manufacture.

Manufacturing Controls

Allergen HACCP Risk Analysis - FoodDrinkEurope Guideline

http://www.fooddrinkeurope.eu/uploads/publications_documents/Guidance_on_Food_Allergen_Management.pdf

Identification of all allergens present on site

- Materials intentionally added
- Potential cross contact within suppliers' operation
- Includes non-food material, semi-finished product

Identification of potential cross contact risk within own operations

- Includes all products/processes/lines
- Includes all situations cross contact can occur
- Allergen Map

Assessment of potential issues

- Probably of occurrence (likely/unlikely)
- Evaluation of severity (allergen potency, prevalence, protein level, physical form allergenic ingredients)

Assessment of control measures

- Identification of critical elements based on best practice guidance
- Effectiveness of the control measure
- Ongoing verification procedures

Determination of appropriate risk communication (labelling)

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Manufacturing Controls

FoodDrinkEurope Guideline

Example for a risk assessment with critical element „Manufacturing“ (Cleaning)

Best Practice Consideration	Cross-contact Probability		Rationale for Cross-contact Probability	Allergen Hazard Rating	Control Measures
	Likely	*Unlikely*			
Contamination of adjacent lines by cleaning regime	X		Compressed air used for cleaning	Peanut pieces - High Refined soya oil - Low	Cleaning regime changed, no compressed air used. Advisory labelling not required.

Manufacturing Controls

Key Elements of the Mondelēz Int'l Allergen Assessment Checklist

- Identification of all allergens
- Identification of concerned products / processes / lines and their respective allergen profiles
- Adjacent Lines
- Multiple Locations (facilities)
- Training & Awareness
- HACCP (forms, PP's, CCP's, validation)
- Handling and identification in receiving and storage areas
- Production scheduling
- Work in process, locally manufactured ingredients, rework
- Manufacturing controls (hygienic design, allergen change over, hold & release, tools & utensils)
- Labeling controls
- GMP's

Manufacturing Controls

Sources of Issues and Risk Levels at a Manufacturing Site will vary

Area of Concern	Potential Issue	Perceived Risk Level
Labelling	Undeclared allergens	High
Rework, WIP, LMI	Cross contact/Carry Over	High
Training	Skills & Awareness	High
Raw Materials	Undeclared allergens	High
Change Over Regimes	Allergen carry over	High
Hygienic Design	Cross contact/Carry Over	Medium
Shared Equipment & Tools	Cross contact/Carry Over	Medium - High
Receiving & Storage	Cross contact/Carry Over	Medium
Adjacent Line Situation	Cross contact	Medium
Traffic Patterns	Cross contact	Low

Example

Some examples of Manufacturing Controls

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Manufacturing Controls- Example Labelling

Area of Concern	Potential Issue	Perceived Risk Level
Labelling	Undeclared allergens	High

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

Area of Concern	Potential Issue	Perceived Risk Level
Rework, Work in Progress (WIP), Locally Manufactured Ingredient (LMI)	Cross contact/Carry Over	High

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

Area of Concern	Potential Issue	Perceived Risk Level
Training	Skills & Awareness	High

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

Area of Concern	Potential Issue	Perceived Risk Level
Raw Materials	Undeclared allergens	High

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

Area of Concern	Potential Issue	Perceived Risk Level
Change Over Regimes • Cleaning • Flushing • Sequencing	Allergen carry over	High

Control Measures

- Product change over: Removal of allergen containing materials prior to a production of non-allergen containing product via cleaning or 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)
- Validation (at minimum every 2 years).
  - *Physical validation (tear down inspection and documentation check)*
  - *Analytical testing using validated methods*

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Manufacturing Controls

Area of Concern	Potential Issue	Perceived Risk Level
Change Over Regimes • Cleaning • Flushing • Sequencing	Allergen carry over	High

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)
- Don't contaminate adjacent lines when cleaning a line:
  - *Use of vacuum cleaning rather than air hoses/compressed air.*
  - *Dedicated cleaning tools / cleaning tools program.*

