

Allergen Control - challenges, perspectives and solutions'

Deb Smith
Global Hygiene Specialist



Allergen control

Why it's important



Courtesy of the Anaphylaxis Campaign: <https://www.youtube.com/watch?v=yQhISQVrBXk>



Why it's important

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

2 types of 'allergic' reaction.

- Immunological - IgE-mediated - **Food Allergy**
 - Reactions range from severe (anaphylaxis), which can be life threatening, to an itchy red rash.
 - Usually develop very shortly after eating the food.
- Non-immunological - **Food Intolerance**
 - Less severe.
 - Symptoms can take much longer to develop.
- Food allergy affects 1-2% of UK adults & 5-8% of children.
- UK peanut allergy cases have tripled in the last decade.
- UK fatalities: ~ 10 per year.

Food allergens: almost always *proteins



*Sulphur dioxide - Not a protein. Must be declared on label if at concentrations >10mg/kg or 10mg/Litre in the finished product.

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.

Global food safety Standard requirements



5.3 Allergen Management (includes pet food and animal feed)



Fundamental

The site shall have a system for the management of allergenic materials which minimises the risk of allergen contamination (cross-contact) of products and meets legal requirements for labelling in the country of sale.

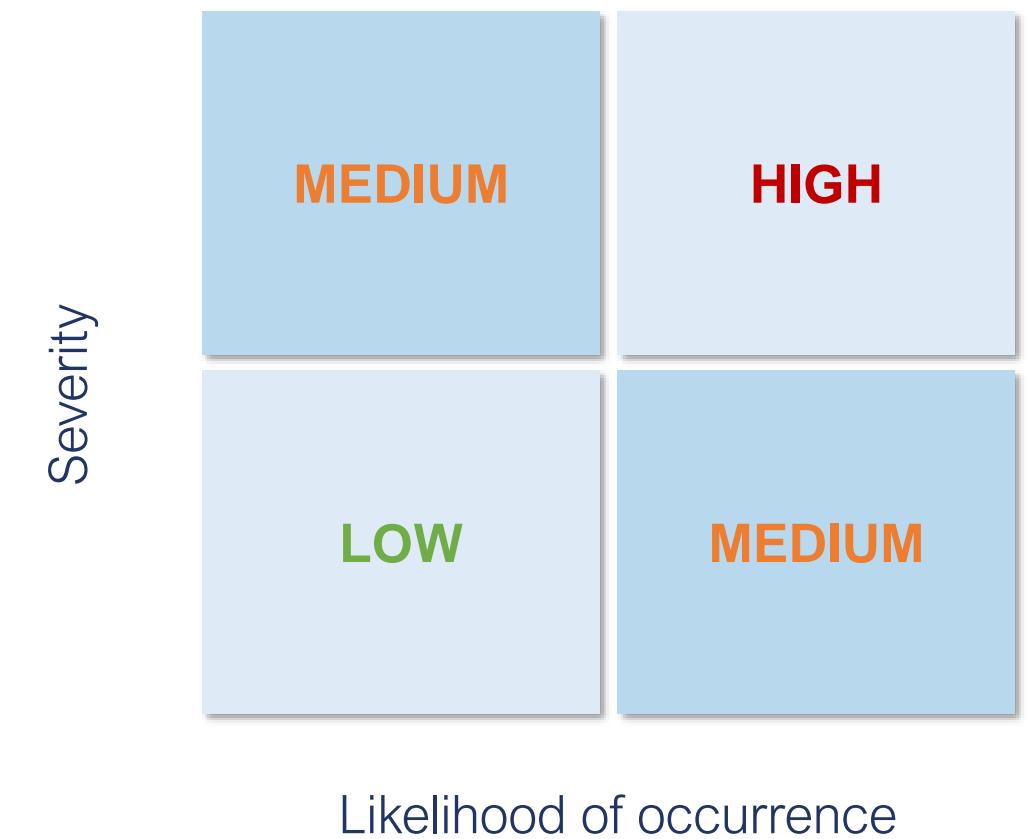
5.3.2

The company shall identify and list allergen-containing materials handled on site. This shall include raw materials, processing aids, intermediate and finished products, and any new product development ingredients or products.

5.3.3

A documented risk assessment shall be carried out to identify routes of contamination (cross-contact) and establish documented policies, and procedures for handling raw materials and intermediate and finished products, to ensure cross-contamination (cross-contact) is avoided. This assessment shall include:

- consideration of the physical state of the allergenic material (e.g. powder, liquid, particulate)
- identification of potential points of cross-contamination (cross-contact) through the process flow
- assessment of the risk of allergen cross-contamination (cross-contact) at each process step
- identification of suitable controls to reduce or eliminate the risk of cross-contamination (cross-contact).



Basic principles of hazard (allergen) management

- Hazard identification (*BRCGS 5.3.2*) Challenges
 - Allergens.
 - Known or potential health effects associated with each allergen.
 - Risk assessment (*BRCGS 5.3.3*)
 - 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.
- ➔ Allergens vary in different areas of the world. Potential health effects very variable - severity of symptoms, threshold of elicitation.
- ➔ Lack of likelihood and severity data
- ➔ Often a natural component of the food. Lack of qualitative and/or quantitative data on acceptable levels (*infective* dose).
- ➔ Lack of definitive limits.

Allergen limits



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.
- Should be determined through consensus, based on prevalence, severity and potency (threshold dose).
- Propose a framework for transparent decisions on risk tolerability, founded on full participation of stakeholders.

Allergen control

How much is too much?

Peanut allergic patients present with different levels of sensitivity.



Ballmer-Weber and Hourihane

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)

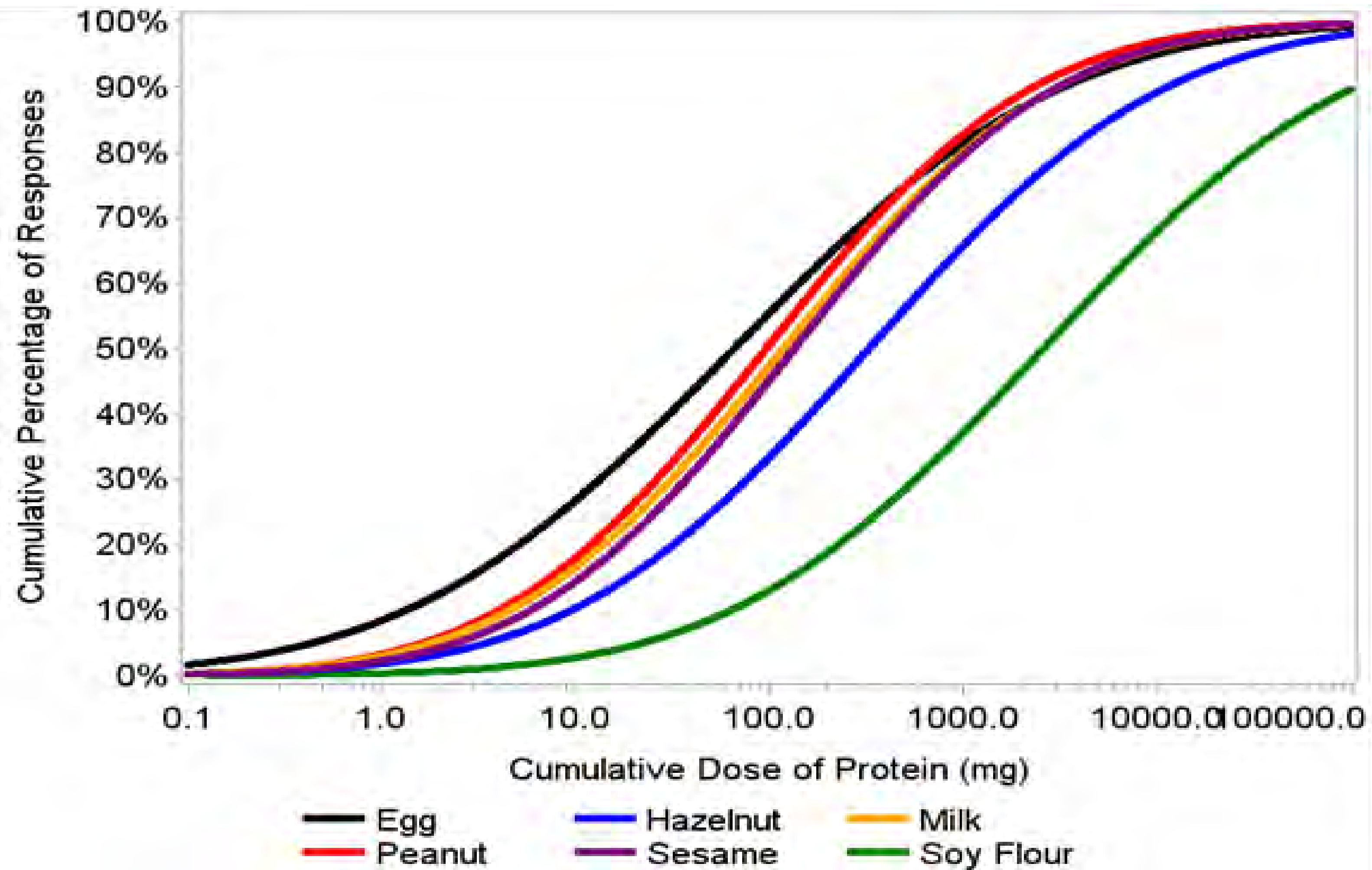
400 mg
(100 mg peanut protein)

*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.



Not all food allergens are created equal

Dose Distributions for Various Food Allergens



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.

$$\text{Action Limit (mg/kg)} = \frac{\text{Reference dose (mg)}}{\text{Portion size (kg)}}$$

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 $0.1/0.1 = 1\text{mg/kg}$

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

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 foods/areas where they are allowed, to those where they are not.
 - Label final product to meet legal requirements of the designated country of use.



Preventing entry

- Raw materials & Packaging: (*BRCGS 5.3.1, 3.5.1.1 & 3.6.1*)
 - Supplier quality assurance - Certificates of Analysis.
 - Allergen-free.
- Maintenance: (*BRCGS 4.7.5*).
 - Allergen-free lubricants
- Process flow & control: (*BRCGS 6.1.1*)
 - Area and equipment segregation (allergen / non-allergen product)
 - Introduction of allergen at latest point in process.
 - Controlled introduction of re-work (*BRCGS 5.3.5*)
- NPD: (*BRCGS 5.1.1*)
 - Restrict scope of new product developments to control the introduction of allergens.
- Catering: (*BRCGS 4.8.8*)



Clause	Requirements
5.3.1	The site shall carry out an assessment of raw materials to establish the presence and likelihood of contamination (cross-contact) by allergens. This shall include a review of the raw material specifications and, where required, the acquisition of additional information from suppliers (e.g. through questionnaires to understand the allergen profile of the raw material, its ingredients and the factory in which it is produced).

