Allergen Control: From Problem to Solution

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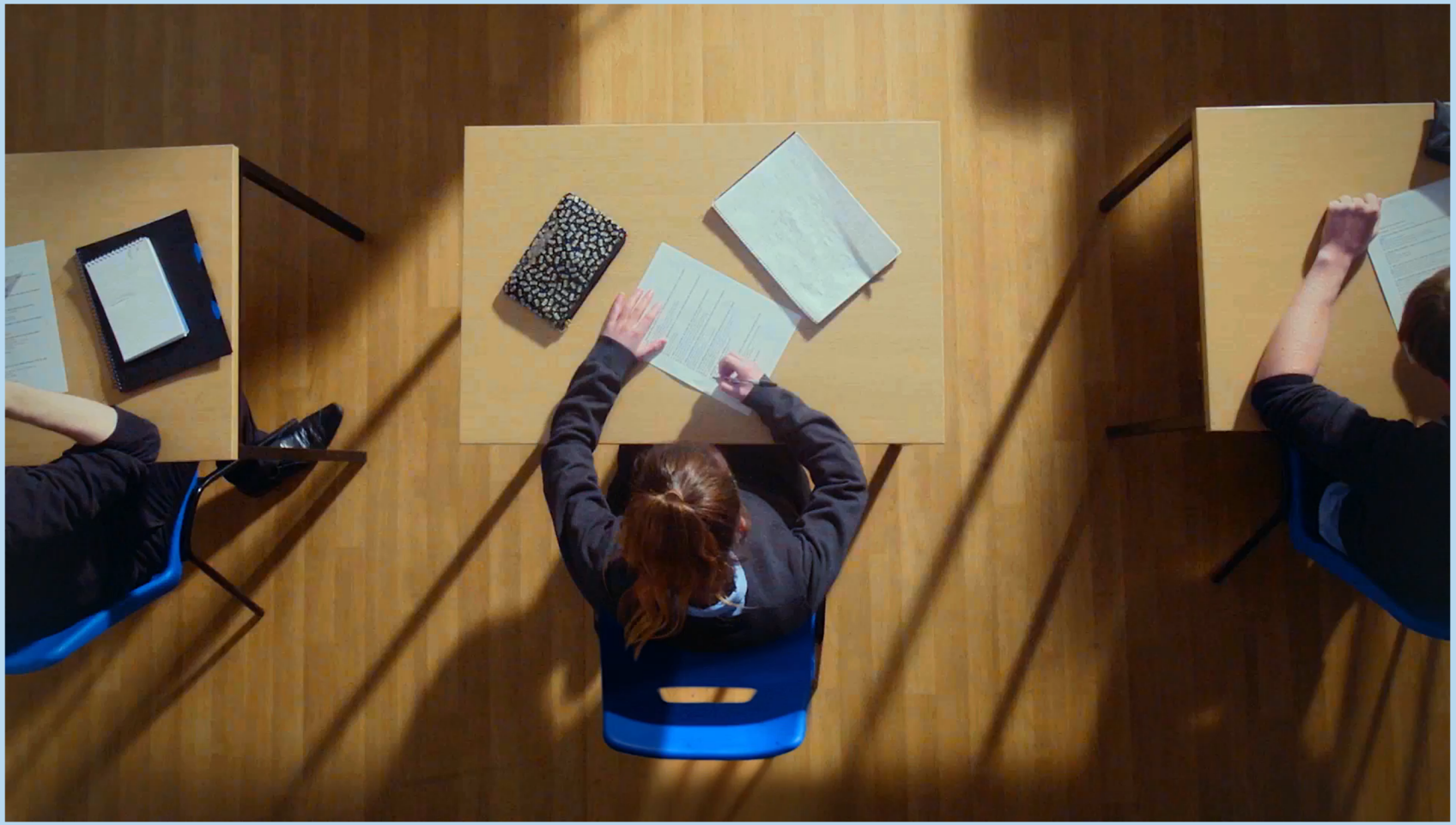
Allergen control

Why is it important?



Allergen control

Why is it important?

Allergen: A known component of food which causes physiological reactions due to an immunological responses.

2 types of ‘allergic’ reaction.

- Immunological - IgE-mediated
  - Usually develop very shortly after eating the food.
  - Reactions range from severe (anaphylaxis), which can be life threatening, to an itchy red rash.
  - It can also include swelling of the face, mouth, throat; itchy eyes; shortness of breath; dizziness; and nausea.

Food Allergy

- Non-immunological
  - Less severe.
  - Symptoms can take much longer to develop.

Food Intolerance

Allergen control

Why is it important?

UK: Source: UK Anaphylaxis Campaign

- Food allergy affects 1-2% of adults & 5-8% of children.
- 1 in 50 children has a nut allergy.
- Peanut allergy cases have tripled in the last decade.
- 2015-16: 29,544 hospital admissions in England related to allergic reactions and there has been a significant increase in last 5 years.
- Fatalities: about 10 per year.

EU:

- >17 million people in the EU are estimated to suffer from food allergies (EAACI, 2013).
- Up to 6% of the population in some parts of the EU have been clinically confirmed with food allergies (AAAAI, 2019).

USA: Source: Food Allergy Research & Education (FARE)

- Food allergy affects 6-10% of the U.S. population (32 million people).
- 6-8% of children (1 in 13) More than 40% have experienced a severe reaction.
- 10% of adults (1 in 10) >50% have experienced a severe reaction.
- 377% increase in claim line diagnosis of anaphylactic food reactions between 2007 – 2016.
- Childhood food allergy economic impact : $24.8 billion annually.
- Every 3 minutes, a food allergy sends someone to the ER in the US
- Fatalities: about 5 per day.

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Legal requirements (EU & UK)

Europe

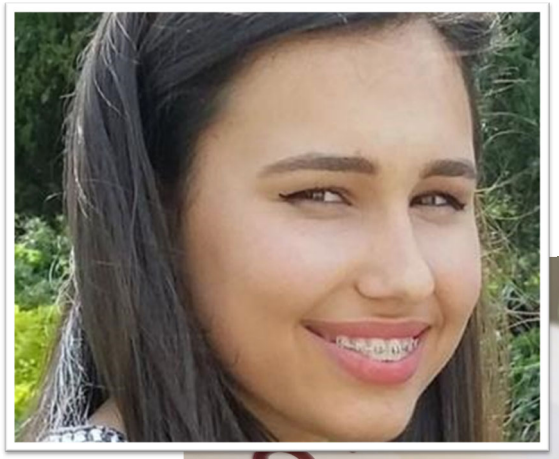
- EC General Food Law Regulation (EC) No 178/2002 laying down the general principles and requirements. Prohibits unsafe food being placed on the market.
- EU Hygiene Regulations, 2004.
- Provision of Food Information to Consumers EU Regulation No. 1169/2011.

UK

- UK Food Safety Act 1990.
  An offence to sell food which is not of the nature or substance or quality demanded by the purchaser.
- The Food Hygiene (England) Regulations, 2006.
- Food Information Regulation 2014 (SI 2014/1855) and subsequent amendments.

Allergen control

‘Natasha’s Law’



Natasha Ednan-Laperouse, Age 15

- Died in 2018 after suffering an allergic reaction due to sesame in a Pret a Manger baguette.
- 2019 – Amendment to Food Information (England) Regulation, 2014.
  - ‘All foods pre-packed for direct sale, will need a full ingredients label’.
- ‘Natasha’s Law’ - comes into force in October 2021.

NOTE:

FDA is considering Voluntary Disclosure of Sesame as an Allergen. This still subject to Public Comment until 25/02/2021. Source: Draft Guidance for Industry: Voluntary Disclosure of Sesame as an Allergen | FDA. Effective November 2021

Allergen control

EU Provision of Food Information

EU Regulation No. 1169/2011.

- Provides information about *14 EU allergens.
- Major allergens must be highlighted in **bold** font in the ingredients list of the product label.
- The label must use the wording “Allergy Advice – for allergens, see ingredients in **bold**”.
- In the absence of an ingredients list, the presence of allergens must be indicated by use of the word “contains” followed by the name of the allergen.
- The use of “Contains” boxes, detailing allergens present in the ingredients list, is no longer allowed.

Food allergens: almost always proteins

*Priority list of controlled allergens may be different in different countries.
Sulphur dioxide - Not a protein. Must be declared on label if at concentrations >10mg/kg or 10mg/Litre in the finished product.

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Major allergens in the U.S. The Big 8


Milk


Egg


Crustacea


Fish


Peanut


Soybean


Tree nuts


Wheat

Allergen control

U.S. Regulation

- Code of Federal Regulations Title 21 Part 117: Current Good Manufacturing Practice, Hazard Analysis and Risk Based Preventive Controls for Human Food.
- Food Allergen Labeling & Consumer Protection Act of 2004 (FALCPA): Intentionally-added allergen ingredients (The Big 8) must be explicitly declared, by their generic names, on food labels of FDA regulated products.
- FSIS-registered facilities (e.g., meat & poultry) have their own allergen guidelines, similar to FALCPA.
- Voluntary advisory labelling e.g., 'May contain', can be used for the presence of unintentional allergens, if GMP and Allergen controls have been followed.