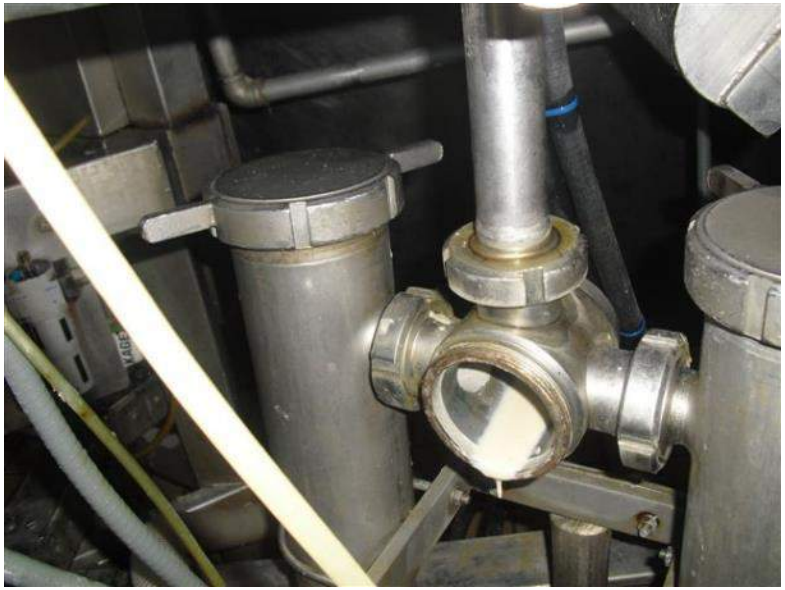
Manufacturing Controls

Area of Concern	Potential Issue	Perceived Risk Level
Hygienic Design (Factory and Equipment)	Cross contact/Carry Over	Medium

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



Allergen Testing, Verification & Validation

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Definitions

Validation:

- The validation is a one off assessment conducting a systematic collection and evaluation of data from the process (series of measurements, adjustments, checks) to establish scientific evidence that a process, piece of equipment or system can successfully and consistently operate to control identified hazards by eliminating or minimizing the risk below set critical limits.
- Validation answers the questions: “Are we doing the right thing and will it work”.
- Cleaning validation = is cleaning capable of removing allergens and minimizing risk of allergen carryover

