International review of the literature and guidance on food allergen cleaning

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1. Acknowledgements

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2. Lay Summary

The aim of this work was to find information in research papers, book chapters, guidance documents and websites about cleaning to remove food allergens from surfaces in food factories (such as mixers, pipework and containers) and in catering businesses, such as restaurants and school canteens (including food preparation areas in kitchens, and equipment such as crockery (plates and dishes), cutlery and utensils (such as spoons and serving tongs), pots and pans).

People with food allergies must avoid eating the foods they are allergic to as they may react to very small amounts of such foods. Allergenic food left on surfaces or equipment could contaminate another food that is also prepared using the same surface or equipment or that may fall into the food from surfaces above in the same area. Cleaning of surfaces and equipment is therefore one way to prevent contamination with food allergens as well as ensure food is prepared hygienically. Food businesses let people know that food could be contaminated with allergens using Precautionary Allergen Labelling (PAL) such as ‘may contain’ statements. But unless businesses know how well cleaning is working and whether contamination may happen, they do not know whether to provide this information.

This study found that cleaning with water containing certain cleaning chemicals was generally better at removing food allergens than other types of cleaning, such as dry cleaning using brushes and vacuuming without water. However, how well particular ways of cleaning work depends on many things, such as the type of food to be removed, and what the surface is made from and its condition. Also, how well cleaning works can depend on the amount of time spent cleaning or whether items are left to soak rather than being washed quickly, the amount of effort or energy put into cleaning, the type and amount of cleaning products used and whether the water is hot or cold. There is therefore no single way of cleaning that will be effective at removing all types of foods from all surfaces.

It was found that more research is needed, for example, on how well dishwashers in catering kitchens can remove food allergens. The report provides an overview of the information found and recommendations for future work to help businesses provide safe food for consumers with food allergies.

3. Executive Summary

This report describes a review of international peer-reviewed academic works, book chapters and ‘grey’ literature (incorporating codes of practice, guidance documents, ndustry and professional body publications, corporate white papers, websites, blogs, reports) about cleaning to remove food allergens. The literature review was commissioned under the Food Standards Agency’s (FSAs) Food Hypersensitivity programme, which aims to improve the quality of life for people living with food hypersensitivities and support them to make safe and informed choices to effectively manage risk. This work particularly supports the Precautionary Allergen Labelling (PAL) policy area.

PAL should be used when there is an unavoidable risk of the unintended presence of food allergen/s that cannot be sufficiently controlled. Small and medium sized enterprises (SMEs) face difficulties in assessing whether the risk of allergen cross-contact has been sufficiently controlled. Without routine assessment, there is uncertainty as to how effective control measures are, in particular cleaning.

A narrative literature review was undertaken, which borrows from the methodology of a systematic review. However, it did not follow the constraints of the method in order to provide a wider variety of information sources. A bibliographic database (Food Science and Technology Abstracts) was searched using search terms agreed with the FSA over a span of ten years, 2012 to 2022. ‘Grey’ literature was sourced by targeting searching to websites of authority, agency and governmental websites identified from those countries and geographical regions where specific food allergens are listed in legislation. In addition, websites of organisations, trade associations, analytical test kits and cleaning chemical suppliers and analytical laboratories were searched for specific information on cleaning to remove food allergens.

The results of studies into the efficacy of routine cleaning procedures described in peer-reviewed journal articles were consolidated into summary tables detailing the study design and key findings. For guidance documents and codes of practice, information on each cleaning methodology was summarised and key principles of validation and verification were extracted, collated and discussed. Summary tables were produced for

most other literature sources and the information is reported in the results section of this report. A database of relevant literature sources has also been produced.

Throughout the literature many factors were described that affect the efficacy of cleaning for removal of food allergens including:

- Foodstuff: soil type, physical form and food matrix – for example generally sticky paste residues are more difficult to remove than dry residues.
- Surface: material and its properties – for example stainless steel is generally the easiest surface to clean, whilst wood and cloth are the most difficult.
- Equipment: accessibility – for example inaccessible equipment may need to be dismantled or cleaned using techniques such as 'push-through' (the use of an inert material, physical object ('pigs') or foodstuff that does not contain any allergenic proteins).
- Cleaning parameters: time, mechanical action, chemical properties (of detergents or cleaning chemicals applied) and temperature.