- Food allergies have emerged as a major public health issue.
- FDA views the risk as the presence of undeclared allergens but has not established thresholds or defined allergen-free, except gluten-free (<20 ppm gluten).
- With the implementation of FSMA regulations, allergen control becomes a preventive control issue, with increased focus on allergen control programs including,
  - supply chain management,
  - cleaning strategies,
  - allergen testing, etc.

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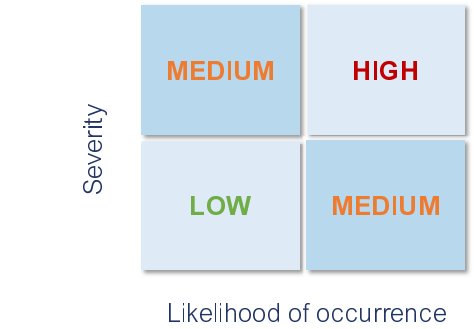
Allergen control

Basic principles of allergen management



- Hazard identification
  - Allergens.
  - Known or potential health effects associated with each allergen.
- Risk assessment
- Implementation of validated controls to "prevent, eliminate or reduce" the occurrence of each allergen to acceptable levels.
- Monitoring and verification to measure the efficacy of the allergen control systems.

Challenges

- Allergens vary in different areas of the world.
- Potential health effects very variable - severity of symptoms, threshold of elicitation.
- Often a natural component of the food.
- Lack of qualitative and/or quantitative data on acceptable levels (*infective* dose).
- Lack of definitive limits.

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How much is too much?

Peanut allergic patients present with different levels of sensitivity.

0.2 mg (0.05 mg)	0.4 mg (0.1 mg)	1.0 mg (0.25 mg)	5.0 mg (1.25 mg)	25 mg (6.25 mg)	100 mg (25 mg)	400 mg (100 mg peanut protein)

*0.4 mg peanut (0.1 mg peanut protein) is the eliciting dose of the most sensitive peanut-allergic patient reported in the published clinical literature and remains the smallest amount of peanut known to provoke an objective (visible to clinical staff) reaction in trials of nearly 2000 peanut-allergic individuals.

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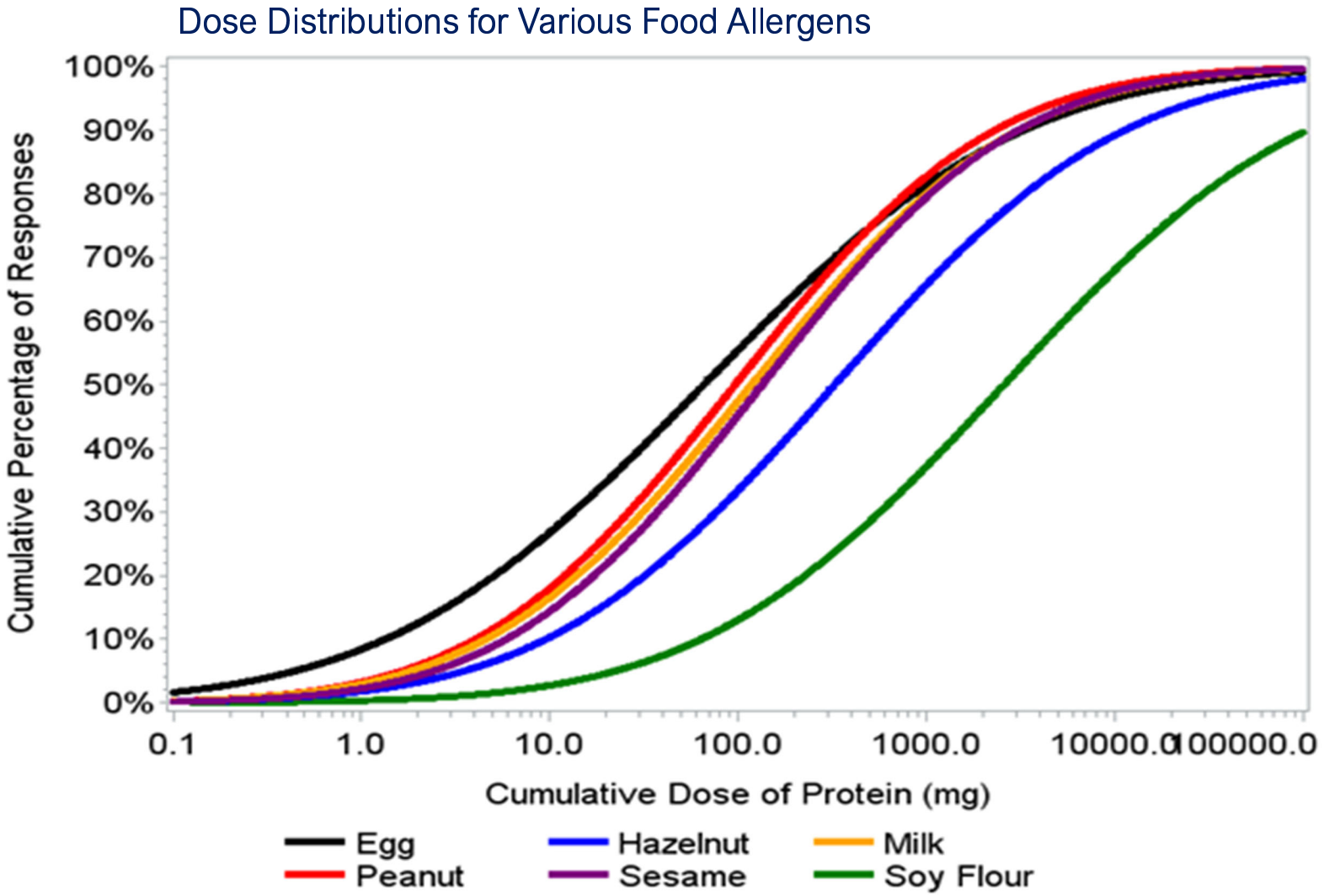
Not all food allergens are created equal



Allergen limits

- Priority list of allergens may be different in different countries.
- Should be determined through consensus, based on prevalence, severity and potency (threshold dose).
  - Europe - International Life Sciences Institute (ILSI) expert panel.
  - U.S. - National Academy of Medicine expert panel.

Can we define a level of protection for allergic consumers that everyone can accept? (ILSI review, 2000)

- https://www.sciencedirect.com/science/article/pii/S027323002030177X

- Quantitative limits for unintended allergen presence have in general not been defined across and within jurisdictions.
- Diverse approaches (pragmatic to risk-based) have been adopted to define quantitative limits for other food safety hazards but how tolerability decisions were reached, in the case of those hazards, is unclear.
- The inability to define what risk is tolerable is a major obstacle to defining limits.
- Propose a framework for transparent decisions on risk tolerability, founded on full participation of stakeholders.

Allergen control

VITAL and action Limits

- The VITAL (Voluntary Incidental Trace Allergen Labelling) Program is a standardised allergen risk assessment process for food industry developed by the Allergen Bureau of Australia & New Zealand (funded by industry).

- VITAL suggests protein reference doses (total minimum amount of allergen), necessary in a whole serving to cause a reaction in 95-99% of allergen sufferers, based on clinical reactivity in food challenge studies, at or below which voluntary labelling is unnecessary.

Action Limit (mg/kg) = Reference dose (mg) / Portion size (kg)

e.g., if a chocolate bar weighs 100g (0.1kg) and the reference dose for peanut is 0.1mg, the Action Limit for peanut would be 0.1/0.1 = 1mg/kg

Allergen	VITAL 3.0 reference dose (mg protein) 2019
Peanut	0.1
Milk	0.2
Egg	0.2
Hazelnut	0.1
Cashew	0.05
Soya	0.5
Wheat	0.7
Mustard	0.05
Lupin	2.6
Sesame	0.1
Shrimp	25.0
Walnut	0.03
Celery	0.05
Fish	2.6

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Allergen control in manufacturing

Similar to those for microbial control except that sometimes we knowingly bring allergens into the food production area as ingredients.