5.3.5	Where rework is used, or reworking operations are carried out, procedures shall be implemented to ensure rework containing allergens is not used in products that do not already contain the allergen.
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5 Product control

5.1 Product design/development

Product design and development procedures shall be in place for new products or processes and any changes to product, packaging or manufacturing processes to ensure that safe and legal products are produced.

Clause	Requirements
5.1.1	<p>The company shall have a procedure for new product development and changes to existing product, packaging and manufacturing processes.</p> <p>This procedure shall include any restrictions to the scope of new product development to control the introduction of hazards which would be unacceptable to the site or customers (e.g. the introduction of allergens, glass packaging, microbiological risks or the introduction of ingredients that may affect product claims).</p>



Cross-contamination control

BRCS

5.3.4

Procedures shall be established to ensure the effective management of allergenic materials to prevent cross-contamination (cross-contact) of products not containing the allergen.

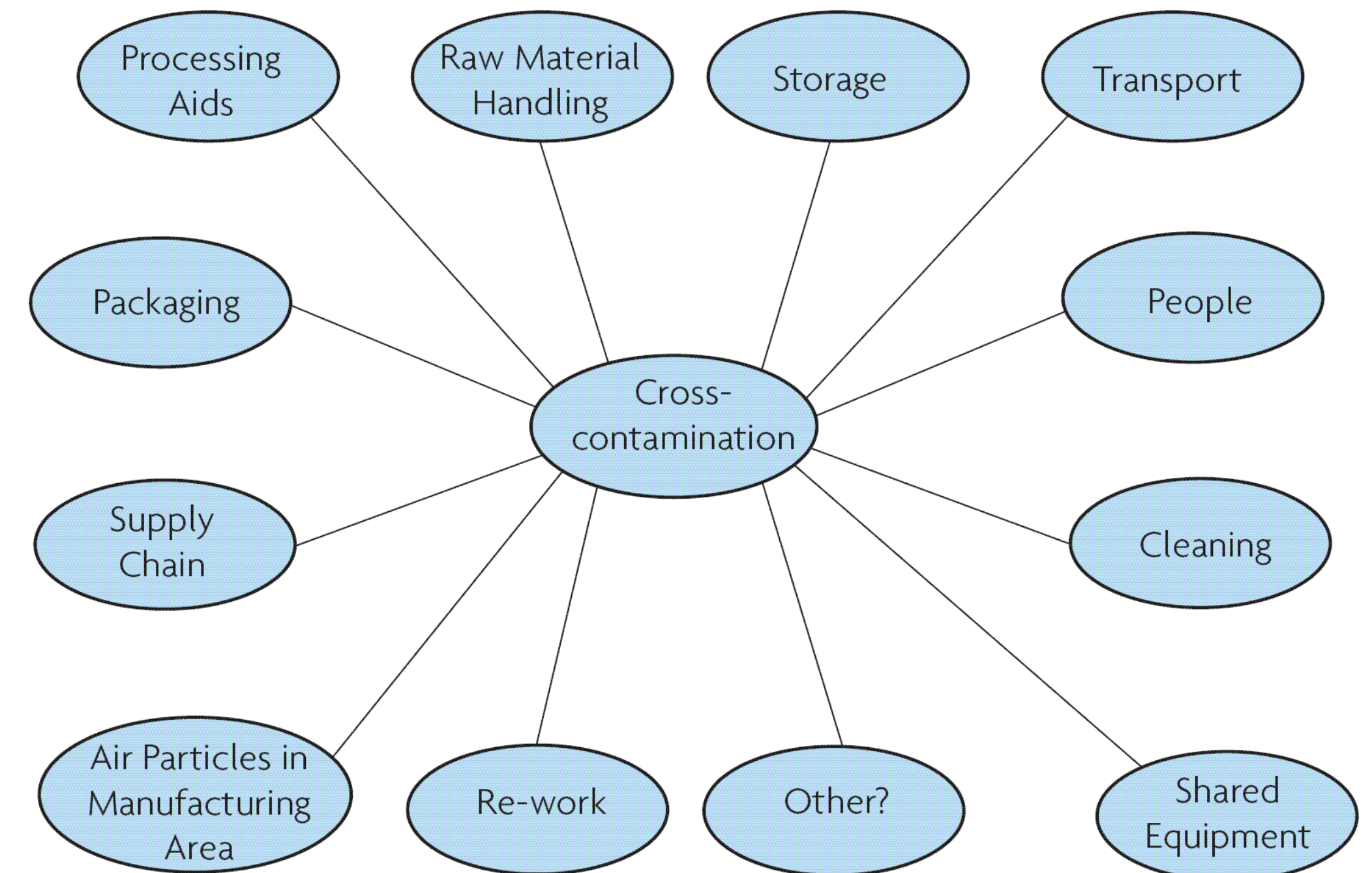
These shall include, as appropriate:

- physical or time segregation while allergen-containing materials are being stored, processed or packed
- the use of separate or additional protective overclothing when handling allergenic materials
- use of identified, dedicated equipment and utensils for processing
- scheduling of production to reduce changes between products containing an allergen and products not containing the allergen
- systems to restrict the movement of airborne dust containing allergenic material
- waste handling and spillage controls
- restrictions on food brought onto site by staff, visitors and contractors and for catering purposes.

Cross-contamination control

Key things to consider:

- Hygienic design of equipment and buildings
- Physical or time segregation of allergen-containing materials.
- Process flow & control
- Cleaning: physical removal of contamination (allergens)
- Systems and procedures (including cleaning activities) that restrict the movement of airborne dust and aerosols containing allergenic material.
- People
 - Training
- Waste handling & spillage controls.



Allergen control

Cross-contamination 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, Non-absorbent.

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/>.



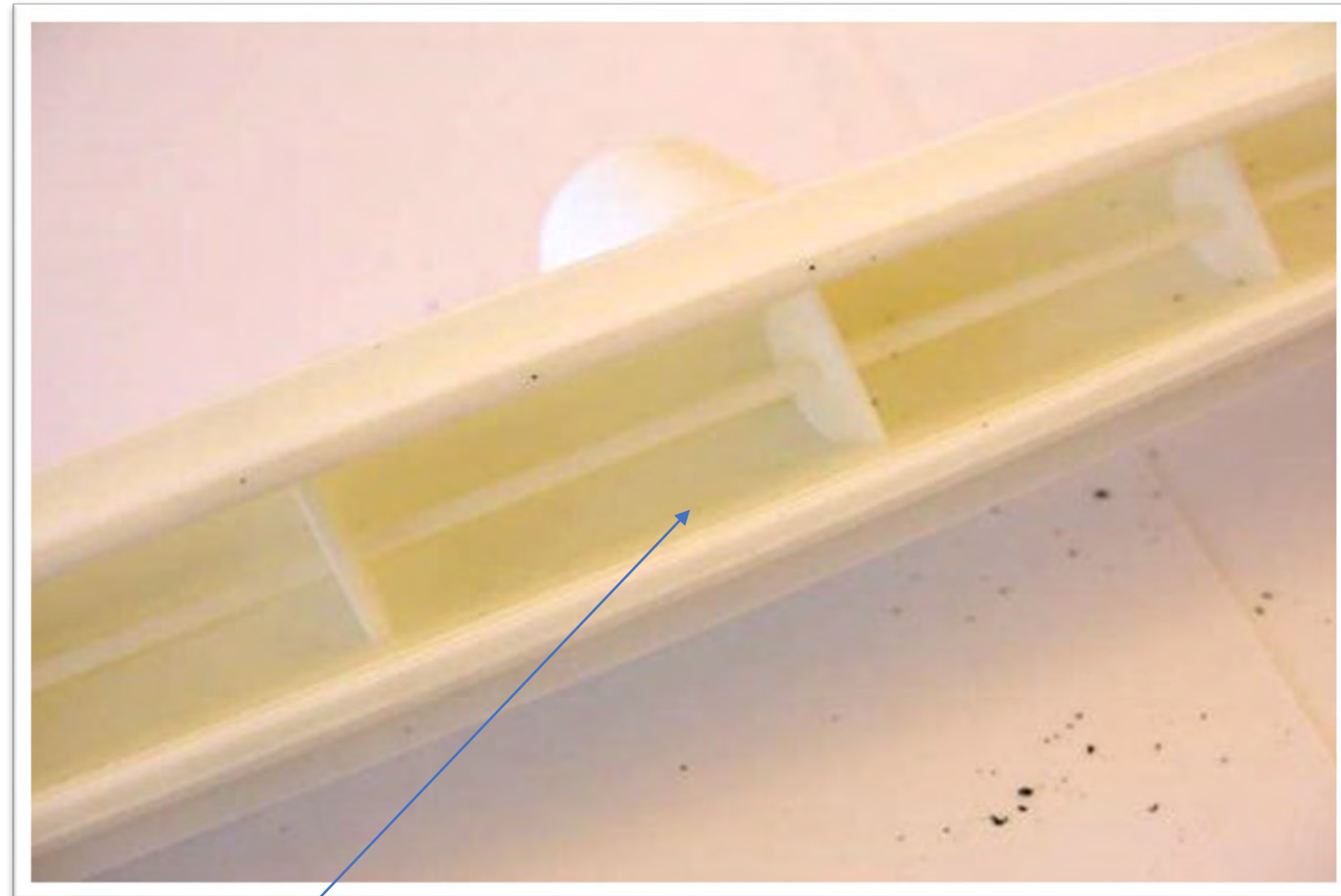
Cross-contamination control: Hygienic Design

BRCS

4.6 Equipment

Clause	Requirements
4.6.2	<p>The design and construction of equipment shall be based on risk, to prevent product contamination. For example, the use of the correct seals, impervious surfaces or smooth welds and joints, where they are exposed to product and could otherwise result in foreign-body, microbiological or allergen contamination of the product.</p> <p>Equipment that is in direct contact with food shall be suitable for food contact and meet legal requirements where applicable.</p>