Evidence from studies on the efficacy of routine methodologies for allergen removal in scientific journal articles and theses is limited by the low number of published studies found (n=23), which apply specific cleaning methodologies in circumscribed contexts. Not all the allergenic foods requiring mandatory labelling declaration in the UK were studied (in fact only six), and wet cleaning methodologies (i.e. those using water, with or without cleaning chemicals) were most commonly investigated. Findings suggest that wet cleaning is generally more effective at allergen removal than dry cleaning (i.e. the use of equipment such as brushes, scrapers, and vacuum without water), although it is recognised that wet cleaning is not always feasible. The use of alkaline detergents, and in particular chlorinated alkaline detergents, was shown to be more effective than other chemicals, but it was pointed out that there is no single chemical or wet cleaning regime that will be effective in all situations, due to the various factors that affect cleaning efficacy as highlighted above.

In terms of other cleaning methodologies, controlled wet cleaning (use of commercial 'wet wipes' or cloths, which may be wetted with a specific cleaning chemical or antibacterial solution, to clean a surface in a controlled manner) was found to be effective in some scenarios. Dry cleaning techniques were shown to be capable of visually removing dry powder, but soil containing allergens was often still detected by analysis of

the visually clean surfaces. Using a material that does not contain allergenic foodstuffs (‘push through’) was found to be variously effective; again, this depended on multiple factors. Clean-in-place (CIP - where cleaning chemicals and rinses may be pumped through equipment (such as pipe work and vessels), without first dismantling it, to remove food residues and contamination) was shown to be effective in the one study in which it was investigated using rigorous protocols.

Rather than giving specific advice on cleaning regimes, guidance documents provided general information to the effect that food business operators (FBOs) are recommended to independently develop an appropriate cleaning procedure suitable for the context in which they are cleaning. Many of the guidance documents do, however, provide advice on validation and verification of cleaning to remove food allergens, from which 14 principles were derived and are described in this report.

Other literature sources provide information ranging from general overviews of the topic, through practical considerations for cleaning, including the design and accessibility of equipment, to details on some cleaning methodologies, although this was limited to descriptive information about the cleaning protocol without being prescriptive.

There is a lack of information on the efficacy of COP, open-plant cleaning (OPC), laundering of workwear and the use of commercial dishwashing appliances with regard to allergen removal. In addition, much of the information that has been published is of relevance primarily to large food processing and manufacturing operations with the time, resources and expertise to conduct validation studies and ongoing verification involving analytical testing. As a result, there is a need to conduct research to fill the evidence gaps in the literature for food service and micro, small and medium food processors. Primarily, research needs to focus on understanding the capability of existing, widely applicable cleaning practices to demonstrate what is achievable, for example in food service, using commercial dishwashers, to inform development of best practice guidance for these businesses, and to advise dishwasher manufacturers and dishwasher cleaning chemical manufacturers in product development, design and application.

The report does not explore the inherent limitations or benefits of different analytical methods, apart from recommendations to use specific, sensitive, relevant, validated testing methods where appropriate. It is observed that many sources state that visual inspection should not be the only method of gauging cleaning efficacy, as visually clean

surfaces may still harbour detectable allergen residues. There is an absence, however, of studies relating levels present on visibly clean surfaces to potential levels of contamination in products in contact with those surfaces; this is especially pertinent with reference to quantitative risk assessment and the use of ‘threshold’ or ‘action levels’ to decide on the need for PAL.

Ultimately, selection of an efficient cleaning methodology will be determined on a case-by-case basis, taking into account the factors described that may affect efficacy. It must be remembered that what classifies as ‘microbiologically clean’ does not necessarily correlate to ‘allergen clean’, as food allergens cannot be ‘killed’ or necessarily made ‘non-allergenic’ by cleaning. Some best practice advice can be drawn from existing literature and guidance, notably relating to manual cleaning and washing of hands. However, it is not possible to state that one cleaning methodology will effectively clean in all scenarios, as there are just too many variables in each scenario.