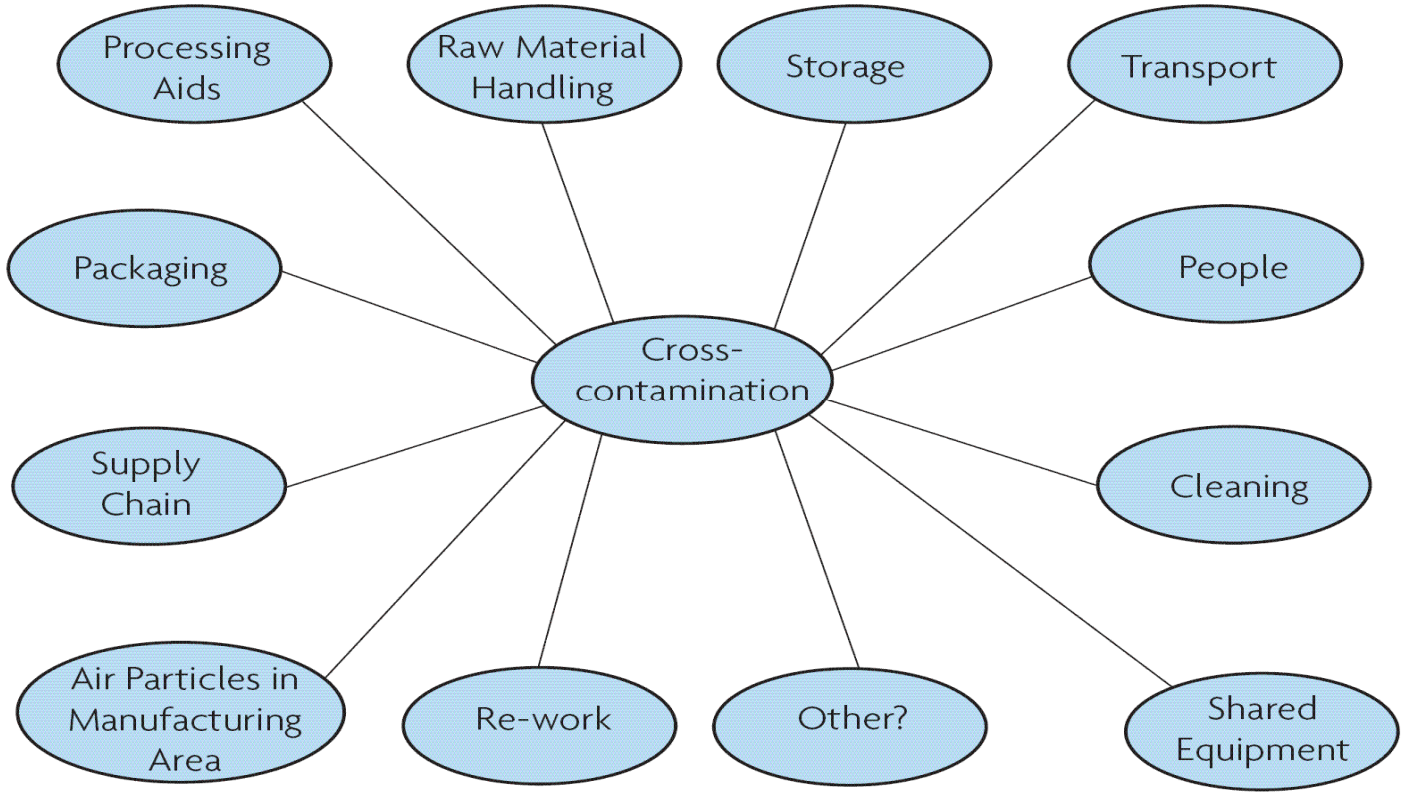
- Key controls:
  - Prevent entry of known allergens into areas where they are not used/allowed.
  - Prevent cross-contamination of allergens from areas where they are allowed, to those where they are not.
  - Label final product to meet legal requirements of the designated country of use.

Allergen control: Preventing entry

- Raw materials:
  - Supplier quality assurance - Certificates of Analysis (allergen-free).
- Building design design / Process flow
  - Segregation of allergen / non-allergen product areas and equipment.
  - Introduction of allergen at latest point in process.
  - Controlled introduction of re-work.
- Maintenance:
  - Allergen-free lubricants.
- NPD:
  - Restrict scope of new product developments to control the introduction of allergens.
- Packaging:
  - Allergen-free.
- People:
  - Controlled movement
  - Separate/colour-coded protective clothing.
  - Restrictions on food brought onto site by staff, visitors, contractors and caterers.
    - Training,
      - awareness of allergens as a hazard and consequences to an allergic consumer.
      - allergen handling & segregation procedures.

Allergen control: Cross-contamination

Potential sources of cross-contamination



Allergen control: Cross-contamination

- Physical or time segregation of allergen-containing materials are being stored, transported, processed or packed.
  - Separate factories – unlikely.
  - Separate rooms/areas– possible.
  - Separate times/lines/equipment – most likely.
- Building design / Process flow
  - Segregation of allergen / non-allergen product areas and equipment.
  - Introduction of allergen at latest point in process.
  - Controlled introduction of re-work.
- Systems and procedures (including cleaning activities) that restrict the movement of airborne dust and aerosols containing allergenic material.
- People:
  - Controlled movement
  - Separate/colour-coded protective clothing.
  - Restrictions on food brought onto site by staff, visitors, contractors and caterers.
    - Training,
      - awareness of allergens as a hazard and consequences to an allergic consumer.
      - allergen handling & segregation procedures.
- Waste handling & spillage controls.
- Hygienic design of equipment and buildings
- Cleaning: physical removal of contamination (allergens).

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Allergen control

Minimising cross-contamination

- Cleaning is a major control to ensure allergen removal from processing lines & environmental surfaces prior to production of allergen-free product.
- There are no specific chemical agents for removal of allergens.
  - Caustic chlorinated products are best for protein removal.
  - Although disinfectants, radiation (UV) and heat may denature the protein they may not inactivate the site of allergenicity.
- Efficient and effective removal is achieved through good cleaning method & equipment selection, application and maintenance.
  - Use methods that maximise allergen removal and minimise their spread.
  - Use hygienically designed, identifiable (colour-coded), dedicated cleaning tools and utensils for allergen cleaning (inc. spillage control) and processing activities.
  - Use physical or time segregation of cleaning activities.
  - Use dedicated, trained staff.
  - Ensure that the cleaning has been achieved to the required standard – Validation, Verification, Monitoring (of both the item to be cleaned & of the cleaning equipment).

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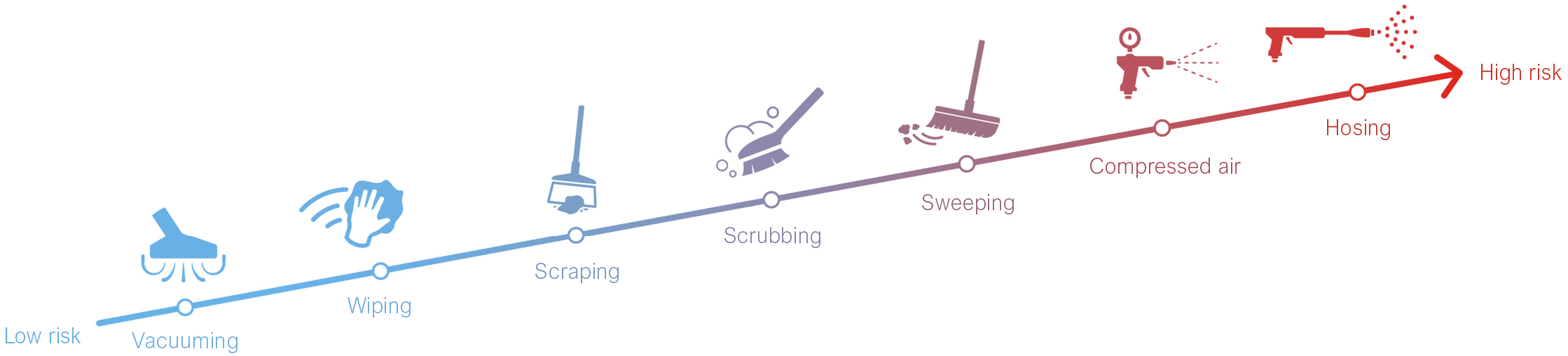
Allergen control

Minimising cross-contamination

All cleaning activities spread contamination



Choose cleaning equipment and methods that maximise allergen removal and minimise their spread

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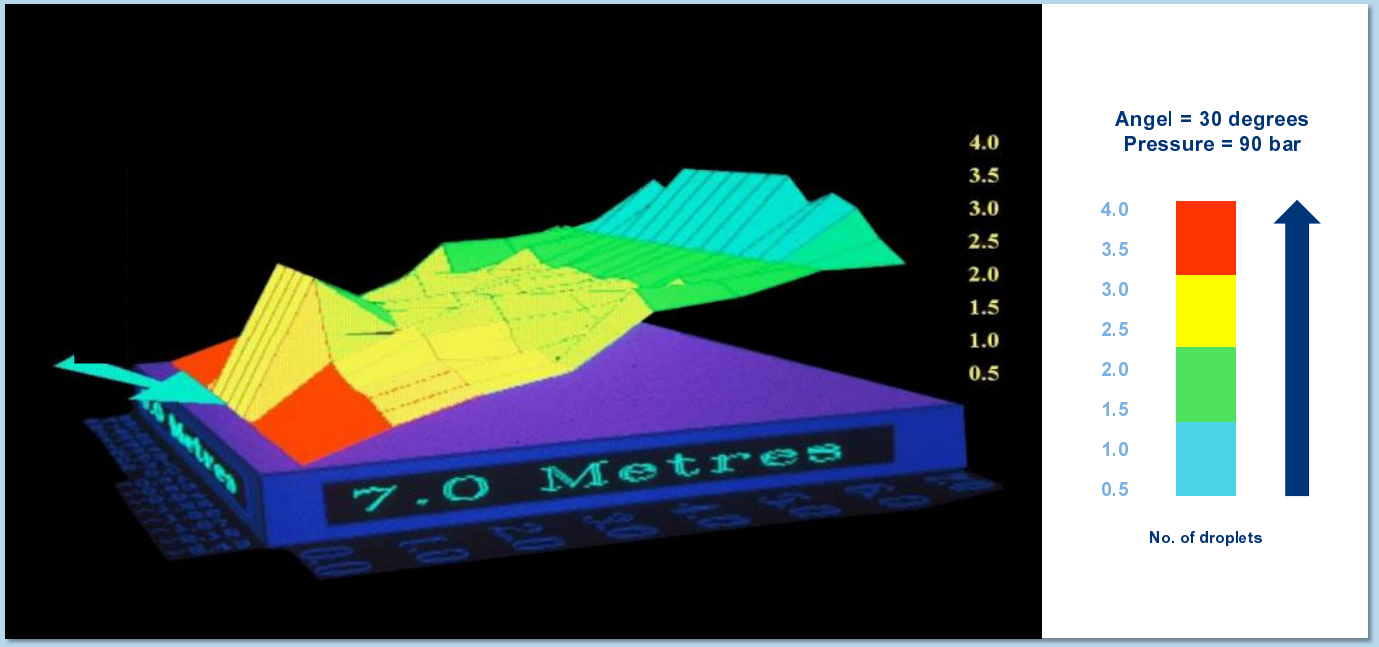
Allergen control