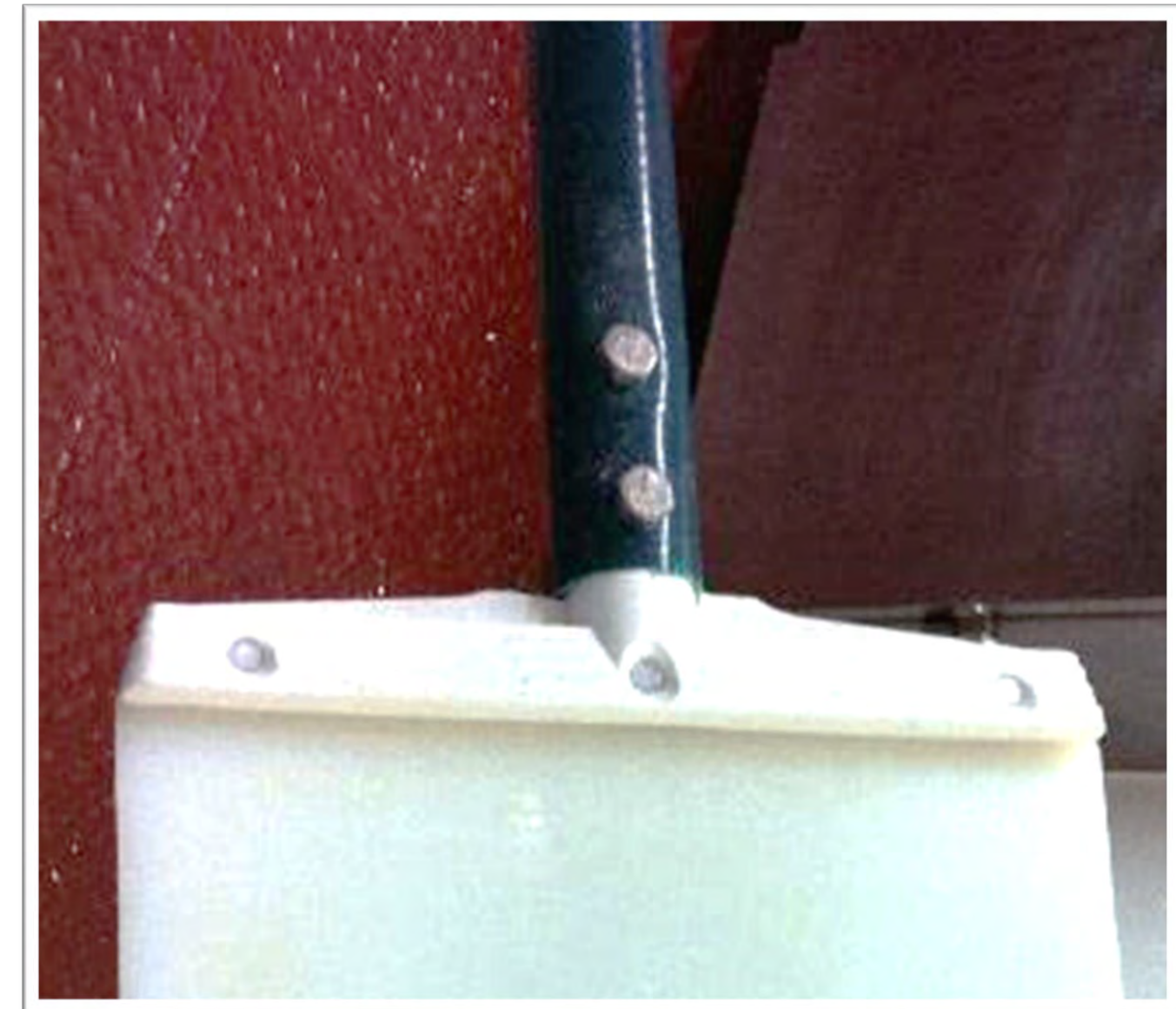
Cross-contamination control: hygienic design



Multiple deep compartments
– difficult to clean

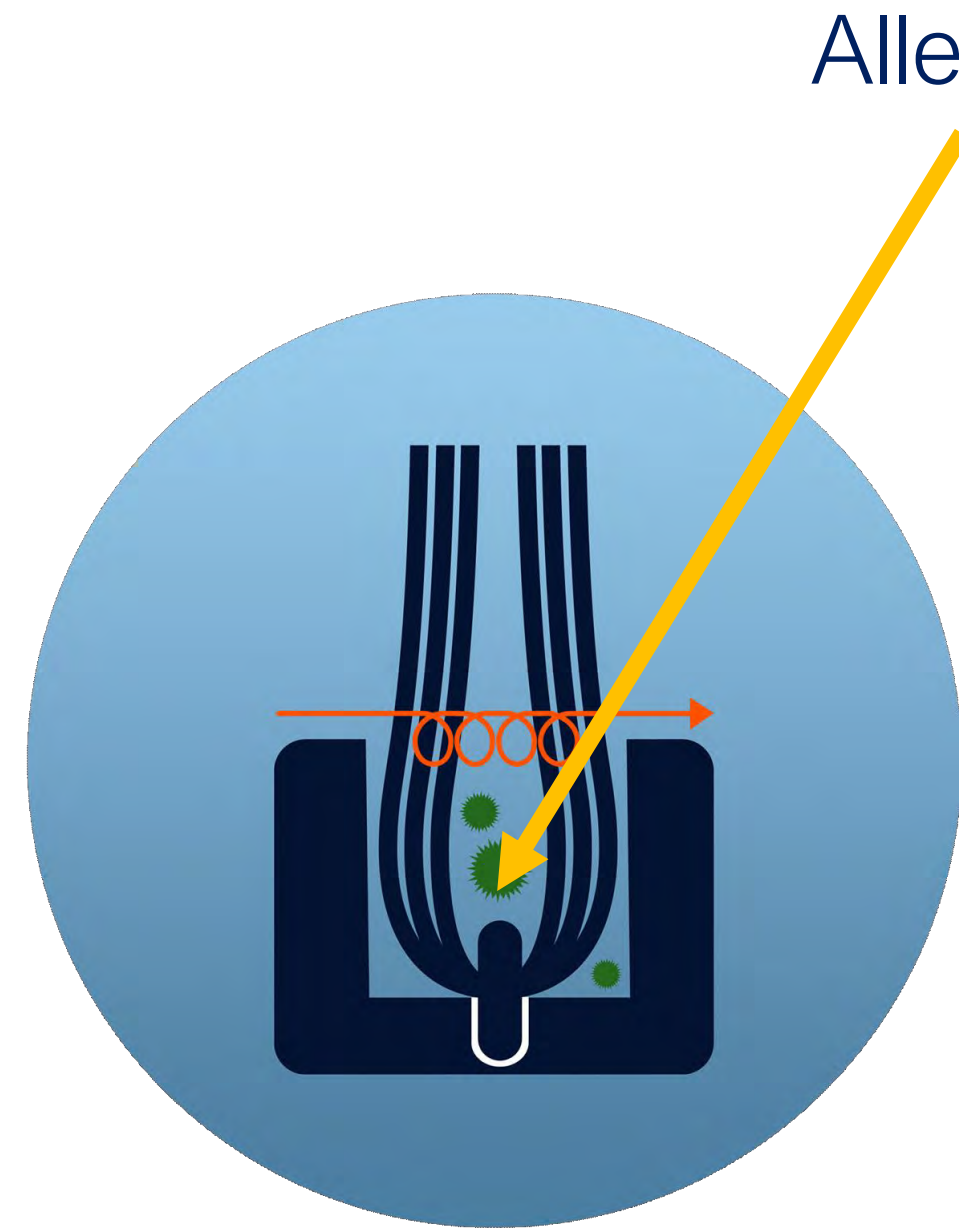


Contamination build-up
under the screw thread
handle fixing

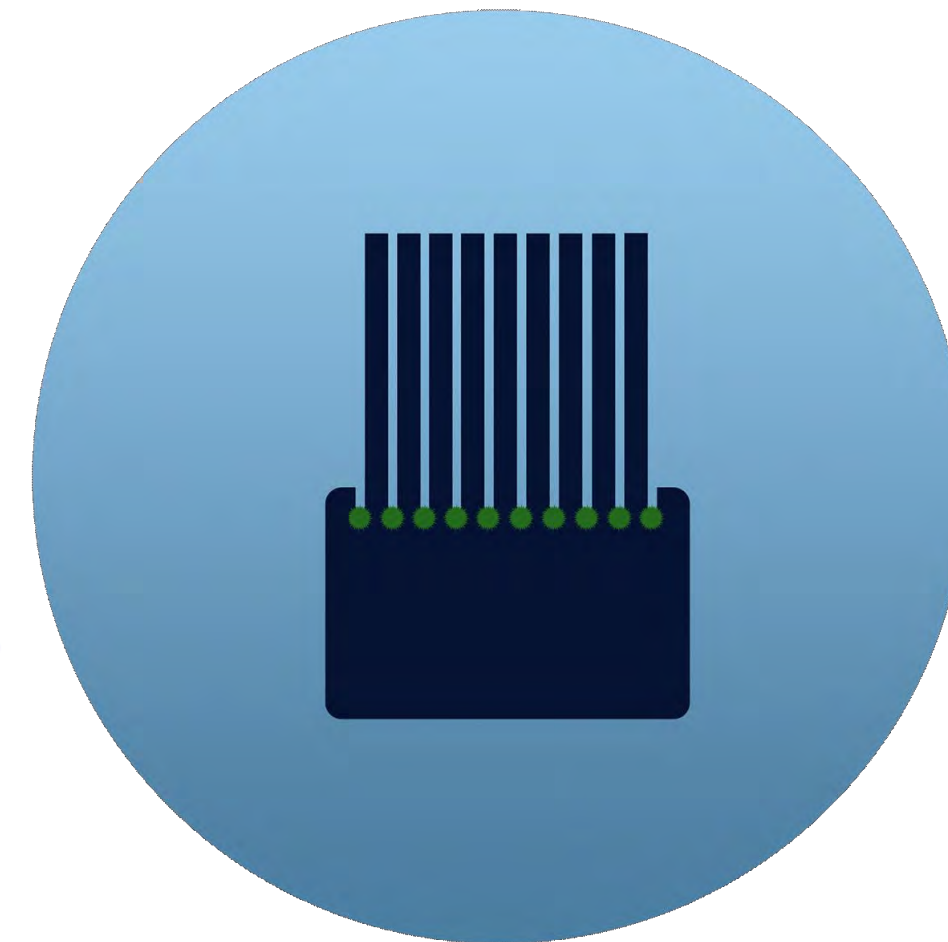


Site-made floor scraper
contamination traps / difficult
to clean

Cross-contamination control: Hygienic design



Drilled and stapled construction



Fully moulded construction



Choosing hygienically designed cleaning tools
- what are they and why it matters

GLOBAL HYGIENE SPECIALIST DESIGN GROUP
VIKAN A/S, RIVERBU T, 7500 SILE, DENMARK

WHAT ARE HYGIENICALLY DESIGNED CLEANING TOOLS?
The hygienic design of something is related to how easy it is to clean. It can also relate to the materials it is made of!

The principles of hygienic design have been defined by the European Hygienic Engineering Design Group (EHEDG, see www.ehedg.org).

Vikan is a Company Member of EHEDG

WHY ARE HYGIENICALLY DESIGNED CLEANING TOOLS BETTER?

- easy to clean (and dry) e.g. quick and easy to dismantle/assemble, or of one piece construction, or with easy access to all areas for cleaning and disinfection
- made of food safe materials (i.e., non-toxic (in compliance with EU food contact material legislation)
- well constructed e.g. durable
- non-absorbent
- appropriately temperature and chemical resistant (i.e., to dishwashing and autoclaving, to cleaning and disinfection chemicals).