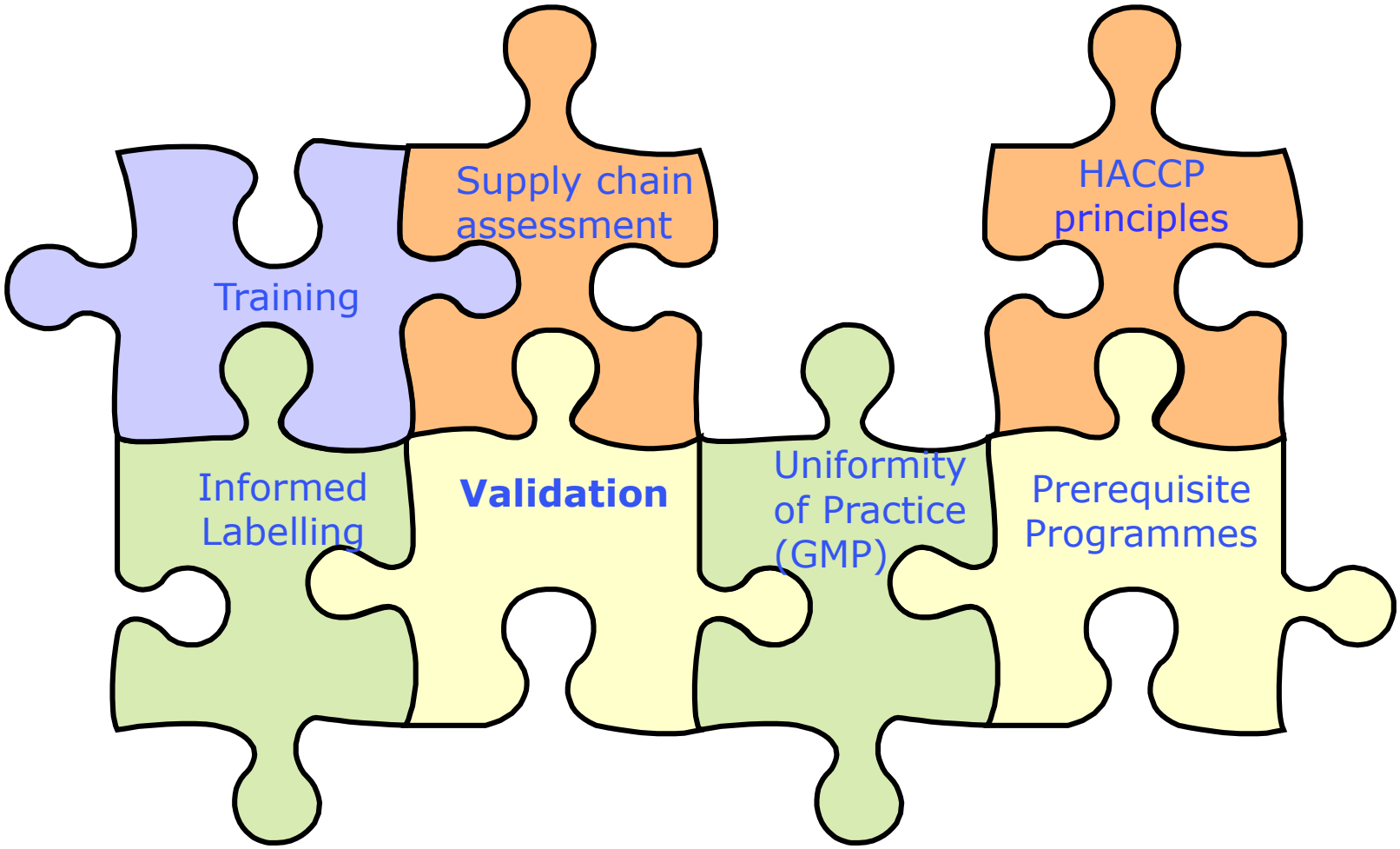
Verification

- Verification is the periodic application of methods, procedures, tests and other evaluations to determine compliance with the requirements identified during the validation.
- Verification answers the questions “Are we doing what we planned to do”
- Cleaning verification = periodic online/ near line checks for allergen residues

Monitoring

- Monitoring is conducted each time a planned sequence of observations or measurements to assess whether control measures are operating as intended. It means to determine the current status and