The report provides researchers, policymakers, and industry with a detailed overview of international literature on the topic of cleaning to remove food allergens and provides a foundation on which to base future research study designs, guidance development and subsequent industry practice.

4. Introduction

4.1 Food Standards Agency project specification

The wording within inverted commas in this section is quoted directly from the Food Standard Agency (FSA) specification for the project; however, where wording has been amended for clarity, this is denoted by the use of square brackets.

“This work was commissioned under the FSA’s Food Hypersensitivity programme. The programme aims to improve the quality of life for people living with food hypersensitivities and support them to make safe and informed choices to effectively manage risk. This work particularly supports the Precautionary Allergen Labelling (PAL) policy area.

PAL should be used when there is an unavoidable risk of the unintended presence of an allergen that cannot be sufficiently controlled. Small and Medium Sized Enterprises (SMEs) face difficulties in assessing whether the risk of allergen cross-contact has been sufficiently controlled, because without [defined and agreed] routine [assessment], there is uncertainty as to how effective control measures [such as] cleaning, are [in preventing risks of allergen cross-contact].

Evidence gathered from stakeholders has shown that uncertainty around the effectiveness of allergen cleaning is a notable barrier to effective use of PAL, because testing for allergens to validate cleaning is typically only feasible for the largest food businesses.

This review is a starting point in co-developing allergen cleaning guidance with industry to support judicious application of PAL: It reviews evidence and identifies gaps to inform further research and guidance development.”

4.2 Background

It is estimated that 2.6 million people in the UK live with a diagnosed food allergy (Acharya, 2021), i.e. an immune-mediated food hypersensitivity (Codex Alimentarius, 2020a). The amount of allergenic foodstuff that can cause an allergic reaction differs between individuals, however, it has long been known that very small amounts of allergenic protein (in the milligram range) can cause a severe or possibly even fatal

reaction (Taylor et al., 2002). For food-allergic individuals this necessitates the adoption of a strict avoidance diet to prevent consumption of foodstuffs to which they react. Such individuals, as well as those associated with them, for instance their family, friends, and caregivers are therefore obligated to be vigilant for allergen information on product labels of prepacked food and for food sold loose, for example in food service situations, when preparing or purchasing food. Allergic individuals face a significant food safety hazard of consumption of food allergens. To enable them to make safe, informed choices, it is vitally important that the correct allergen information pertinent to the risk from consuming a food is conveyed clearly at the point of decision-making for consumers, i.e. information that accurately describes allergen content whether deliberately added or potentially present due to the risk of a food containing allergenic foodstuffs through adventitious cross-contact.

All food businesses have a legal responsibility to produce safe food. The general food law (retained Regulation (EC) No. 178/2002) provides the overarching principle that food shall not be placed on the market if it is ‘unsafe’, which is considered to be ‘injurious to health’ or ‘unfit for human consumption’. Article 14 goes on to state that when determining whether food is ‘unsafe’ regard shall be had to the information provided to the consumer regarding the avoidance of specific adverse health effects from a particular food or category of foods. Food containing undeclared allergens would therefore not be considered safe.

Food business operators (FBOs) are obliged to put in place procedures based on Hazard Analysis and Critical Control Points (HACCP) principles (as laid down in Article 5 of retained Regulation (EC) No. 852/2004) and verify that food law requirements are met (as required by Article 17 (1) of retained Regulation (EC) No. 178/2002). HACCP risk analysis confirms that exposure to (undeclared) food allergens for specific sensitive populations is a risk requiring deliberate allergen risk management procedures with controls, validation, verification and monitoring in place. Cleaning is a critical step in preventing contamination or re-contamination of products; physical, chemical and biological cleanliness is a prerequisite for food safety (Schmitt and Moerman, 2016). Cross-contact can occur in food processing and food service environments when allergenic foodstuffs are handled, prepared or processed on surfaces or equipment or using utensils that are not then cleaned appropriately before preparation of a food product that does not contain those allergenic ingredients, or following spillage in food handling, storage and transport environments which is not cleaned up effectively. Such

contamination raises concerns around consumer safety for allergic individuals and FBOs alike.