WHY HYGIENIC DESIGN MATTERS:
Thanks to EHEDG, many food manufacturers already appreciate the benefits of using hygienically designed production equipment, i.e. that it is quicker and easier to clean, and minimises the risk of product contamination by microbes, allergens, foreign bodies etc. This in turn maximises food safety and quality, reduces the risk of expensive product rejection or recall, and minimises food waste. However, when it comes to the equipment used to clean the food production environment and production equipment, very few cleaning tools are developed with good hygienic design in mind.

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<http://viewer.ipaper.io/vikan/food-safety-information/ultra-hygiene/ultra-hygiene-advertorial-en-300/>

<https://www.vikan.com/uk/services/hygienic-design-of-cleaning-tools>

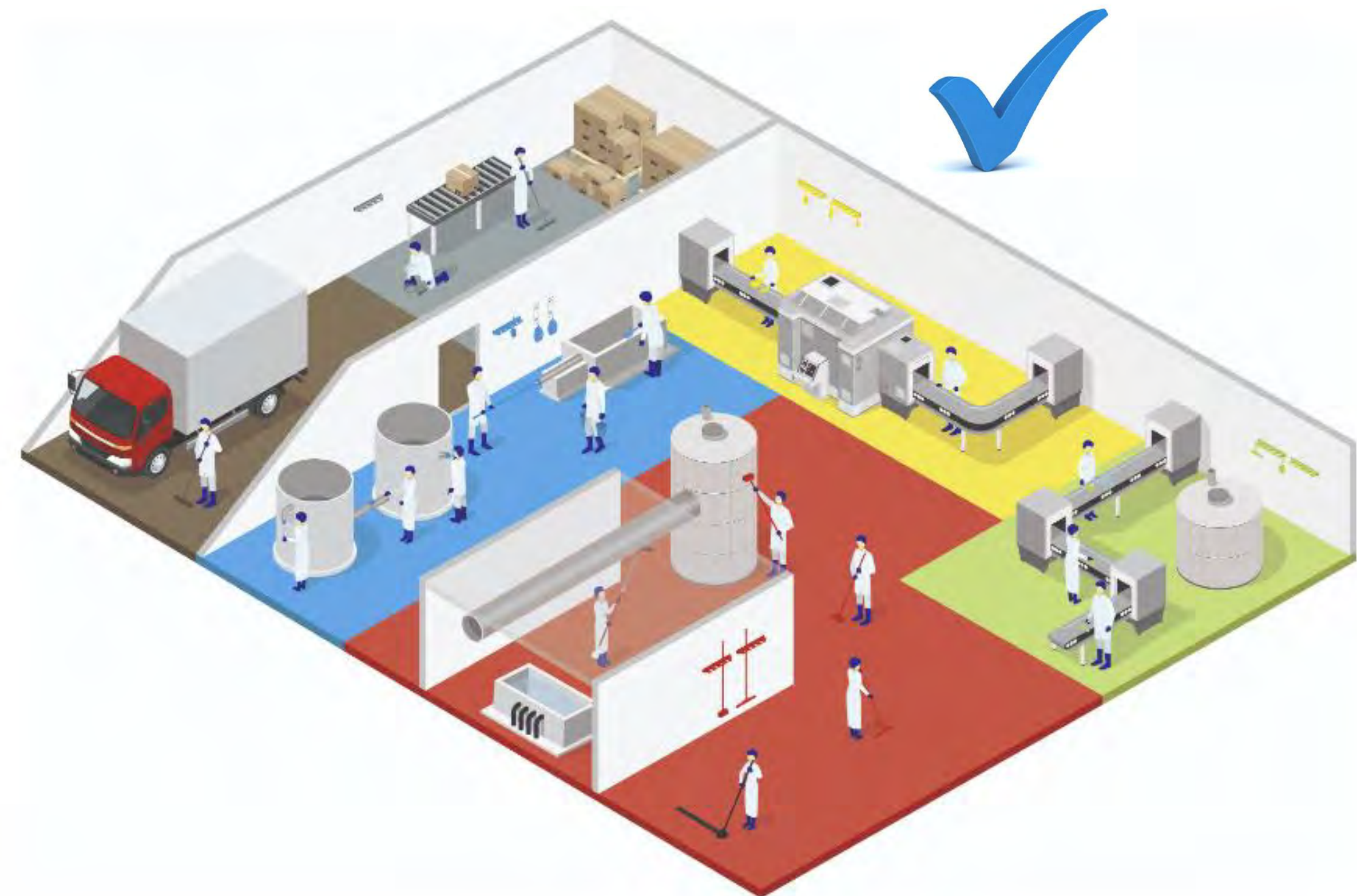


Cross-contamination control: Segregation

- Physical or time segregation of allergen-containing materials are being stored (*BRCGS 4.15.1*), transported, processed or packed.
 - Separate factories – unlikely.
 - Separate rooms/areas – possible.
 - Separate times/lines/equipment – most likely.
- Process flow & control
 - Segregation of allergen / non-allergen product areas and equipment.
 - Introduction of allergen at latest point in process.
 - Controlled introduction of re-work.

Site colour zoning plans – for segregation of allergen production areas and equipment.

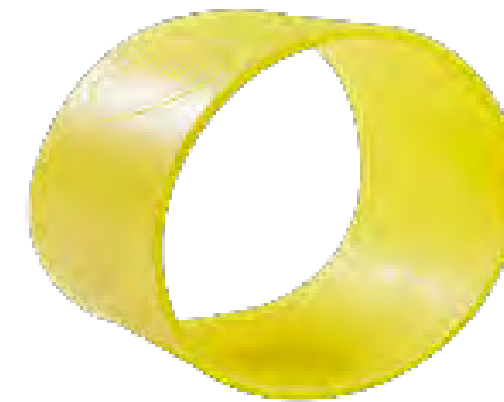
https://www.vikan.com/media/8246/allergencontrol_1_eaflet_en.pdf



Allergen control

Cross-contamination control: Segregation

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



Coloured silicone bands

Cross-contamination control: Cleaning

BRCS

5.3.8

Equipment or area-cleaning procedures shall be designed to remove or reduce to acceptable levels any potential cross-contamination (cross-contact) by allergens. The cleaning methods shall be validated to ensure that they are effective and the effectiveness of the procedure routinely verified. Cleaning equipment used to clean allergenic materials shall either be:

- identifiable and specific for allergen use
- single use
- effectively cleaned after use.

Colour-coded



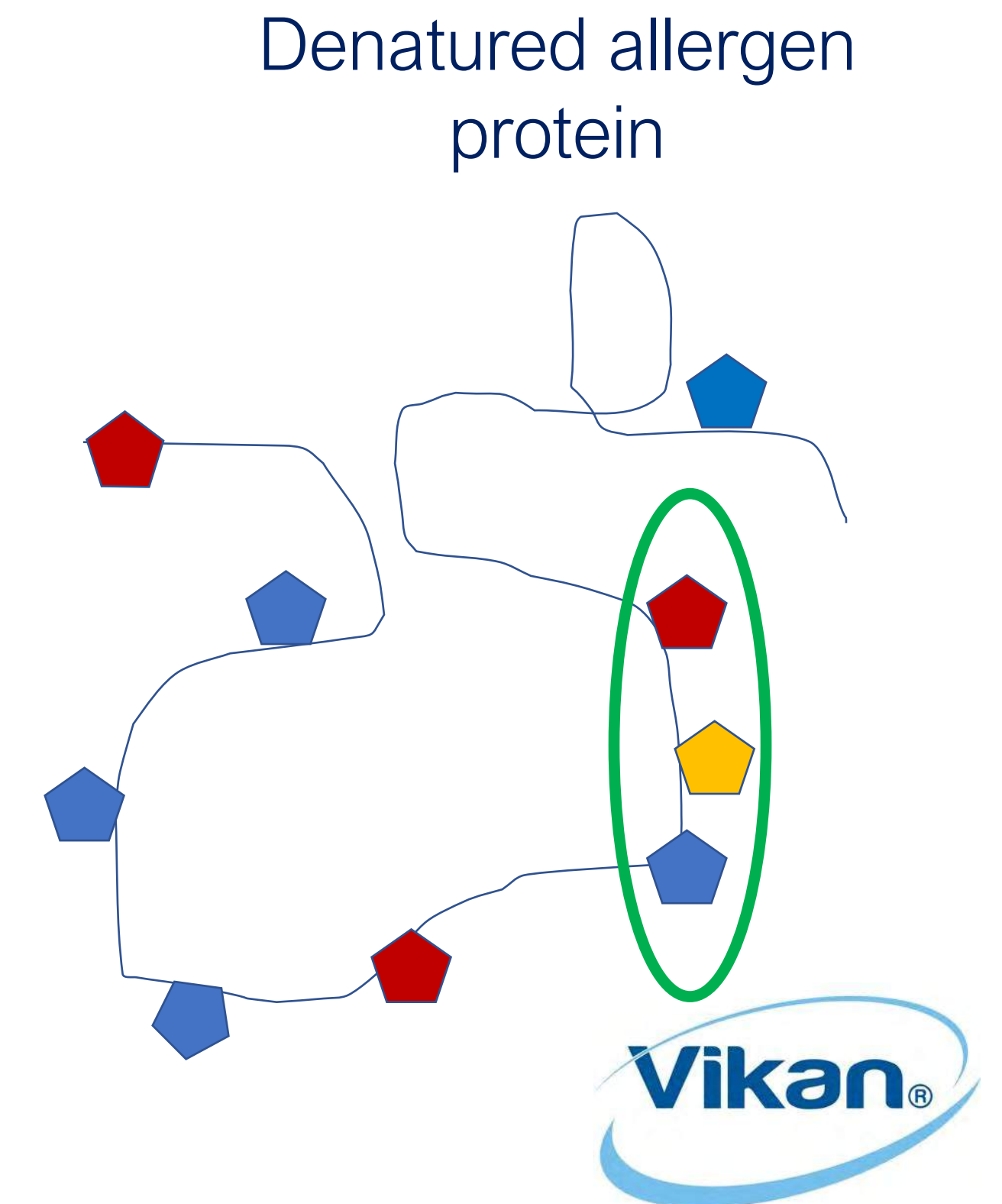
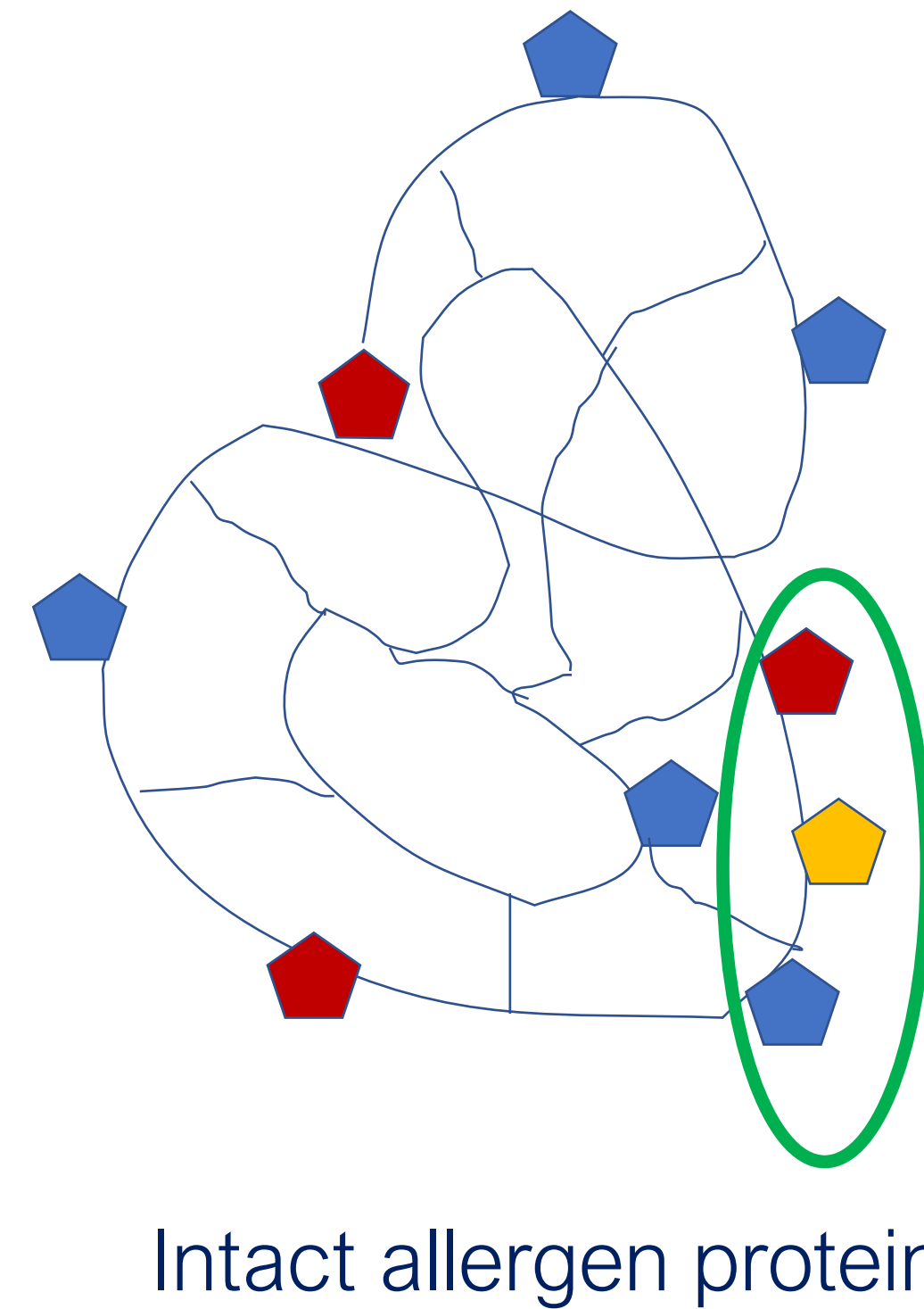
Housekeeping & Hygiene 4.11.3