Minimising cross-contamination

Spread of contamination:

High pressure hosing

Courtesy of Campden BRI



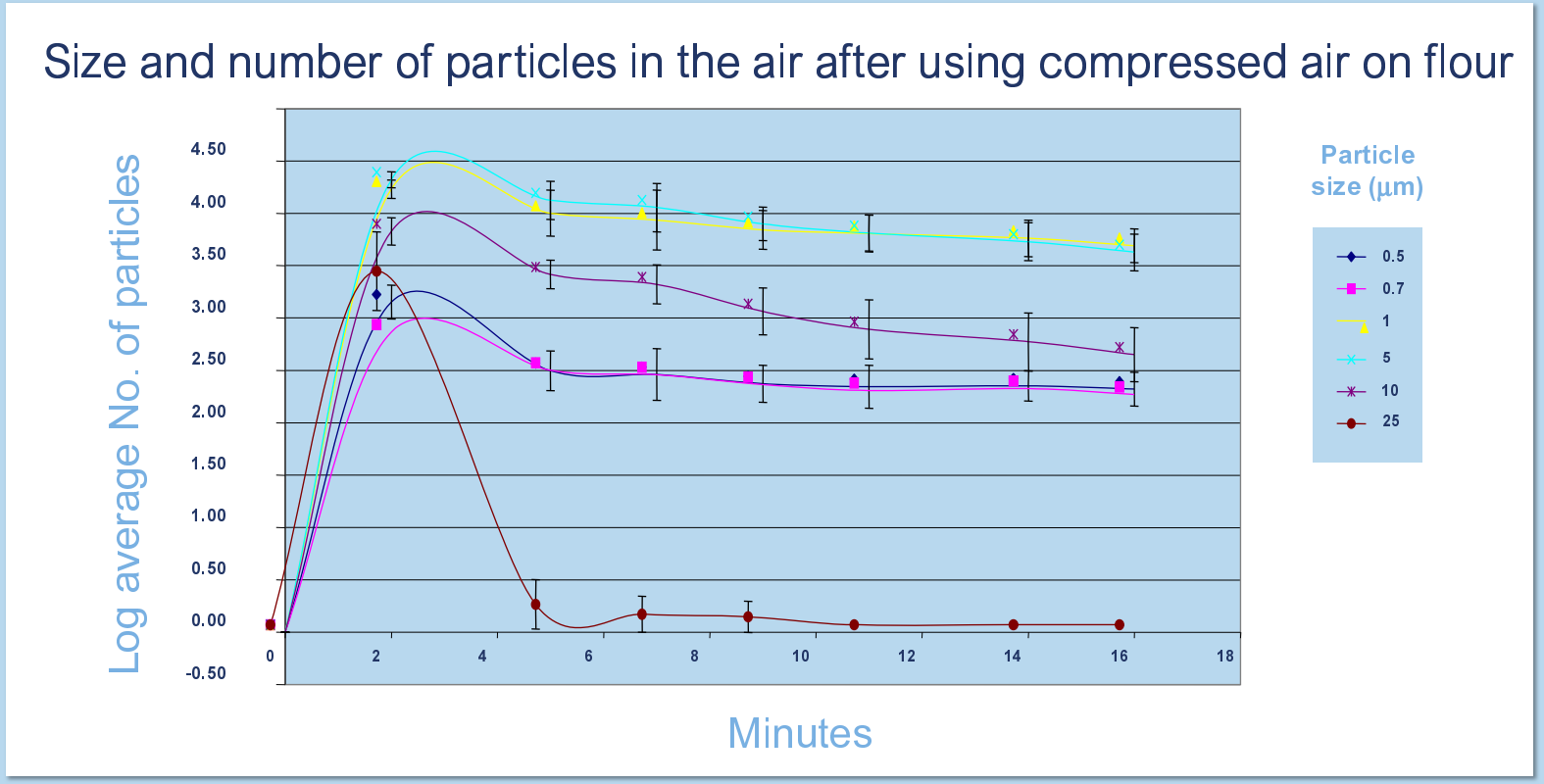
Allergen control

Minimising cross-contamination

Spread of contamination:

Compressed air

Courtesy of Campden BRI



Allergen control

Minimising cross-contamination

Effective cleaning:

Foaming – Open surface wet cleaning

- Good for decontaminating large areas such as floors, walls, conveyors, and tables and large, open production equipment
- A spray nozzle is used to cover equipment with a foam detergent or sanitiser. This is given time to act on the soil and is then rinsed off with the released soil.
- Often used in conjunction with manual cleaning, to aid the cleaning process, and detail cleaning.

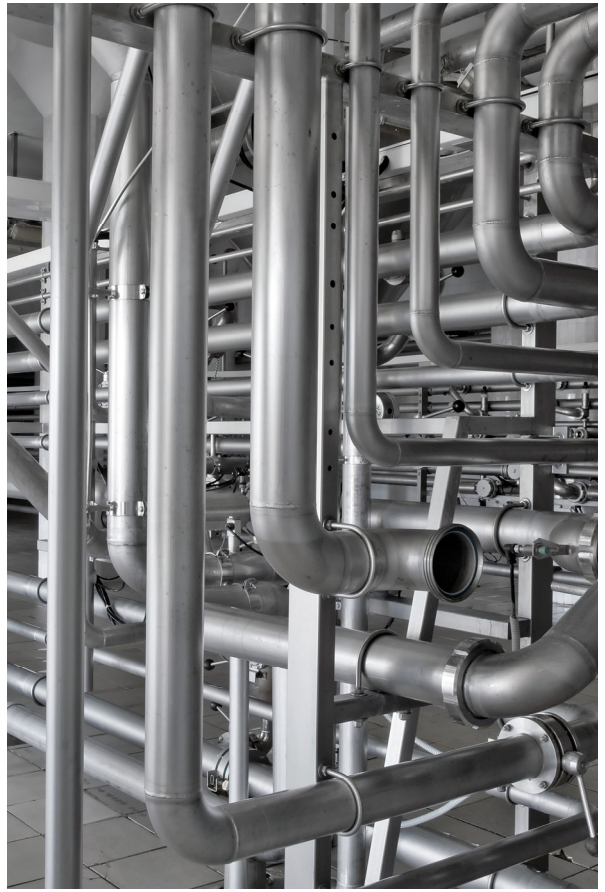
Allergen control

Minimising cross-contamination

Effective cleaning:

Cleaning in Place (CIP) - Closed surface wet and dry cleaning.

- Commonly used to clean pipework and closed vessels used for liquid/semi-solid foods, e.g., dairy products, sauces.
- Uses aggressive cleaning chemicals and rinse water, sometimes at high temperatures, pumped around a system.
- Turbulent flow rates generated by automated CIP system provide ‘friction’ for the allergen removal.
- Salt or sugar scrubs for dry foods.
- ‘Pigging’ sometimes use to remove gross debris.
- Manual cleaning tools can be used for additional detail cleaning of valves and sampling ports.



Minimising cross-contamination

Effective cleaning:

Vacuuming - Dry cleaning

Vacuum cleaners need to be:

- certified against ATEX 95 equipment directive 94/9/EC - Equipment and protective systems intended for use in potentially explosive atmospheres.
- fitted with appropriate bag and exhaust filters to prevent allergens from being expelled again, e.g., HEPA.

Allergen control

Minimising cross-contamination

Effective cleaning:

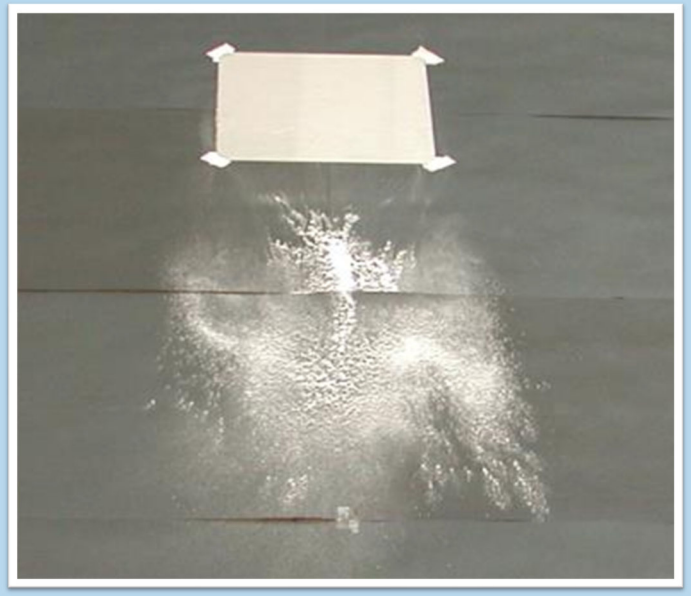
Manual cleaning - Open surface wet and dry cleaning.