to assess if required or expected performance levels are actually being achieved and in case not to initiate a corrective action. The regular repetition is a central element of this program in order to be able to drive conclusions by comparison of data. Monitoring answers the question “Has it worked every time we did it”
- Monitoring of cleaning = visual inspection post cleaning at key inspection points against visual standards

Allergen Validation



Allergen Validation

Two Step Approach

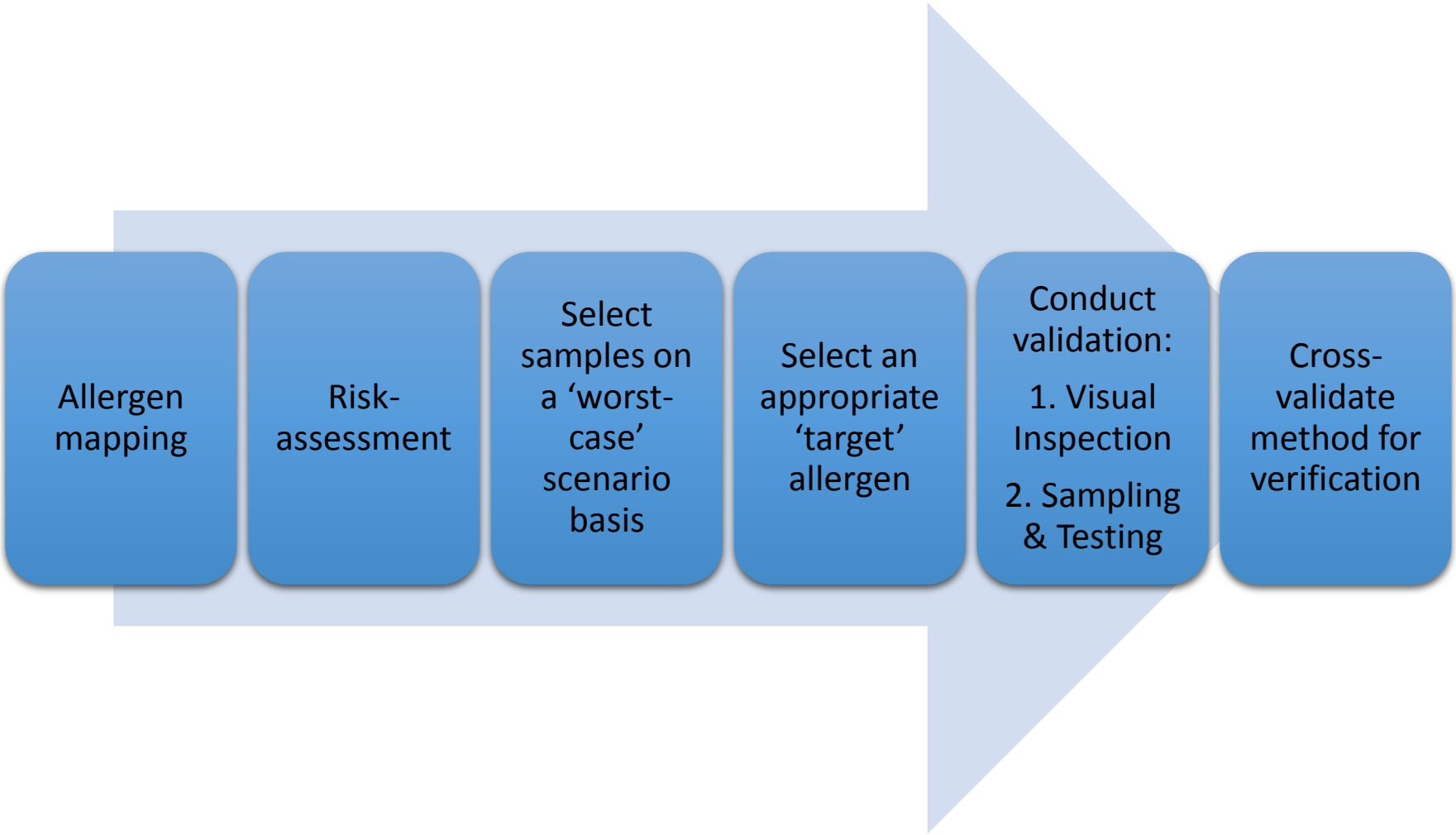
1st Step: Physical Validation of an Allergen Change Over