To protect public health of consumers with allergies and intolerances, specific provisions relating to food allergens and food information for prepacked food are provided in retained Regulation (EU) No. 1169/2011 (FIC). Intentionally present specified substances or products causing allergies or intolerances, or derived from those substances or products (the allergenic foods for which labelling is mandatory listed in FIC Annex II; exemptions that apply are also listed in this Annex) are declared on the label, either in the name of the food, emphasised throughout the ingredients list or in a 'contains' statement where there is no ingredients list. This mandatory labelling only applies where allergenic products or substances have been intentionally added as ingredients or processing aids.

The FIC also extends the legal responsibility to provide information relating to intentionally present allergenic foods listed in FIC Annex II to non-prepacked food but provides no specific requirements on how this should be achieved. The Food Information Regulations (FIR, 2014), as amended, and parallel legislation in Wales, Northern Ireland and Scotland state that allergen information for non-prepacked food can be provided by any means the FBO chooses, including orally, as long as consumers are notified that they need to ask for such information in the ways specified in the legislation. Amendments to the FIRs brought about the requirement to provide allergen information for food sold prepacked for direct sale, which are aligned with the requirements under the FIC for prepacked food. FBOs therefore have a legal requirement to convey information about the intentional presence of the allergenic foods listed in Annex II to the FIC (excluding exempt derivatives) in food that is prepacked, non-prepacked and prepacked for direct sale.

Currently, in UK there is no specific legal requirement to provide PAL or precautionary allergen information (PAI, for non-prepacked food) to indicate possible allergen cross-contact; although of course the over-arching requirement to provide safe food applies. Many FBOs, however, provide this information voluntarily to indicate the possible presence in food products of unintentional substances that people may be allergic to. The voluntary use of PAL is permitted; the basis for this is contained within Article 14 of retained Regulation (EC) No.178/2002, which refers to the information provided to the consumer concerning the avoidance of specific adverse health effects from a particular

food or category of foods. In addition, Article 36 (2) to the FIC is relevant, as it is required that such voluntary food information shall not mislead the consumer, shall not be ambiguous or confusing for the consumer and it shall, where appropriate, be based on the relevant scientific data. Therefore, PAL should only be applied upon substantial risk of unintentional allergen presence based upon scientific risk assessment and evidence.

Guidance has been developed to ensure that industry is providing PAL appropriately and only after identifying potential issues after a robust risk assessment, for example the FSA website (last updated November 2021), which states that PAL "should only be used when, following a thorough risk assessment, a genuine risk of allergen cross-contact within the supply chain is identified that cannot be removed through careful risk management actions." Cross-contact can occur at any stage of food production including (for example) primary production, harvesting, slaughter, handling, transportation, storage, processing or preparation, and packing. Control measures implemented to prevent or minimise the likelihood of allergen cross-contact should be based on risk assessment conducted by FBOs (Codex Alimentarius, 2020a - Code of Practice on Food Allergen Management for Food Business Operators (CXC 80-2020)), which represents international consensus in this field) and should therefore address each stage of food production.

Strategies involved in the management of food allergens are well documented (for example Codex Alimentarius, 2020a; FoodDrinkEurope, 2022) and are of particular importance where FBOs are handling, transporting, producing and/or storing allergenic and non-allergenic foods using the same equipment or on the same premises (particularly for food service operators).

It has been recognised that, as part of a wider allergen control plan, when procedures are performed correctly, cleaning is one of the most powerful strategies for preventing allergen cross-contact (Jackson, 2018). Segregation by space and time is also recognised as an effective measure for prevention of allergen cross-contact (for example segregated production lines, receptacles and storage facilities, when possible; dedicated utensils and containers, or specific work methodology/production order for example by scheduling, i.e. end of the day production of products with the highest amount of allergens) (European Commission, 2022).