4.11.6. 'cleaning equipment should be hygienically designed

8.5.3. 'equipment used for cleaning in high-care/risk areas shall be hygienically designed'

Cross-contamination control: Cleaning

- 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.



Cross-contamination control: Cleaning



Foaming:
Good for decontaminating large areas such as walls & large production equipment



CIP: (*BRCGS* 4.11.7.1 & .2).
Commonly used to clean pipework used for liquid/semi-solid foods



Manual cleaning:

Good for,

- decontaminating small to medium sized production areas/equipment;
- deep cleaning
- detail cleaning; and
- cleaning of complex equipment

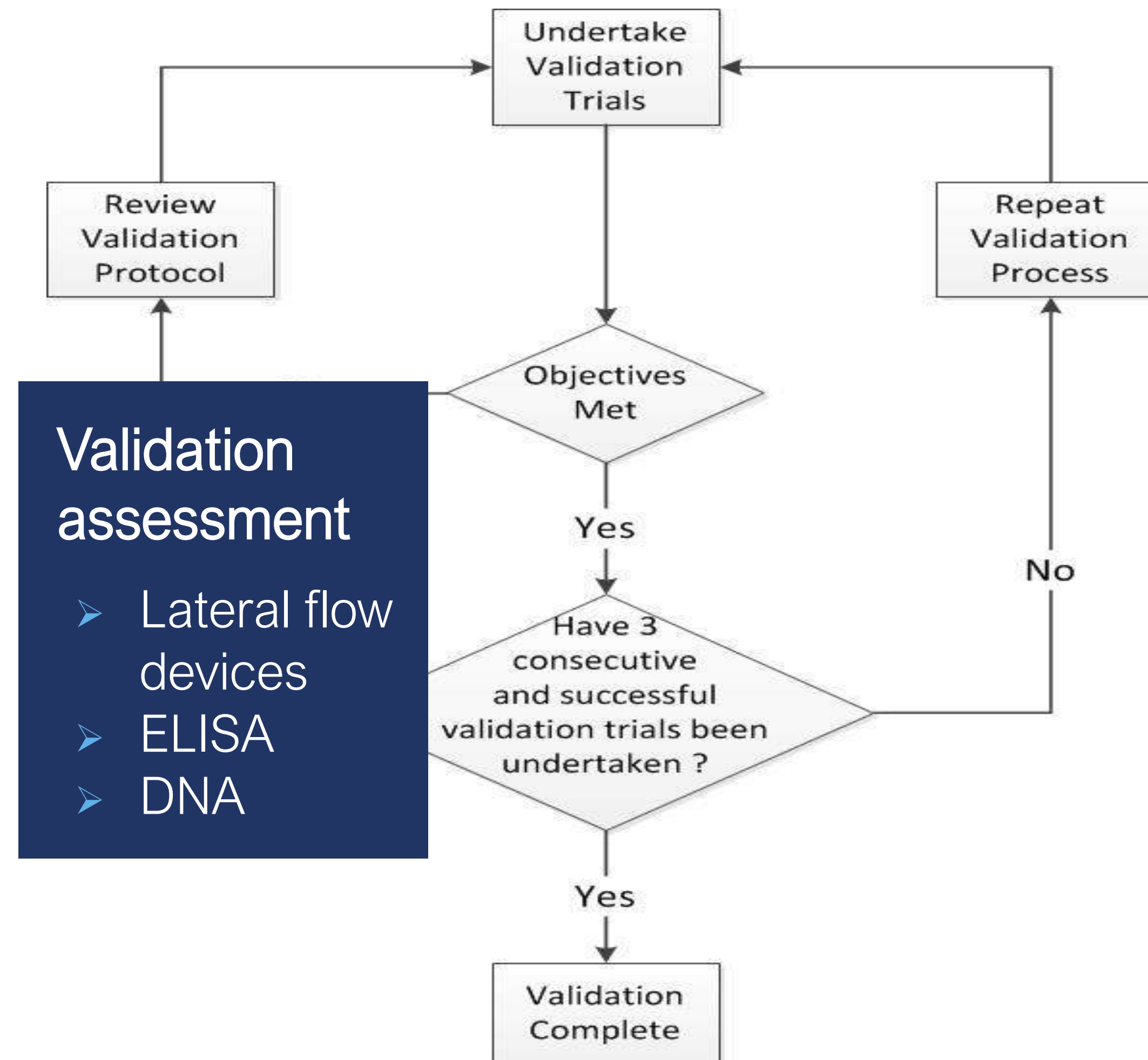
Cross-contamination control: Cleaning validation

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.



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

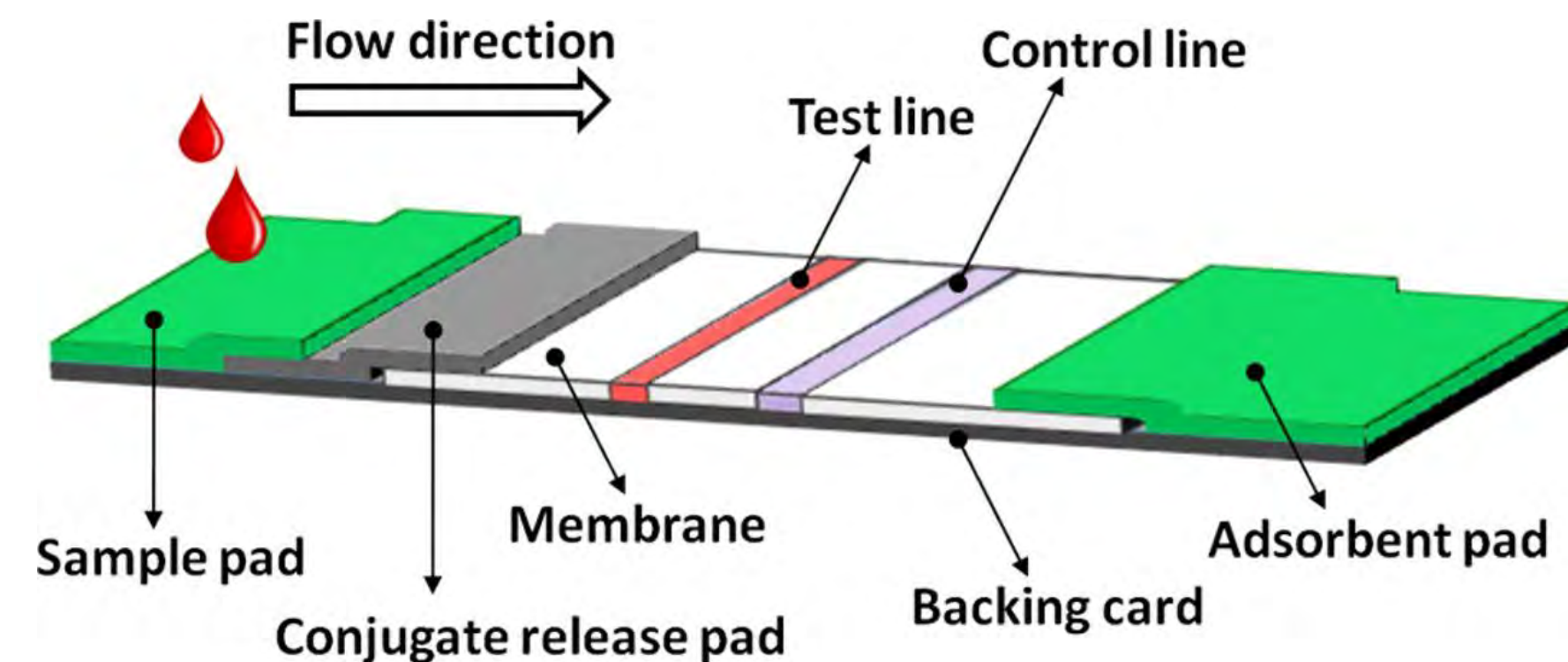
Lateral flow devices

➤ Advantages

- Rapid (~10 mins)
- Easy to read results (presence/absence)
- Cheap, no expensive instrumentation