- 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
- A visually clean standard must be achieved

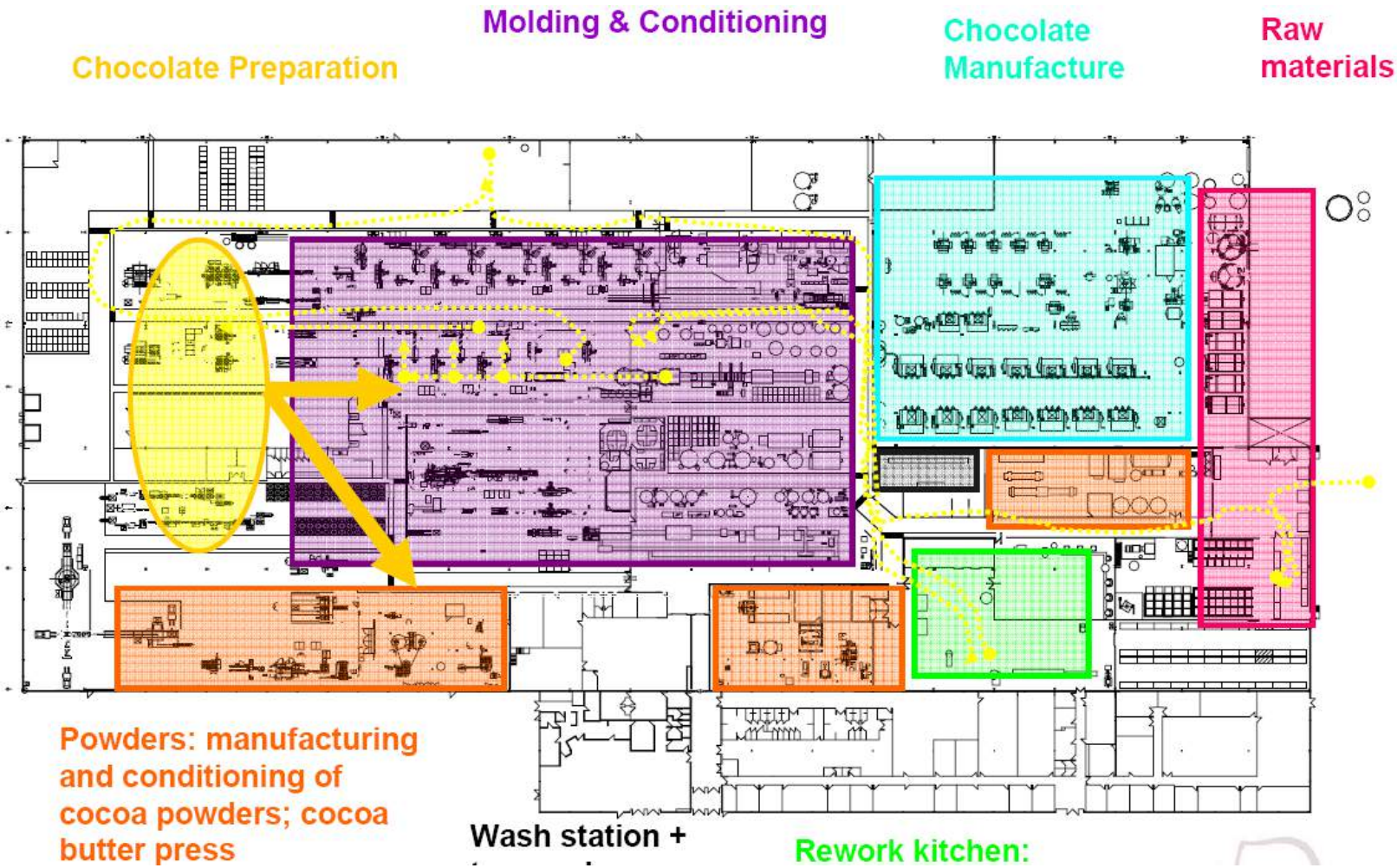
2nd Step: Analytical Validation of Allergens Using Allergen Test Kits (ELISA)