Cleaning is part of a holistic food safety management system (FSMS), incorporating prerequisite programmes, supplemented with control measures at Critical Control Points (CCPs) (as appropriate) that when taken as a whole ensure that food is safe and suitable for its intended use (Codex Alimentarius, 2020b). The FSMS is also the combination of control measures and assurance activities. The latter aims to provide evidence that control measures are working properly such as validation and verification, documentation and record keeping (European Commission, 2022). Efficient intermediate cleaning to control cross-contact between batches containing different allergens, is given as an example of typical good hygiene practice and/or Operational Prerequisite Programmes (European Commission, 2022).

Cleaning to remove food allergens can, however, prove to be complex. There are clear differences between cleaning to reduce microbiological risk and what is considered as “allergen clean” (Schaffner, 2020). Allergenic foodstuffs or materials (including lubricants or packaging materials) cannot be ‘made safe’ by processing or modifying them using chemical or physical methods. Treatments lethal for pathogenic microorganisms, such as heating, high pressure processing, etc. generally do not destroy allergenic proteins (Codex Alimentarius, 2020a) in terms of their potency to trigger allergic reactions. Cleaning to prevent allergen cross-contact is therefore focussed on removal of allergenic foodstuff and materials from shared equipment, surfaces and utensils. However, allergenic proteins are often difficult to remove (Schmidt, 1997) and are rarely present alone, but rather as part of a complex food matrix, which can impact the level of adhesion to surfaces (Fryer and Asteriadou, 2009).

In addition to the complexities of the removal of food soils from different surfaces, different FBO frameworks (ranging from agricultural settings to transport, storage, processing, retail and food service settings as well as different sizes of operations) affect the implementation of cleaning regimes in terms of complexity, mode of operation and time. These factors can affect the accessibility and ease of use of the diverse range of available measures to both clean and subsequently monitor for the presence of allergens.

Although cleaning is an important control measure to reduce or prevent allergen cross-contact, general evidence of its capability (in terms of validation) is lacking. Cleaning validation conducted in accordance with best practice (for example Campden BRI, 2009) and defined as “the process of assuring that a defined cleaning procedure is able to

effectively and reproducibly remove the allergenic food from the specific food processing line or equipment" (Jackson et al., 2008) involves analysis, which is too resource intensive for many FBOs.

Jackson et al. (2008) noted the lack of published data from which to establish cleaning procedures for allergen removal that are backed by evidence, and in addition, found little consensus on the principles of validation, verification and review. The current work contributes to filling the gap by consolidating the allergen cleaning literature and guidance produced after this seminal publication. Findings from this project map the international resources and advice regarding allergen cleaning. Identifying recent (post-2012) literature that investigates specific cleaning methodologies as well as pertinent international guidance documents was a fundamental step to deliver the recommendations outlined in this report.

4.3 Aims and objectives of this research

The aim of the work is to present to the FSA information from international literature and guidance relating to the removal of food allergens from common food contact surfaces in food processing and food service environments, gathered during a narrative literature review. The work will inform the FSA of gaps in the available information and guidance and will provide advice on further research and the development of guidance to meet the needs of different sectors within the food industry.

The process of generating this report involved searching a bibliographic database (Food Science and Technology Abstracts, FSTA) with defined search terms to identify relevant literature in the public domain. The search spanned ten years, from 2012 to 2022. The search strategy borrows from the methodology of a systematic review, however, does not follow the constraints of the method in order to provide a wider variety of information sources. In addition, searches of 'grey' literature published between 2012 and 2022, such as codes of practice, guidance documents, industry and professional body publications, corporate white papers, websites, blogs and other information sources were performed to expand the view of the literature review beyond academic journals.