- Most common method used in food manufacturing.
- Good for,
  - Cleaning of small to medium sized production areas / equipment.
  - Deep cleaning.
  - Detail cleaning.
  - Cleaning of complex equipment.
  - Only effective if staff are trained and given sufficient time and appropriate equipment.

Allergen control

Minimising cross-contamination

Manual cleaning: Sweeping



Courtesy of Campden BRI

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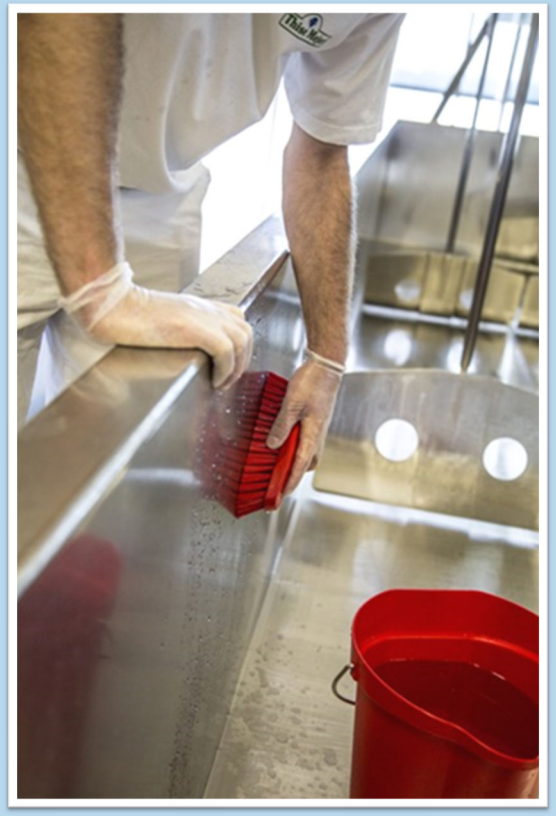
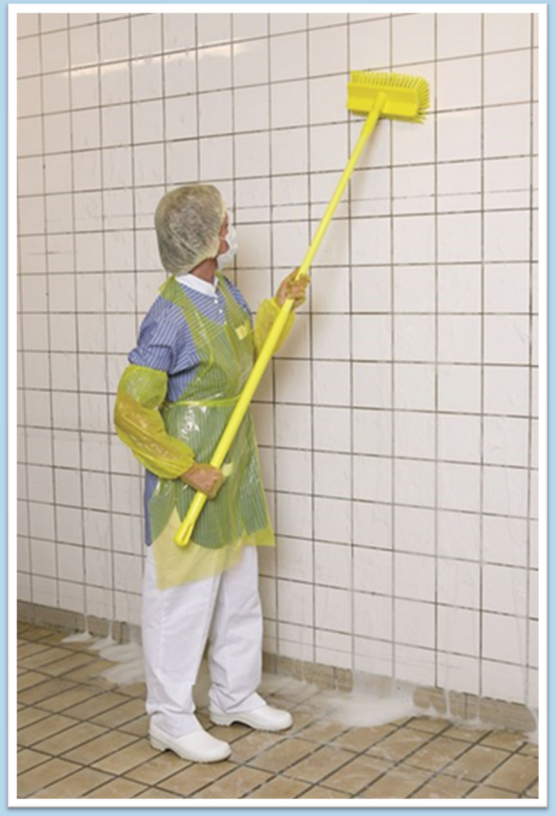
Allergen control

Minimising cross-contamination

Manual cleaning: Scrubbing





Effective, controlled wet cleaning method that reduces the risk of aerosol and droplet formation & maximises allergen removal

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Allergen control

Minimising cross-contamination

Manual cleaning: Brush selection

Soft filament brush

For gross removal of loose dry allergens

Stiff filament brush

Dry - for removal of dried on allergenic soils

Wet - with water/chemicals to remove dried on, sticky or greasy allergenic soils

Squeegee

Wet or dry - Use instead of a brush/broom

(doesn't clog or flick droplets/debris, easier to clean)

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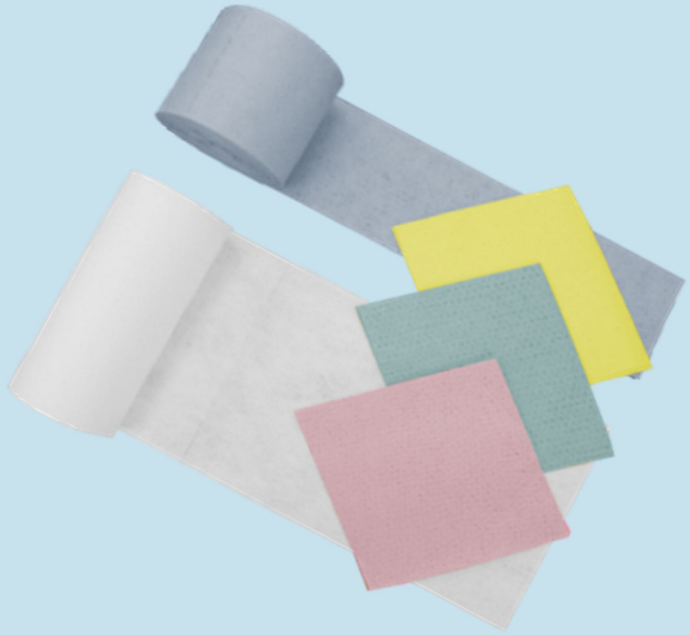
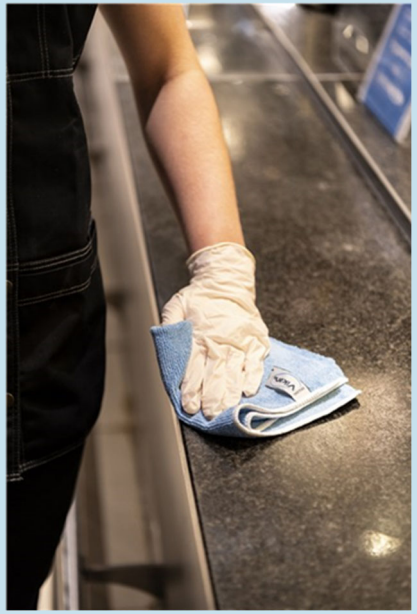
Allergen control

Minimising cross-contamination

Manual Cleaning: Wiping



Disposable fabric and paper cloths, wet or dry



Microfibre cloths

Microfibre mops

- Very good at low level allergen removal (*disinfection*)
- Use damp or dry. Re-useable many times.
- Validated allergen removal laundering process.

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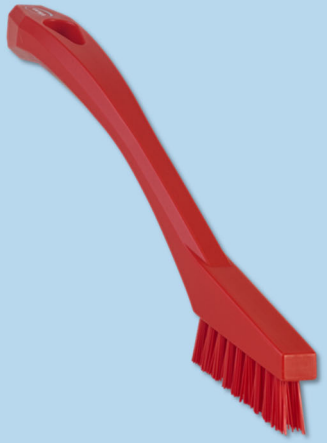
Minimising cross-contamination

Manual cleaning: Detail cleaning



Allergen control

Control of cross-contamination

Manual Cleaning

Scraping - removal of gross and stubborn allergen debris

Allergen spill kits

Allergen control

Cleaning equipment and utensils

- BRCGS
  - 4.11.6. 'Cleaning equipment shall be:- hygienically designed and fit for purpose, suitably identified for intended use (e.g., colour coded or labeled), cleaned and stored in a hygienic manner to prevent contamination'.
  - Clause 5.3.8: Cleaning equipment used to clean allergenic materials shall either be identifiable and specific for allergen use, single use, or effectively cleaned after use.
- FSSC 22000
  - ISO/TS 22002-1:2009 (2013) Prerequisite programmes on food safety Part 1: Food manufacturing.
  - 11.2 Cleaning and sanitising agents and tools: 'Tools and equipment shall be of hygienic design and maintained in a condition which does not present a potential source of extraneous matter.'
- SQF code
  - Section 10.2.9.2 Equipment and utensils shall be designed, constructed, installed, operated, and maintained so as to meet any applicable regulatory requirements and not pose a contamination threat to product.