- 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 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

Select Samples - 'Worst-Case Scenario'

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

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

Selecting a Target Allergen

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)

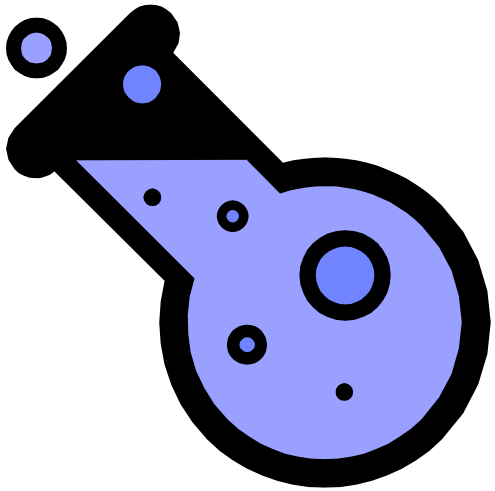
Risk-based Approach To Sampling

Results only as good as samples submitted

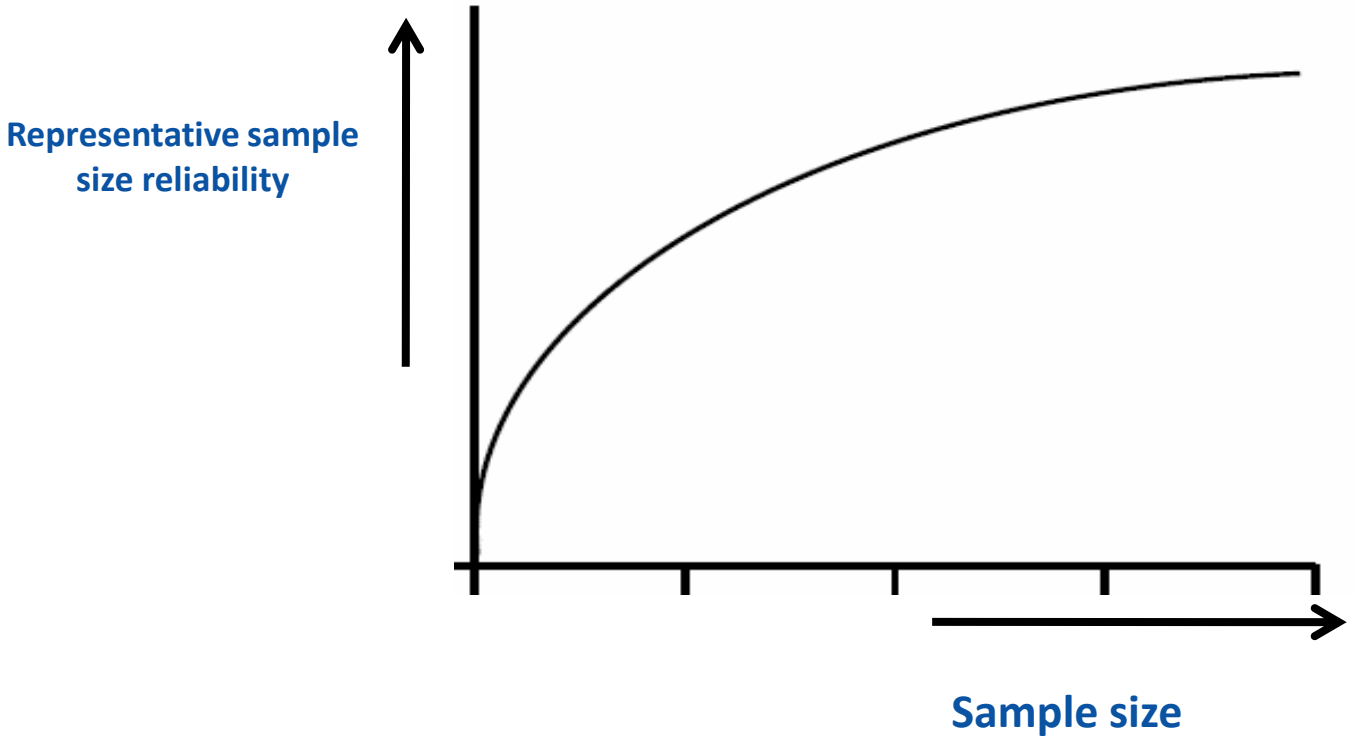
Sampling plan linked to risk analysis to maximise probability of detecting contamination (if present)

Plan must consider:

- Physical nature of contaminant
- Level of processing undergone
- Amount of protein
- Type of production environment



Sampling & Analysis



Analytical Techniques

Lab-based

- Enzyme Linked Immunosorbant Assay (ELISA)
- Polymerase Chain Reaction (PCR - DNA)
- Distillation techniques (Sulphites)

Factory based rapid tests

- Allergen Specific Rapid lateral flow devices
- Non-specific protein tests
- ATP bioluminescence

Rapid Lateral Flow Devices

Validation is vital - Wide range of devices commercially available

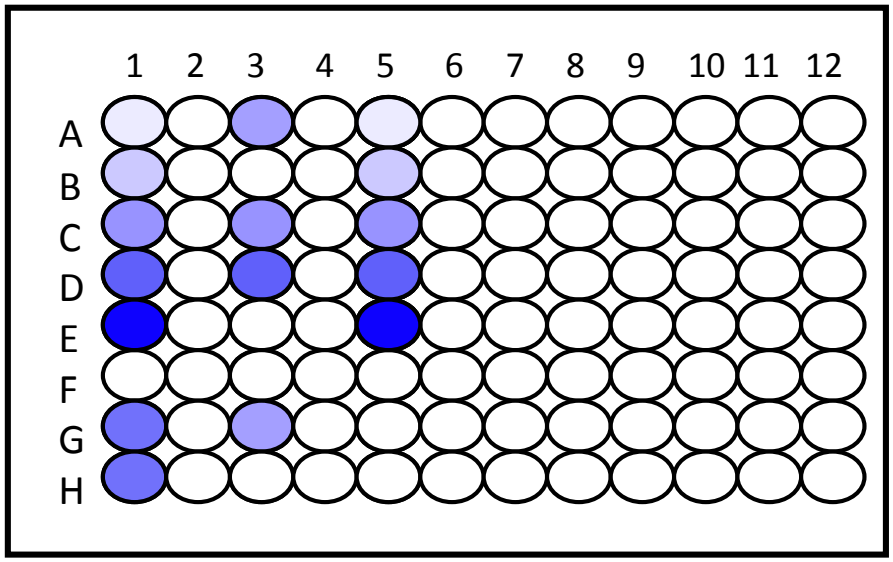
Only recommended for verification testing – 'clean' environmental samples (swabs / CIP rinse waters)

ELISA – Mondelēz International Method of Choice

Kits specific for individual allergenic proteins

Clinically relevant (proven to cause reaction)