➤ Disadvantages

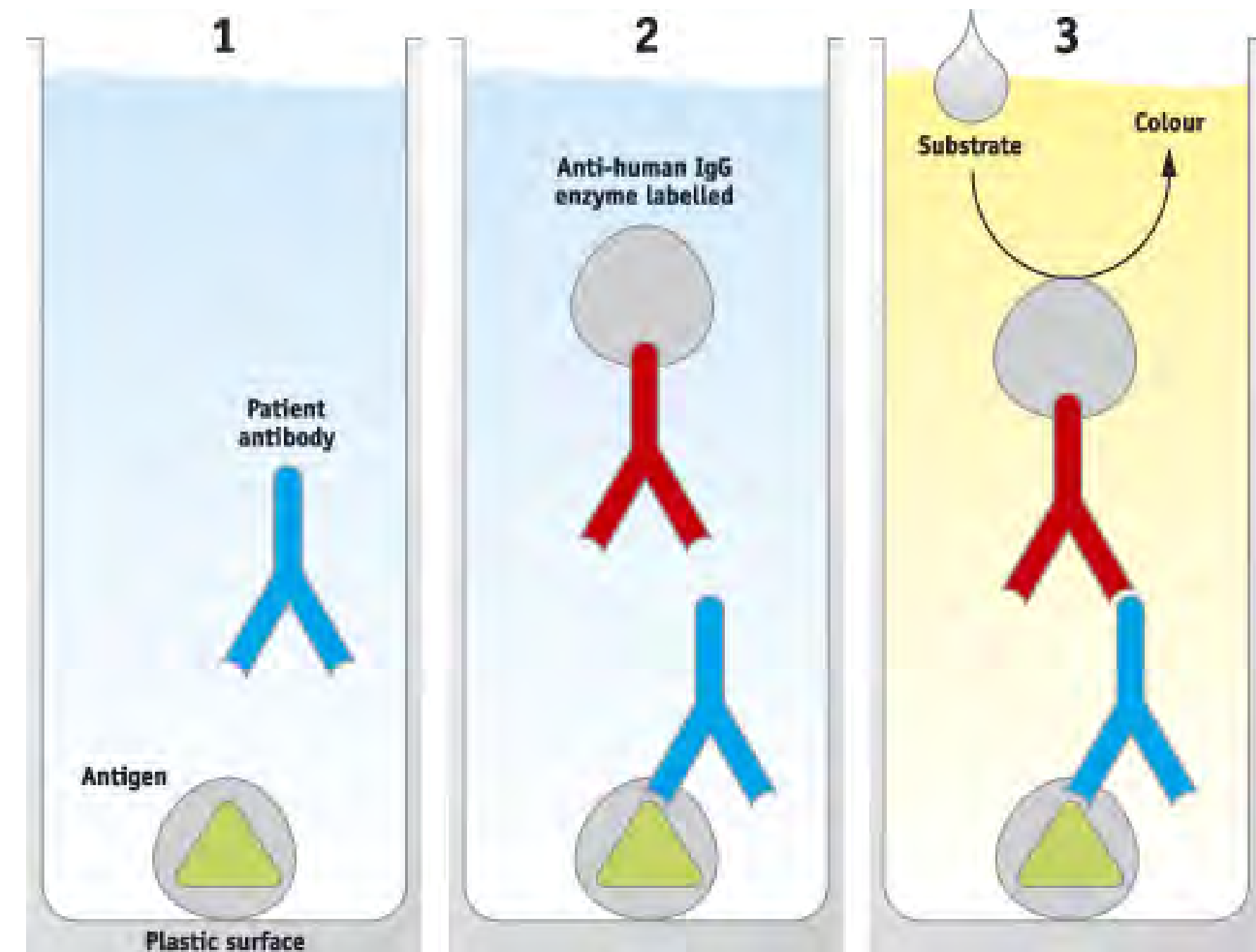
- Less sensitive than ELISA or DNA tests
- Subject to a limit of detection
- Allergen specific swabs not available for all



Analytical validation methods

Enzyme linked immunosorbent assay (ELISA)

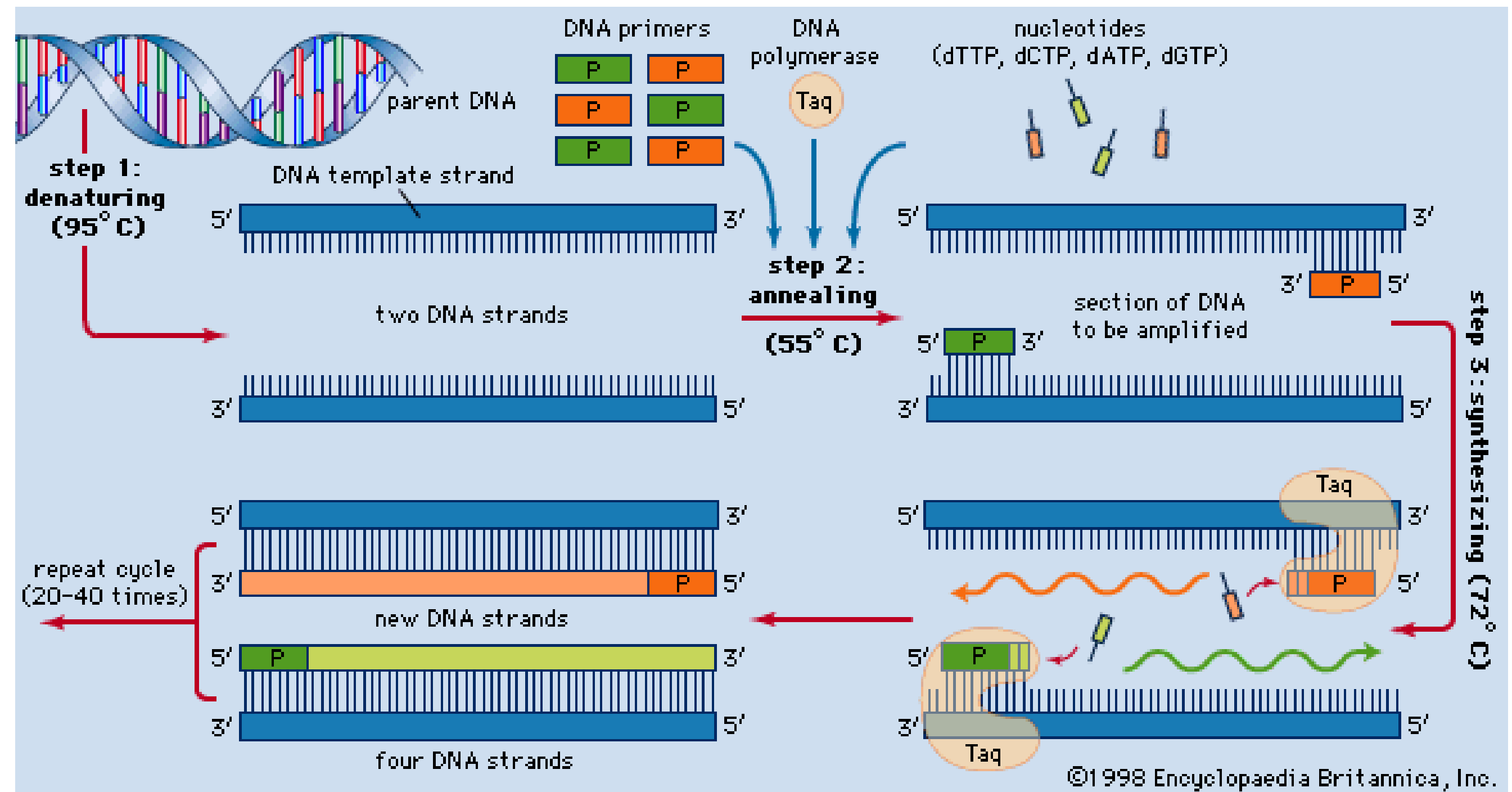
- Detection of proteins that are markers of the allergenic foodstuff.
- Uses antibodies that only bind to the protein of interest.
- The binding of the antibody and protein is linked to a mechanism that produces a colour change.
- Lateral Flow devices work on the same principle.
- Lab based test – typically 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.



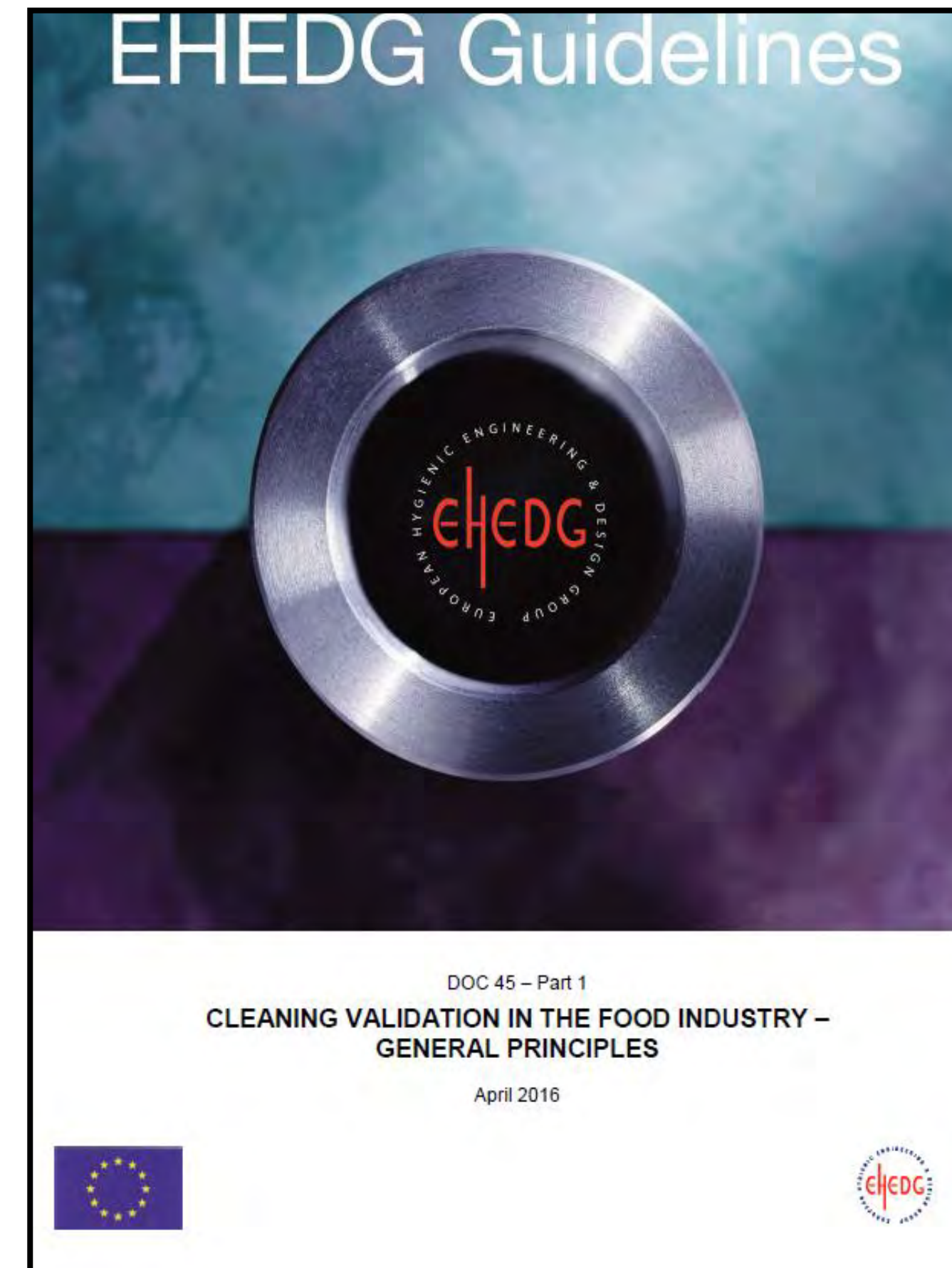
Cross-contamination control: Cleaning validation