Allergen control

Hygienic design

The ability to clean something easily

Good hygienic design principles*

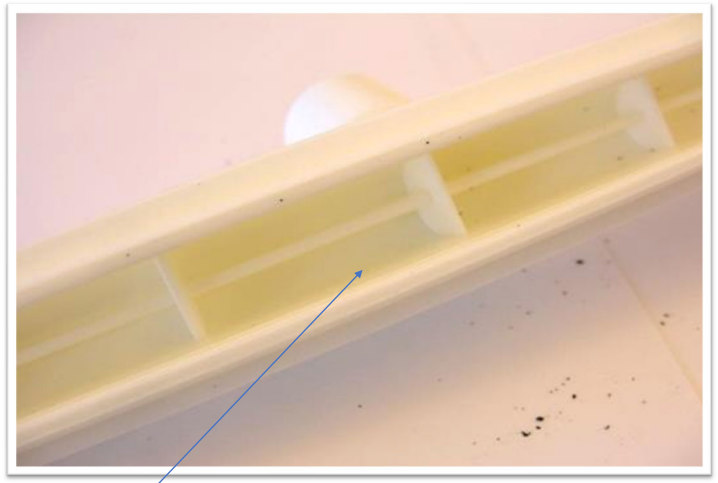
- No sharp internal angles.
- All areas accessible for easy cleaning and disinfection.
- Avoid deep recesses, nooks and crannies.
- Of one-piece construction, or quickly and easily dismantled / re-assembled.
- Smooth surface finish.
- Made of appropriate materials.
  - Durable; Food contact compliant.

New GFSI Benchmarking requirements on Hygienic Design

- https://www.ehedg.org/ehedg/new-gfsi-hygienic-design-benchmarking-requirements/.

*EHEDG Guideline 8
"Hygienic Equipment Design Criteria"
https://www.ehedg.org/guidelines/free-documents/.

Bad hygienic design



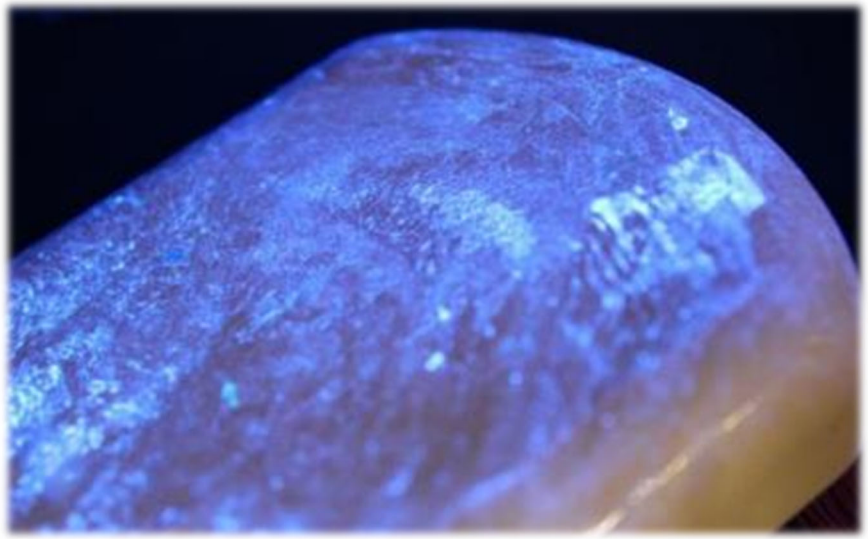
Multiple deep compartments – difficult to clean

Contamination build-up under the screw thread handle fixing

Site-made floor scraper contamination traps / difficult to clean

Allergen control

Bad hygienic design



Poor surface finish

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Crevices / nooks & crannies

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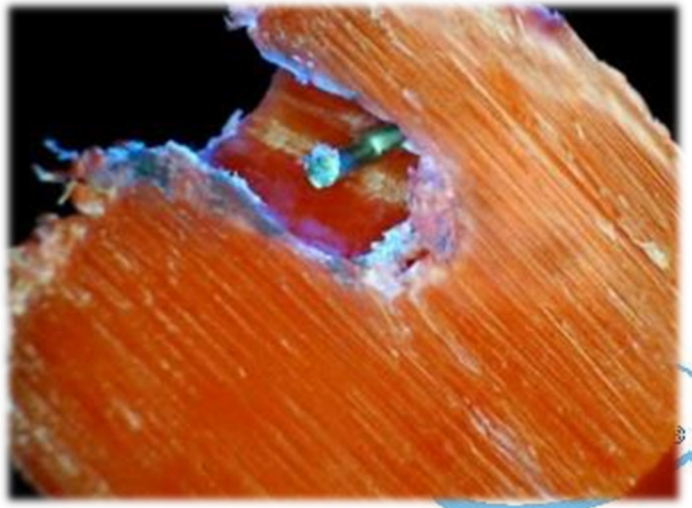
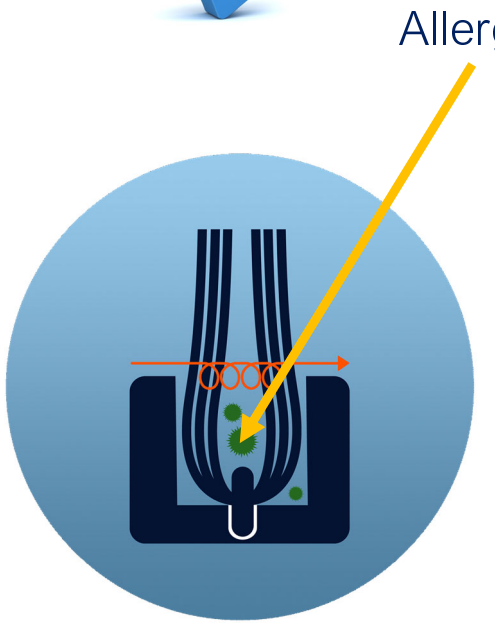


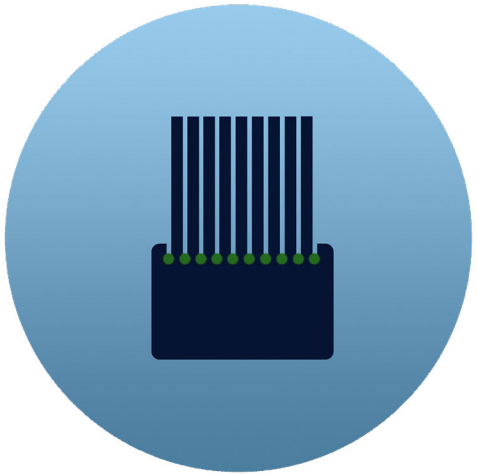
Allergen control

Good hygienic design

1-piece or fully moulded construction



Drilled and stapled construction



Fully moulded construction

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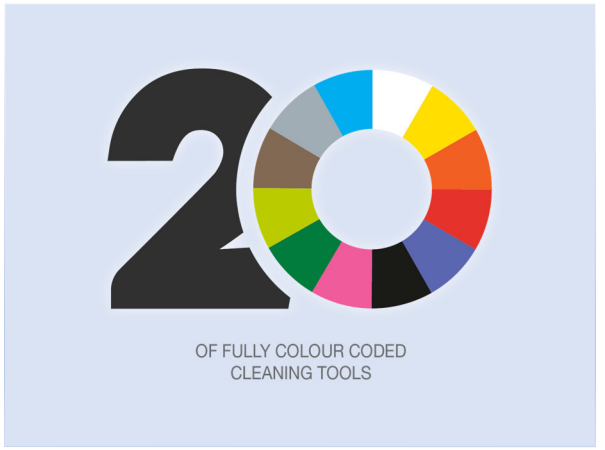
Equipment colour-coding

Use of colour-coded equipment provides a visual check that only equipment colour-coded for use with that allergen is used.

Coloured silicone bands



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Colour-coded equipment and area segregation

- Site colour zoning plans – for segregation of allergen production areas. Provide an easy visual check that only tools colour-coded for use in an allergen area are used.

http://viewer.ipaper.io/vikan/white-papers/colour-coding/colour-coding-white-paper-en/

Allergen control

Equipment storage

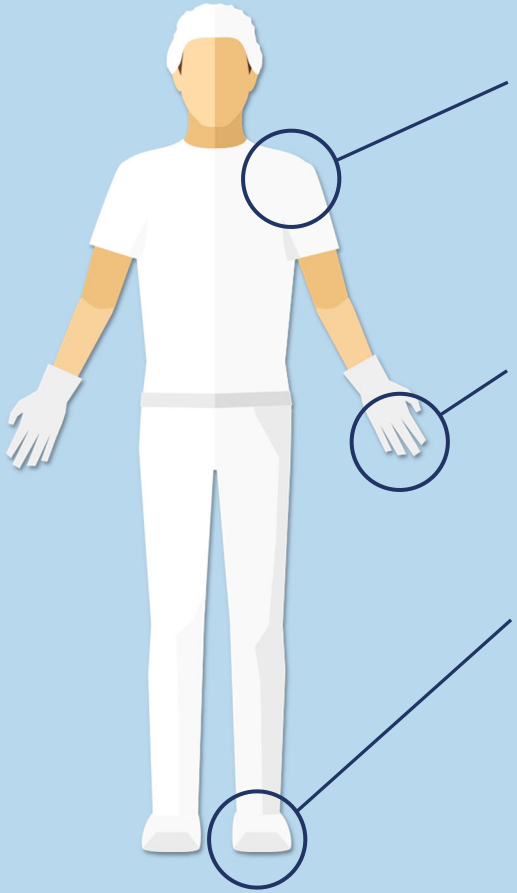
Storage on colour-coded wall racks or shadow boards minimises the risk of allergen cross-contamination.

Staff training

People - an essential asset in allergen control

Training:

- Why it is important.
- How to select, use and maintain cleaning equipment effectively.
- How to minimise the spread of contamination by themselves, their cleaning actions, and the cleaning equipment.