Quantitative within a standard range – actual result vs. detected / not detected



ELISA

Advantages

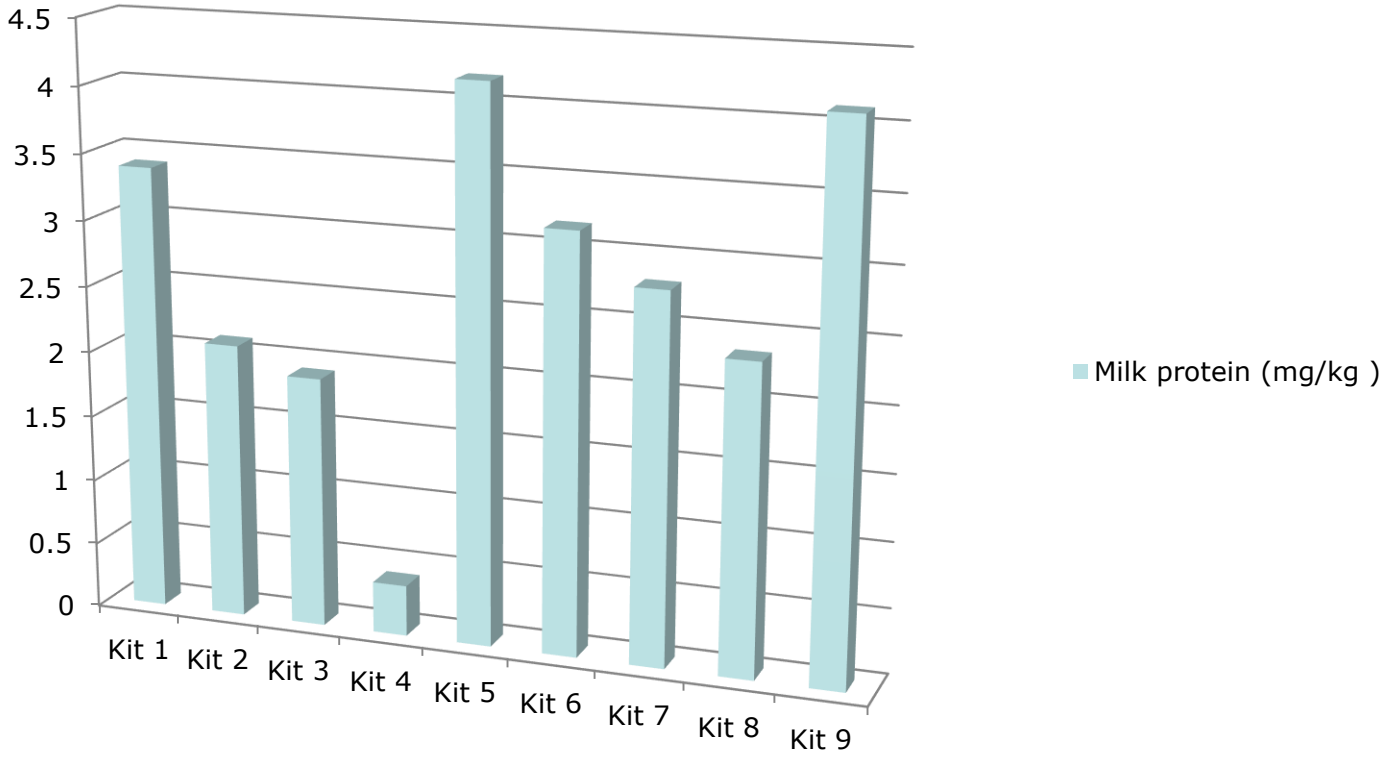
- Improved sensitivity and selectivity (low mg/kg)
- Developed in house improved extraction techniques
- Larger range of commercial kits available
- Fast generation of results

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

Inter-assay Reproducibility (Europrevall Meals)

1 lab (RSSL) - 9 commercial milk ELISA's



Limits of Reporting

Allergen	ELISA mg/kg (ppm)
Casein	2.5
BLG	5
Egg	2
Gluten	10
Peanut	1
Hazelnut	5

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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)

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Summary

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Summary

- Mondelēz International position is NOT to delegate risk to consumers and to decrease food choice. Thus cross contact labelling ("may contain") shall be used as the last resort 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

Mondelēz International Supplier Quality Web Site

The Mondelēz International Supplier Quality web site is designed to facilitate the communication between Mondelēz International and our suppliers.