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



Guideline No. 45
Cleaning validation in
the food industry –
general principles

<https://www.ehedg.org/guidelines/>



Cross-contamination control: Cleaning Monitoring & Verification

Determination of compliance – successful application of validated cleaning protocol

Monitoring

- Real-time assessment that the cleaning has been conducted and that the hazard (allergen) is under control.
 - Visually clean
 - Protein swabs (non-specific protein)
 - Lateral flow devices (specific allergen)

Verification

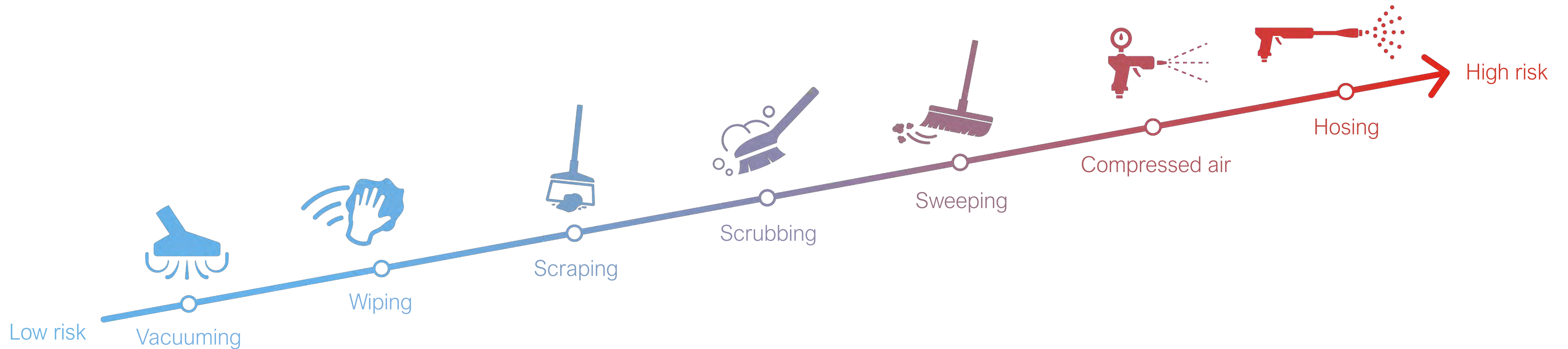
- Objective evidence that the cleaning is/has been routinely working.
 - ELISA, DNA
 - Review of monitoring data
 - Trend analysis
 - Audit reports
 - Training records
 - Validation records (including re-validation)



Allergen control

Cross-contamination control:

All cleaning activities spread contamination



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

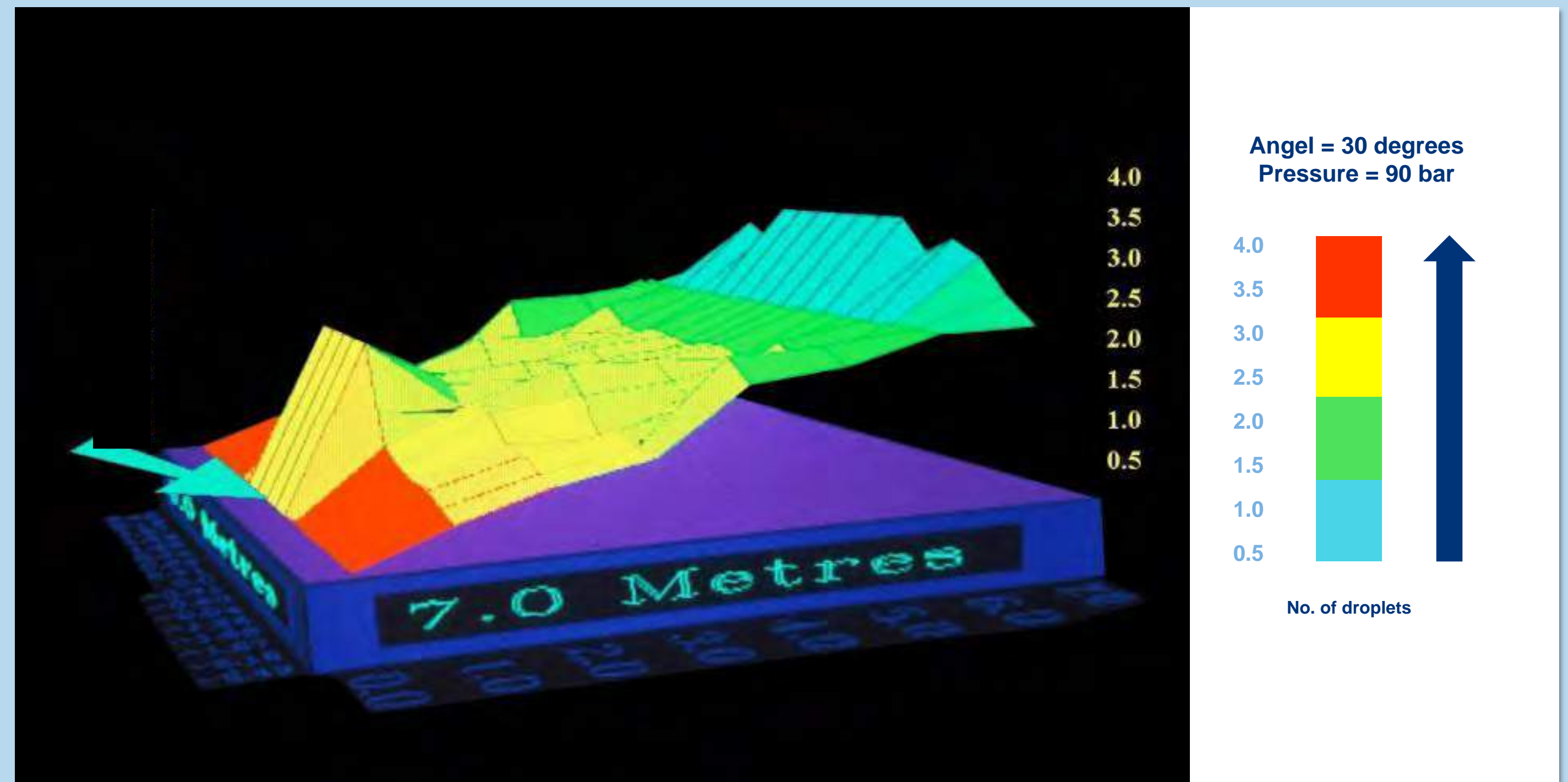
Allergen control

Cross-contamination control:

Wet cleaning: high pressure hoses



Courtesy of Campden BRI



Allergen control

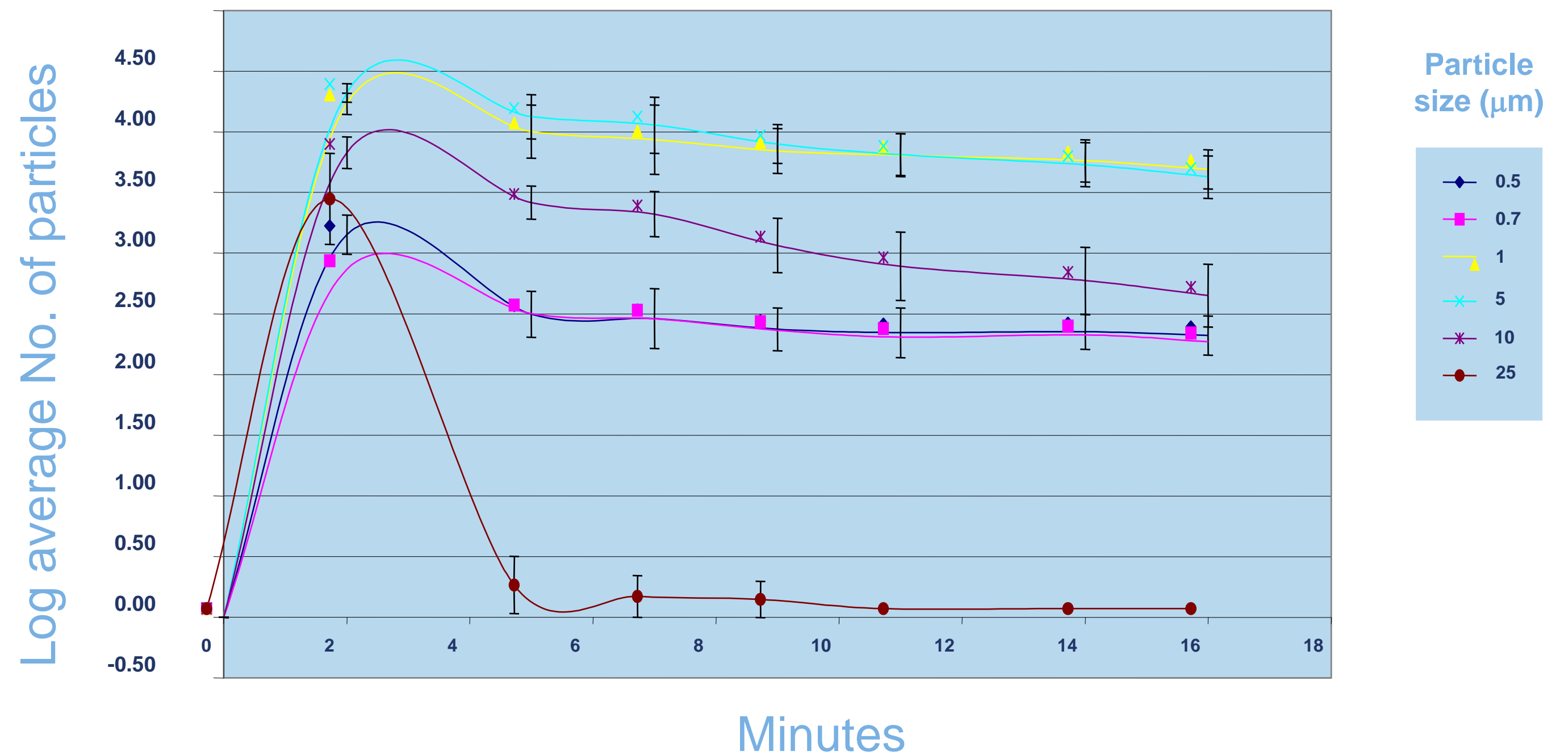
Cross-contamination control:

Dry cleaning: compressed air



Courtesy of Campden BRI

Size and number of particles in the air after using compressed air on flour



Allergen control

Cross-contamination control:

Spill kits



Waste handling

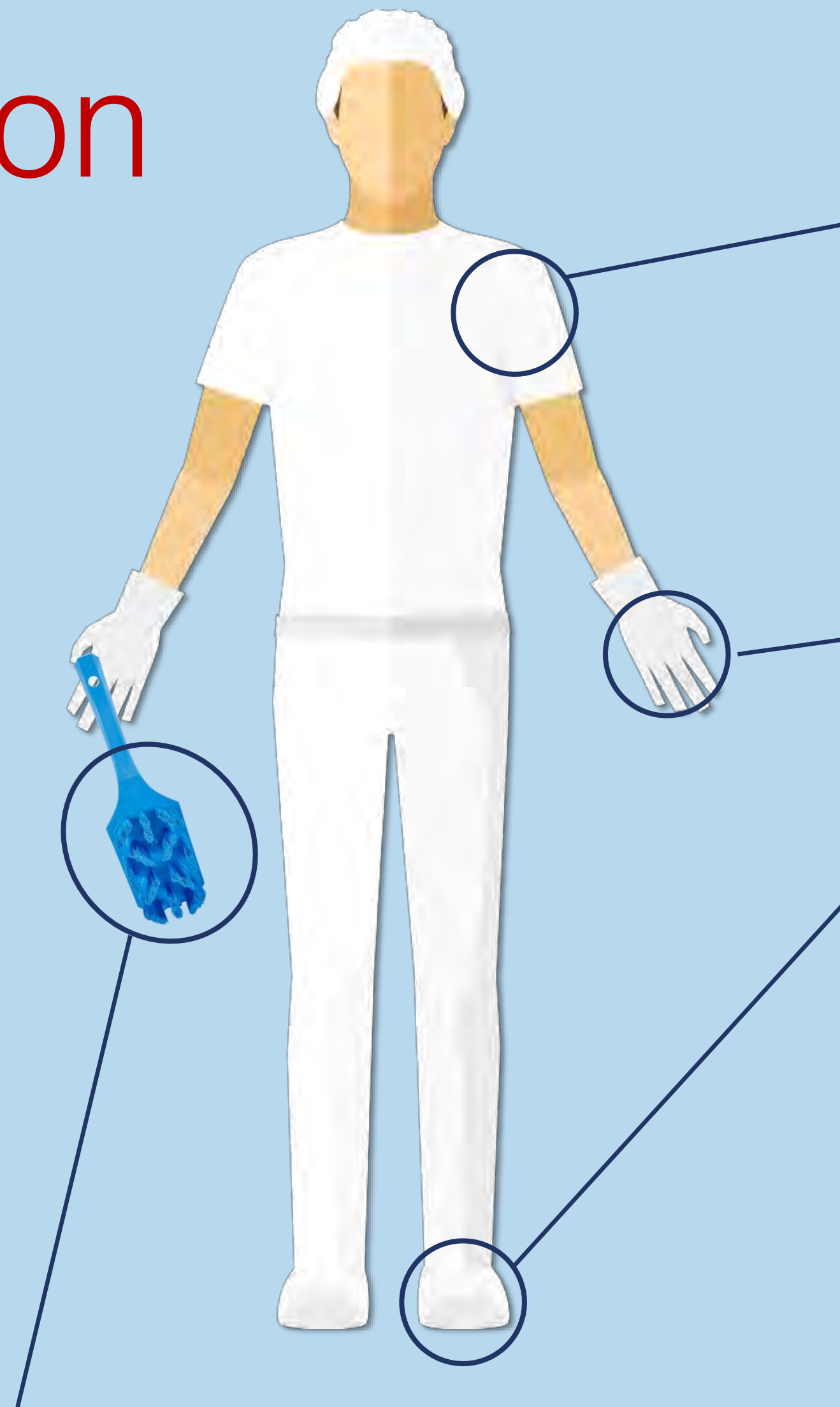


Cross-contamination control: People

People - an essential asset in allergen control

Training: (BRCGS 7.1.4)

- Awareness of allergens as a hazard & consequences to an allergic consumer.
- Allergen handling & segregation procedures.
- Restrictions on allergens brought onto site by staff, visitors, contractors & caterers.
- Controlled movement



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

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

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

Use different staff for Allergen / non-allergen tasks & areas

Allergen transfer by **equipment** -
Keep captive to different areas/tasks -
use color-coding.

Labelling

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.

*Priority list of controlled allergens may be different in different countries.



Natasha Ednan-Laperouse, Age 15

‘Natashas Law’

- 2019 – Amendment to Food Information (England) Regulation, 2014.
 - ‘All foods pre-packed for direct sale, will need a full ingredients label’.
- ‘Natasha’s Law’ - came into force in October 2021.

Labelling



Labelling: (BRCS 6.2.3)

Clause	Requirements
5.2.1	<p>All products shall be labelled to meet legal requirements for the designated country of use and shall include information to allow the safe handling, display, storage, preparation and use of the product within the food supply chain or by the customer.</p> <p>There shall be a process to verify that ingredient and allergen labelling is correct based on the product recipe and ingredient specifications.</p> <p>The company shall have a procedure for artwork approval and sign-off.</p>

Precautionary labelling

5.3.6	<p>Where a justified, risk-based assessment demonstrates that the nature of the production process is such that cross-contamination (cross-contact) from an allergen cannot be prevented, a warning should be included on the label. Legislation, national guidelines or codes of practice shall be used when making such a warning statement.</p>
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Labelling

- Allergen sufferers 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.

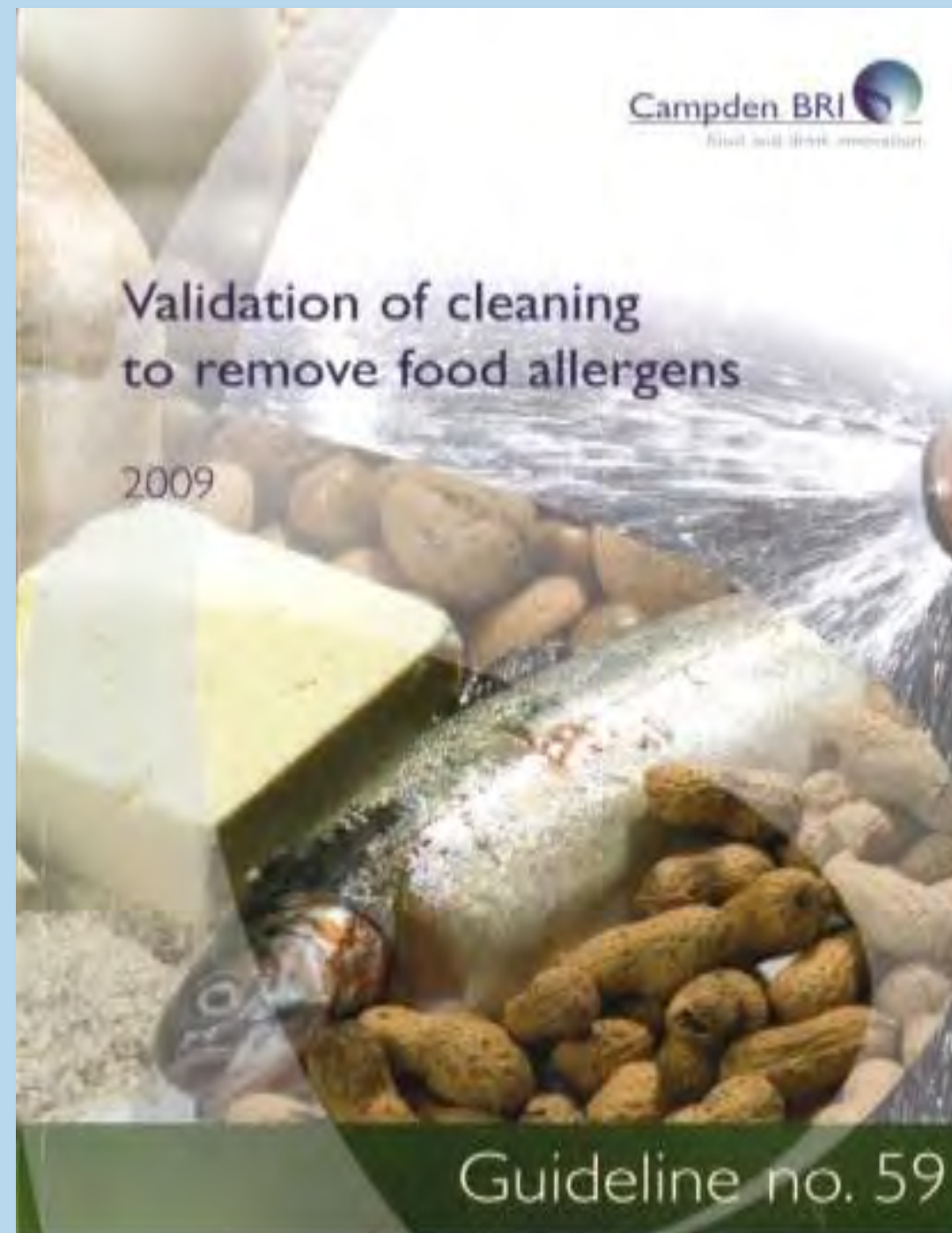
Allergen Control - challenges, perspectives and solutions'

1. Understand why it is important.
2. Establish a site allergen management programme:
 1. Prevent entry
 2. Prevent cross-contamination
 1. Hygienic design
 2. Segregation
 3. Process flow & control
 4. Cleaning
 5. Reduce spread
 6. People
 3. Labelling
3. Use a risk-based approach – use all available sources of information



Allergen control

Further information



<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>



Food Allergens
Knowledge Hub

<https://www.ifst.org/knowledge-hubs/food-allergens-knowledge-hub>

Allergen control

Further information

www.vikan.com – Knowledge centre

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



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