Contamination transfer by **clothing** – use separate colour-coded clothing; disposable aprons; change between tasks.

Contamination transfer by **hands** – wash & dry hands; change gloves between tasks.

Contamination transfer by **footwear** – have separate footwear for separate risk areas; decontaminate regularly.

Use different hygiene staff for different areas:

- allergen/non-allergen.

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Cleaning validation

Development of a consistently effective and appropriate method of decontamination.

Responsibility: The food producer, with support from equipment manufacturer, chemical supplier, (and cleaning contractor).

The method development may require a degree of trial and error to determine a consistently effective method that achieves the level of decontamination required.

Different methods may have to be developed for different equipment/surfaces, or the same equipment/surfaces used for a different purpose.

BRCGS

Clause 5.3.8:

- Equipment or area cleaning procedures shall be designed to remove or reduce to acceptable levels any potential cross-contamination by allergens.
- The cleaning methods shall be validated to ensure they are effective, and the effectiveness of the procedures routinely verified.

FSSC 22000

Clause 11.3 Cleaning and sanitizing programmes:

- Cleaning and sanitising programmes shall be established and validated by the organisation to ensure that all parts of the establishment and equipment are cleaned and/or sanitised to a defined schedule.

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Cleaning validation

FSSC 22000

Clause 11.3 Cleaning and sanitizing programmes:

- Cleaning and sanitising programmes shall be established and validated by the organisation, including the cleaning of cleaning equipment.

http://viewer.ipaper.io/vikan/white-papers/cleaning-tool-maintenance/cleaning-tool-maintenance-whitepaper-en-300/#/

Vikan®

Allergen control

Cleaning validation

STEP 1 – Validation Prerequisites

- 1.0 Develop a validation team
- 1.1 Validation Scope/Hazard Evaluation
- 1.2 Cleaning Acceptance Criteria
- 1.3 Equipment Qualification
- 1.4 Cleaning Qualification
- 1.5 Sampling Techniques
- 1.6 Analytical Methods
- 1.7 Soiling

STEP 2 – Cleaning Validation Protocol

STEP 3 – Cleaning Validation Process

STEP 4 – Cleaning Validation Report

STEP 5 – HMS Documentation

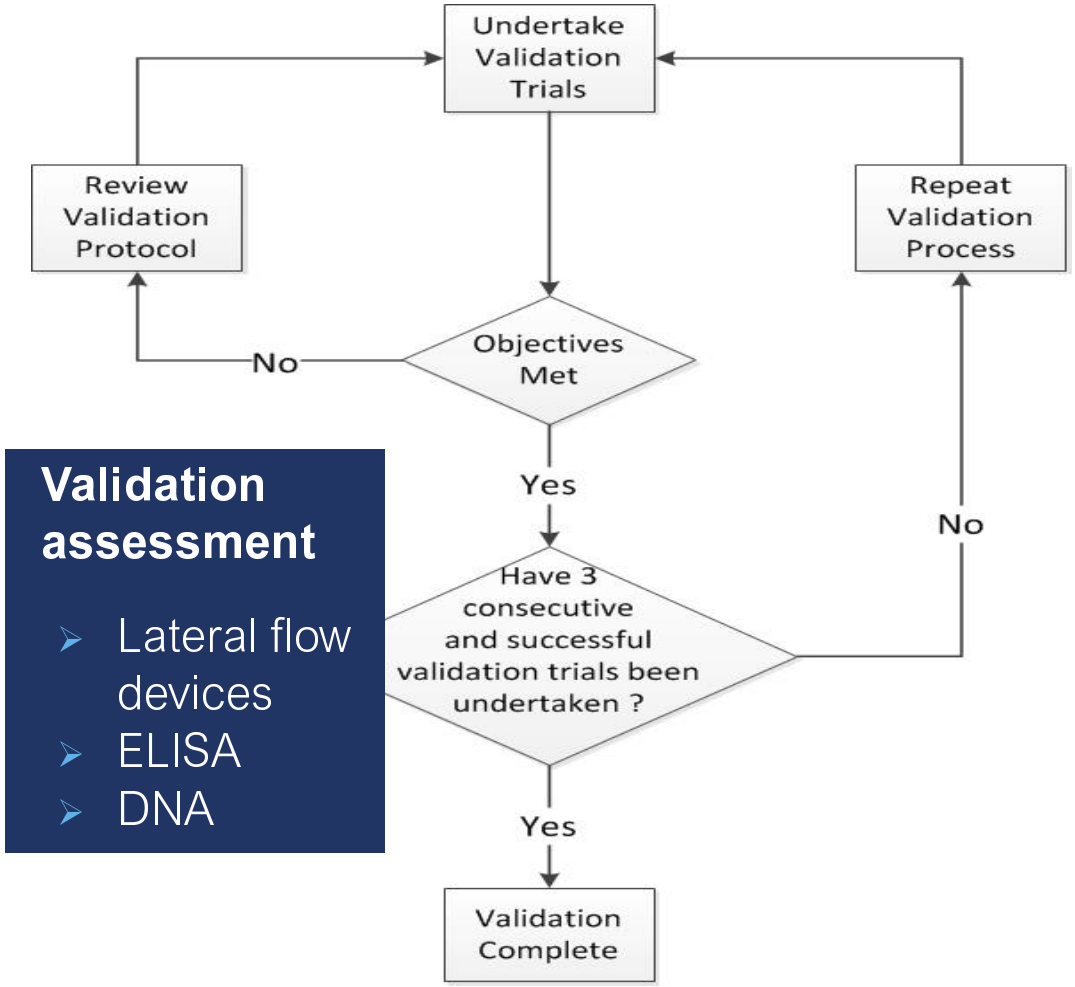
STEP 6 – Maintaining Validated State

STEP 7 – Validation Review

Cleaning Validation in the Food Industry - General Principles, Part 1
Guideline No. 45

https://www.ehedg.org/guidelines/
(free download)

Cleaning Validation Process



Validation assessment

- Lateral flow devices
- ELISA
- DNA

Chemical interference:

- Detergents/cleaning fluids may interfere in tests
- Check during validation study.

EXTRACT TESTED	Tropomyosin (mg/kg)
Prawn extract at 5 mg/kg	0.07
Prawn extract at 5 mg/kg + 1% detergent	< LOQ
Prawn extract at 10mg/kg	0.21
Prawn extract at 10mg/kg + 1% detergent	< LOQ

LOQ = Limit of quantification

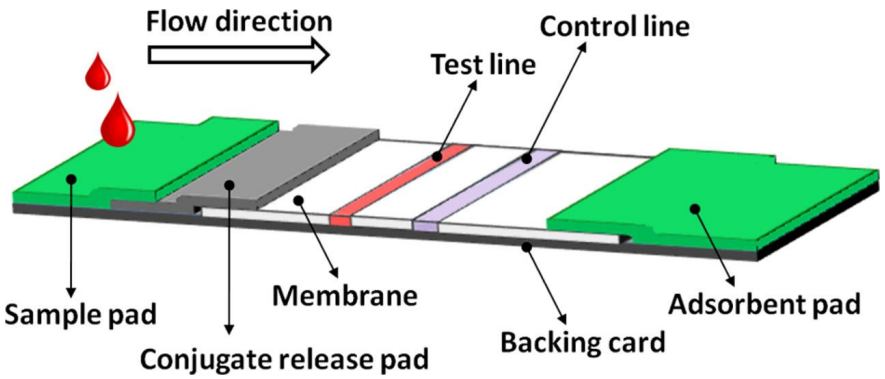
Arrowsmith & Brown, 2009

Analytical validation methods

- Specific, sensitive, representative, reproducible
- Quantitative/ qualitative/semi-quantitative (for allergens)
  - Lateral flow devices
  - ELISA,
  - DNA
  - Mass spectroscopy
- Laboratory facilities and trained staff required for analysis
- Cleaning chemical residues may interfere with reaction

Lateral flow devices

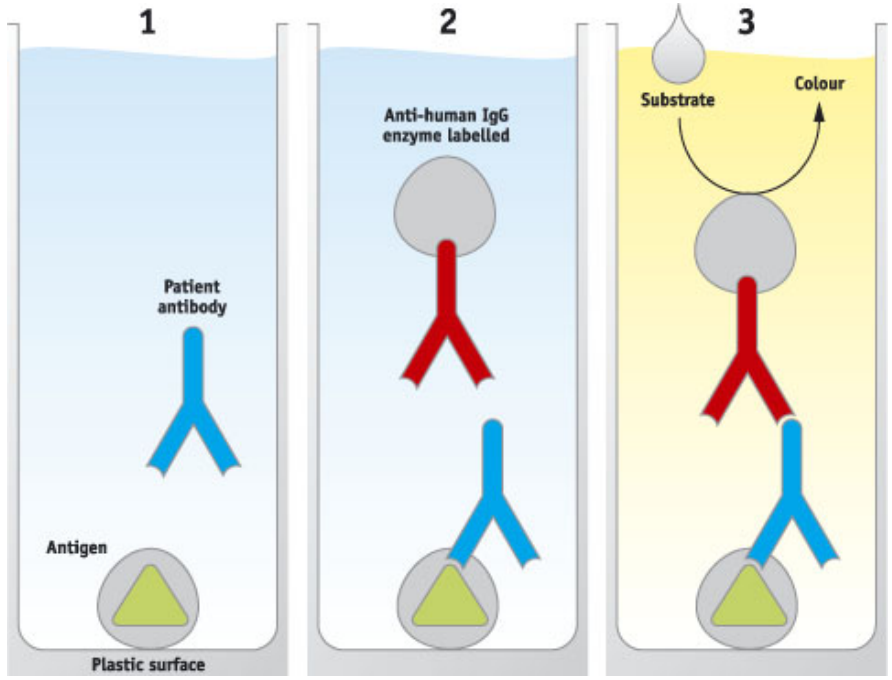
- Advantages
  - Rapid (~10 mins)
  - Easy to read results (presence/absence)
  - Cheap, no expensive instrumentation
- Disadvantages
  - Less sensitive than ELISA or DNA tests
  - Subject to a limit of detection
  - Allergen specific swabs not available for all