The FSA requirement for this project was for a desk-based literature and guidance review of the cleaning methodologies available for the 14 food allergens for which labelling is mandatory in the UK, including the key stages and principles of allergen cleaning and

effective approaches, and to assess the extent to which they are underpinned by an appropriate evidence base. The request was to include:

- The 14 allergens subject to mandatory labelling in the UK in the typical forms they are found within food and how they can be cleaned from common food contact surfaces.
- The different cleaning methods and approaches found within peer-review articles, ‘grey’ literature, and national and international guidance documents, with key steps in the methods outlined.
- The organisation and author that produced the guidance or article and the source country.
- The cost/benefits of each approach, taking into account key factors such as cost, effectiveness, complexity etc. where this information is available.
- Specific limitations of each method.
- Principles for validation and verification of the cleaning method.
- The strength and statistical significance of the evidence base, including key evidence gaps.
- All sources of information should be referenced where applicable, to ensure validity and reliability.

Following the searches of the FSTA database and other internet-based sources for ‘grey’ literature, relevant publications were assessed by the project researchers and project manager for pertinent information to inform the final report and database. Key information was extracted and inputted into summary tables following full-text screening, a process further detailed in Section 5 of this report.

By consolidating research outputs from the literature and key principles and recommendations from guidance documents, the findings have significant implications and, as far as we are aware, give the first comprehensive international review on allergen cleaning, validation and verification.

This work provides the FSA and food industry with a greater understanding of the allergen cleaning literature and guidance available internationally. In addition, it, reviews evidence and highlights gaps, identifying how significant they are, and informs the FSA on how best to develop guidance on cleaning to remove food allergens as a critical part of the FSMS to control the food production environment and process and ensure that the food produced is safe.

5. Materials and Methods

5.1 Search strategy

The aim of the project was to conduct a desk-based literature and guidance review of cleaning methodologies available for the 14 food allergens for which labelling is mandatory in the UK, and also on the principles for validation and verification of the cleaning methods. The project began with searches for relevant peer-reviewed literature in the public domain, as well as 'grey' literature (incorporating codes of practice, guidance documents, industry and professional body publications, corporate white papers, websites, blogs, reports) and book chapters. Criteria were defined by the project team for acceptance or exclusion of publications (see Section 5.3 for details). References relevant to the project were entered into a database in Microsoft Excel (Version 2301). The following sections describe the search strategies employed and generation of the database.

5.1.1 Food Science and Technology Abstracts (FSTA) search

A narrative literature review was undertaken, using a pre-determined search strategy including terms agreed with the FSA to identify relevant journal articles, guidance, codes of practice, industry and professional body publications, and reports. This strategy borrows from the methodology of a systematic review, however, it does not follow the constraints of the method in order to provide a wider variety of information sources. FSTA was searched from 2012 – 2022 using the search strategies in Table 1.

An initial scan of titles from the FSTA search strategy (see Table 1) and, if required, abstracts of the results in search number 7, was undertaken to check for relevance to the project; 84 were selected by the librarian. After an an initial screening process of the selected publications by the project researcher, 20 abstracts were identified that required further checking, 13 of which were ultimately removed after a second round of review by the project manager. The project manager checked the abstracts of all 64 publications for relevance to the project.

To summarise the results of the FSTA screening process (see Table 2), of the 84 selected at initial scan phase, 64 were included in the database, of which 34 were

categorised as journal articles, 25 industry and professional body publications, three book chapters and two guidance documents.