Here you will find all of the Quality Requirements and Guidelines for Suppliers to Mondelēz International, 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://www.mdlzsupplierquality.com/

Questions?

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Appendix

E1 example

MANUFACTURING LINE REFERENCE:		
For each manufacturing line on plant there should be a separate E1 and E2 form (or add additional column and line label). No blank spaces use N/A.		
A	B	C
List all ingredients and rework used on the line: containing allergens and/or /sulfites (>10ppm in final formula) as per Food Allergen Category List (Sect 15 HACCP Standard) and /or containing carryover allergens and/or sulfites (>10ppm in final formula) per allergen profile of raw material spec. List any processing aids that may come in contact with product contact surfaces or product itself that contains allergens or sulfites >10ppm.	List identified allergens and/or sulfites (>10ppm in final formula) of ingredients or components of ingredients (listed as contain in GKIT or RM specification)	List identified carryover allergens and/or sulfites (>10ppm in final formula) in the ingredients that are not direct components of the raw materials (listed as "may contain" or "trace of " in GKIT or RM specification)
Hazelnut	Hazelnut	Almond
Egg	Egg	
Plant Allergen Profile Spec Report:		

Note: New form- update in 2015

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Form E2 example

A	B	C	D	E	F	G	H
List all finished products (current and new ones) produced on the manufacturing line	**List all Allergens and/or sulfites (>10ppm in final formula) from the ingredients allergen profile (E1)**	**List all Allergens and/or sulfites (>10ppm in final formula) coming from cross contamination on the line (use of Line allergen profile)**	**List control mechanism that prevent cross contamination from the line (sPP/CCP /risk assessments).**	**Allergen and/or sulfites (>10ppm in final formula) profile of product as manufactured.**	**Allergen and/or sulfites (>10ppm in final formula) profile from label.**	**List difference of allergen and/or sulfites (>10ppm in final formula) profile between 'as manufactured' and 'label'.**	**If allergen and/or sulfites (>10ppm in final formula) profile is different explain.**
Product A with Handysnack breadstick cracker	Contain: Milk, Wheat, Gluten	Carry over: Egg	Equipment Cleaning (Product Changeover Cracker)-CCP Rework Handling Cracker-CCP Label application - PP	Contain: Milk, Wheat, Gluten	Ingredients line allergen profile (contains): Milk, Wheat, Gluten	Contain: N/A	N/A
	May Contain: N/A	Possible carry over of carry over: Mustard	Assessment for Mustard: Carry over of carry over levels considered too low to cause a risk to mustard allergic consumers	May Contain: N/A	May Contain: N.A	May Contain: N/A	N/A

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Note: New form- update in 2015

Allergen Procedures

Mondelēz International SUPPLIER QUALITY EXPECTATIONS MANUAL (SQE)

- Chapter 7 “Planning and Realisation of safe Products”, Section 7.5 – ALLERGEN MANAGEMENT

SUPPLIER AND EXTERNAL MANUFACTURER HACCP MANUAL (Update Q3 2015)

- Appendix C: Mondelēz International Food Allergen Category List
- Model CCP: REWORK HANDLING (P75)
- Model CCP: EQUIPMENT CLEANING FOR ALLERGEN REMOVAL (PRODUCT CHANGEOVER) (P77)
- Model CCP: PRODUCT FLUSHING FOR ALLERGEN REMOVAL (PRODUCT CHANGEOVER) (P79)

SUPPLIER QUALITY EXPECTATIONS MANUAL RESOURCE SUPPLEMENT

- SECTION N: ALLERGEN MANAGEMENT

Manufacturing Controls

Resources available to help the Industry

FoodDrinkEurope (EU)

- Guidance with 6 annexes (among others: risk management, change over validation, analysis) http://www.fooddrinkeurope.eu/
- Dissemination across stakeholders in the food industry ongoing

Food Standards Agency (UK)

- Guidance on Allergen Management and Consumer Information http://www.food.gov.uk/multimedia/pdfs/maycontainguide.pdf

Allergen Bureau (Australia)

- http://www.allergenbureau.net/
- Allergen Management and Labelling Guide
- Vital 2 Approach

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http://www.mondelezinternational.com/procurement.aspx

Thank you very much!

Questions & Answers

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