Analytical validation methods

Enzyme linked immunosorbent assay (ELISA)

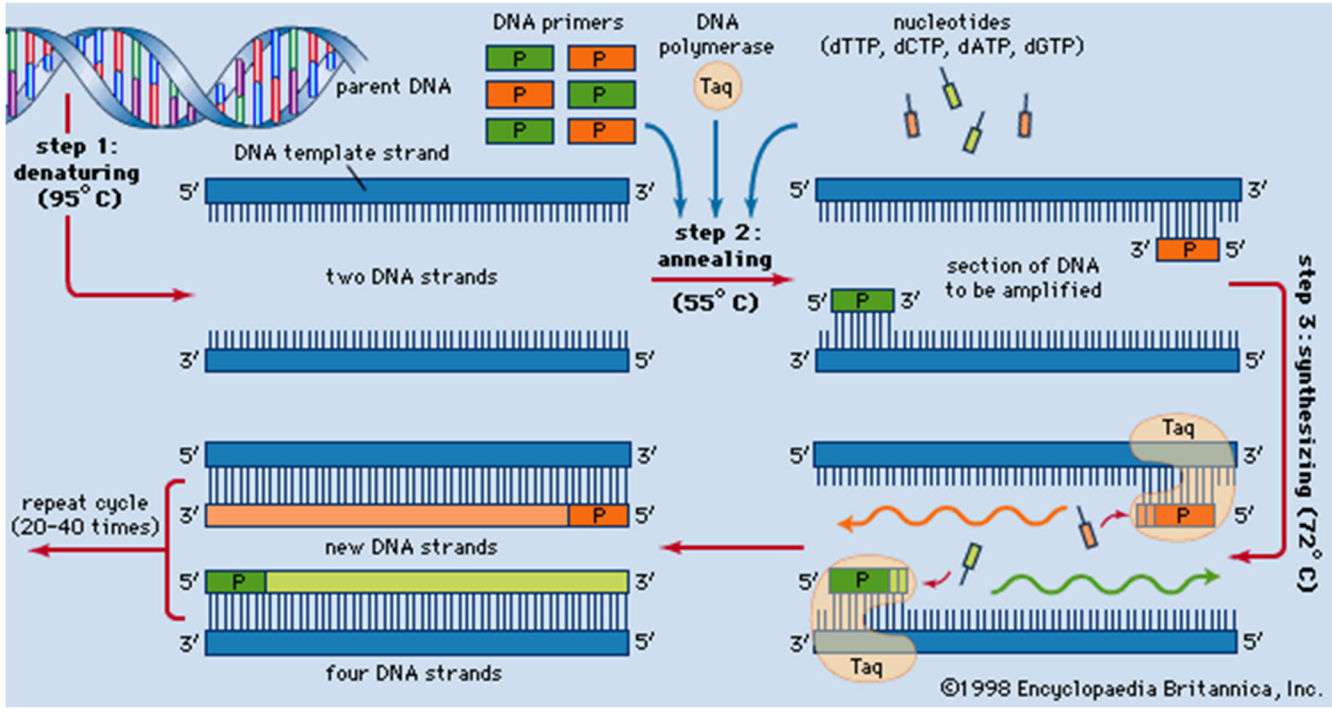
- Detection of proteins that are markers of the allergenic foodstuff.
- Uses antibodies that only bind to the protein of interest.
- The binding of the antibody and protein is linked to a mechanism that produces a colour change.
- Lateral Flow devices work on the same principle.
- Lab based test – typically using a 96 well test plate.
- The degree of colour change may indicate the amount of protein present when suitable controls and calibrations are run in parallel.



Analytical validation methods

DNA

- DNA from the sample is extracted and purified.
- A specific part of the sample DNA, that is unique to the allergenic food, is amplified by the use of the polymerase chain reaction (PCR).
- Detection and potential quantification of the amplified DNA.



Maintaining validated state

Determination of compliance – successful application of validate cleaning protocol

Monitoring

- Real-time assessment that the cleaning has been conducted and that the hazard (allergen) is under control.
  - Lateral flow devices

Verification

- Objective evidence that the cleaning is/has been routinely working.
  - Review of monitoring data
  - Trend analysis
  - 1st, 2nd, 3rd party audits
  - Training records
  - Validation records (including re-validation)

Labelling

- Labelling regulations
  - Provision of Food Information to Consumers EU Regulation No. 1169/2011.
  - Food Allergen Labeling & Consumer Protection Act of 2004

- Allergen suffers are diligent label readers.
  - Worst case scenario that they eat something they thought was safe but turns out to be mislabelled.

- 19th Jan 2021: Poundstretcher pays out £31,500 after food mislabelling prosecution.
  - Various foods found to be mislabelled because allergens were not properly reported on the food labels

- Financial cost and damage to brand reputation of the business.

- Potential cost to human health of much greater concern.

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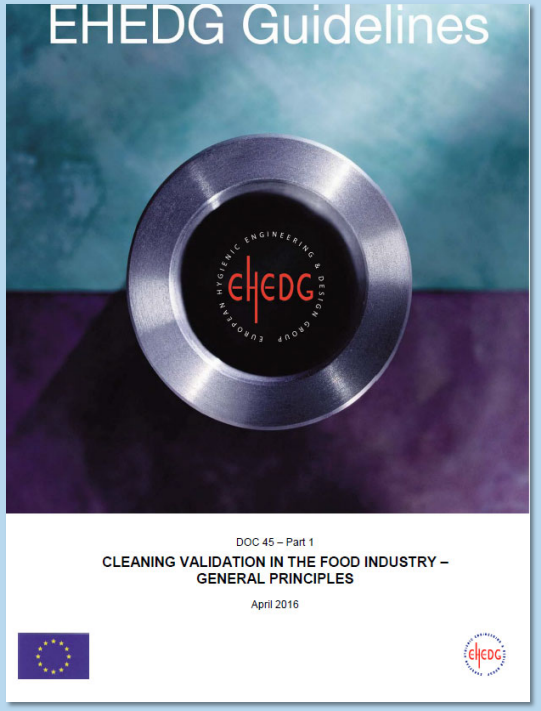
Allergen control: From Problem to Solution

1. Understand why it is important.
2. Understand your sites allergen challenges.
3. Use procedures and validated methods that maximise allergen control and minimise their spread.
4. Use equipment of good hygienic design.
5. Use colour-coding to identify equipment for allergen use and segregation of areas used for allergenic food production.
6. Remember the importance of appropriate
    a. cleaning tool selection, use and maintenance,
    b. staff training and awareness, and
    c. product labelling.

Allergen control

Further information



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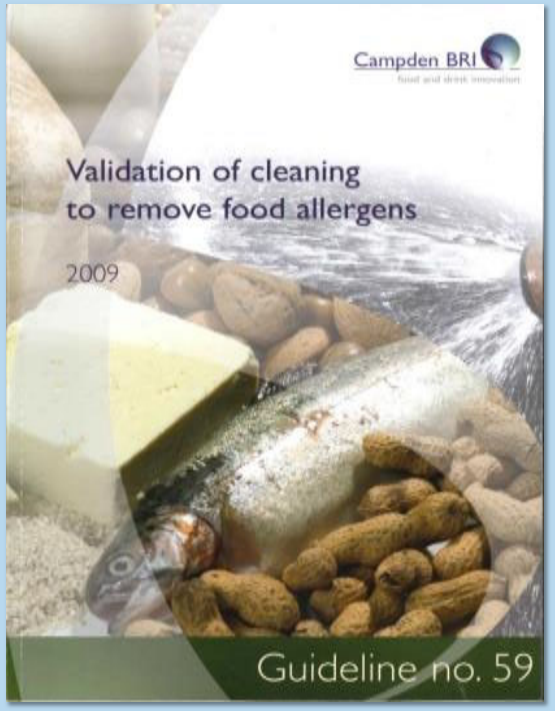

https://www.campdenbri.co.uk/publications/pubDetails.php?pubsID=2487

https://www.campdenbri.co.uk/publications/pubDetails.php?pubsID=202

https://www.campdenbri.co.uk/publications/pubDetails.php?pubsID=4666

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Allergen control

Further information

www.vikan.com – Knowledge centre

- https://www.vikan.com/media/8246/allergencontrol_leaflet_en.pdf

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