Table 1: Food Science and Technology Abstracts (FSTA) search terms

Search number	Search terms	Number of results
1	DAIRY PRODUCTS OR MILK OR PASTEURIZED MILK OR SEMI SKIMMED MILK OR SKIM MILK OR STERILIZED MILK OR UHT MILK OR WHOLE MILK OR PROTEINS MILK OR CASEIN OR WHEY PROTEINS OR LACTOGLOBULINS OR LACTOSE OR EGGS OR EGG WHITES OR EGG YOLKS OR ALBUMINS OR CELERIAC OR CELERY OR LUPINS OR WHITE LUPINS OR NUTS OR BRAZIL NUTS OR CASHEW NUTS OR MACADAMIA NUTS OR PECAN NUTS OR PISTACHIO NUTS OR ALMONDS OR SWEET ALMONDS OR HAZELNUTS OR PEANUTS OR PEANUT PRODUCTS OR PEANUT PROTEINS OR ROASTED PEANUTS OR PEANUT PASTES OR PEANUT MEAL OR PEANUT BUTTER OR WALNUTS OR SOY PROTEINS OR SOYBEANS OR SOY PRODUCTS or FISH OR SHELLFISH OR CRUSTACEA OR MOLLUSCS OR MUSTARD SEEDS OR SESAME SEEDS OR SULFITES OR SULFUR DIOXIDE OR SO2 OR GLUTEN OR WHEAT GLUTEN OR RYE OR BARLEY OR OATS OR SPELT OR SPELT WHEAT (Descriptors) or khorasan (Topic) or nuts (Topic) or queensland nuts (Topic) or soy* (Topic) or soya (Topic) or sulphites (Topic) or sulphur dioxide (Topic)	151,894
2	ALLERGENS (Descriptors) or allergen* (Topic)	7083
3	CONTACT MATERIALS OR SURFACES OR CERAMICS OR ENAMELS OR WORKTABLES OR GLASS OR PLASTICS OR STAINLESS STEEL OR WOOD OR UTENSILS OR KNIVES OR EQUIPMENT OR DISHWASHERS OR COOKERS OR REFRIGERATORS OR PROCESSING LINES OR	96,784

Search number	Search terms	Number of results
	PROCESSING EQUIPMENT OR OVENS OR BAKING OVENS OR MICROWAVE OVENS OR PANS OR SIEVES OR FREEZERS OR CHILLERS OR BOILERS OR CATERING OR CATERING ESTABLISHMENTS OR CATERING INDUSTRY OR FOODS SERVICE OR HOTELS OR KITCHENS OR PUBS OR RESTAURANTS OR CAFETERIAS OR CANTEENS OR COFFEE BARS OR SANDWICH BARS OR RETAIL OR SHOPS OR SUPERMARKETS OR VENDING MACHINES OR WHOLESALE (Descriptors) or pottery (Topic) or china (Topic) or pyrex (Topic) or plastic* (Topic) or hospitality (Topic)	
4	CLEANING OR CLEANING AGENTS OR CLEANING IN PLACE OR WASHING OR HYGIENIC QUALITY OR DISINFECTION OR SANITATION (Descriptors) or remov* (Topic) or validat* (Topic) or clean* (Topic) or cleaning chemical* (Topic) or wash* (Topic) or dishwash* (Topic) or handwash* (Topic)	82,084
5	1 and 3 and 4	1028
6	2 and 3 and 4	77
7	5 or 6 (duplicates and patents removed)	1083

Table 2: Food Science and Technology screening process

Screening strategy	Number of results
FSTA search strategy and initial titles scan conducted by project librarian. Relevant articles were selected for abstract screening.	1083

Screening strategy	Number of results
Initial abstract screening process completed by project researcher to identify relevant articles to be incorporated into the database.	84
Abstracts excluded after initial review and second review by project manager in total, of which: Not relevant to the review Focussed on development of a specific detection method, not relevant to cleaning	**20** 13 7
Results from FTSA search reviewed, of which: Journal articles Industry and professional body publications Book chapters Guidance documents	**64** 34 25 3 2

References included within the list of bibliographic citations of the selected publications were checked to identify any pertinent references that may have escaped the search strategy. Seminal papers outside of the scope of the search timeframe (2012-2022) were also captured from this process to ensure relevant work could be referenced to add context to any research findings.

5.1.1.1 Specific cleaning methodologies screening process for journal articles

When extracting data from articles, the cleaning methodology was categorised according to the following definitions, which are used throughout the project:

- **Wet:** Application of water, whether alone, or in addition to a cleaning chemical, detergent or soap, either by carrying out a rinsing procedure or with a cloth.
- **Controlled wet:** Application of a commercial ‘wet wipe’, or cloth, to clean a surface in a controlled manner, which may be ‘wetted’ with a specific cleaning chemical or antibacterial solution.

- **Dry:** Use of equipment for example brush, vacuum, dry wipe to physically remove the food soil, without the need for any water, cleaning chemical, detergent or soap.
- **Push-through:** The use of an inert material, physical object ('pigs') or foodstuff that does not contain food allergens that are not intentionally added to the subsequent product, sometimes referred to in guidance as flushing.
- **Cleaning-in-place (CIP):** A method used to clean equipment, often involving pipe work and vessels, without first dismantling it. Cleaning chemicals and rinses may be pumped through equipment to remove food residues and contamination.

5.1.2 'Grey' literature search

The organisation websites targeted to search for 'grey' literature (such guidance documents and codes practice, website pages and reports), identified in consultation with the FSA and based on the knowledge of the project team, were searched and are listed in Appendix 11.1. The Authority and Agency and Governmental websites (also listed in Appendix 11.1) were identified from those countries/regions where specific food allergens are listed in legislation as recorded in Food Allergens - International Regulatory Chart (Food Allergy Research and Resource Program, FARRP). All websites were searched between 29 December 2022 and 3 February 2023 and different techniques were used appropriate to the website structure:

- Section headings/site navigation to access appropriate website sections.
- Search facility using terms allergen(s)/* or clean*/ing.

To ensure all relevant website pages and blogs were captured, the project researcher and project manager completed internet (Google) and LinkedIn searches with the terms 'allergen clean', 'allergen cleaning' and 'allergen cleaning validation.'

The project was also discussed with Campden BRI Regulatory Affairs advisors with international expertise to highlight any further international guidance documents not captured by the initial search.

5.2 Producing the bibliographic database

Results of the searches were collated into categories in a Microsoft Excel (Version 2301) spreadsheet with the following headings: Journal article; Thesis; Conference poster;

Guidance/Code of practice; Industry/Professional body publication; Website page; Other information; Book chapter; Webinar.

Table 3: Literature categorisation descriptions and number of references

Literature categorisation	Description	Number of references found in initial searches	Number of relevant references added to database
Journal articles	Peer-reviewed publications in scientific journals, including conference abstracts	34	19
Guidance and codes of practice	Guidance produced by a relevant organisation/regulatory authority, published as a whole document intending to provide guidance on a specific topic	38	28
Industry and professional body publications	Articles included as part of an industry/professional body's regular specialist publication focussed on a specific industry (in this case the food, drink and associated industries) or specialised topics, providing industry perspectives, guidance, best practice and recommendations	30	15
Website pages	Company/regulatory authority website pages and blog articles	44	24
Other information	Literature that fell outside of the previously described categories and took the form of presentation slides or company-published	19	7

Literature categorisation	Description	Number of references found in initial searches	Number of relevant references added to database
	information (for example white papers and reports)		
Book chapters	Relevant chapters within published books	15	2
Theses	Published theses with a single author in association with the author's organisation	6	3
Webinars	Video recordings (without a script or presentation slides) that show presentations delivering general information on a specific topic	7	6
Conference poster	Poster used to present research findings at a conference	1	1

After scanning and confirming the relevant articles from the search results, and excluding those which were not relevant to the project, the final list was consolidated and inputted into a Microsoft Excel (Version 2301) spreadsheet before conversion to the CSV format required. The database includes the following headings: PublicationType; YearOfPublication; PublicationTitle; FirstAuthor; AuthorsOrganisation; FirstEditor; Country; NumberOfPages; WoSCitations; GoogleScholarCitations; ArticleTitle; DOI (digital object identifier). The 'number of pages' and 'number of citations' were included as a metric to summarise the depth of the topic discussed and the pertinence of any journal article in the context of the available literature on allergen cleaning. The 'country' was provided as the country of the organisation of the first author for journal articles and the conference poster; the geographical location(s) where the guidance is applicable for guidance/codes of practice; the country where the publication is published for industry/professional body publications and book chapters, and the country of the organisation responsible for publication for website pages, other information and theses.

Within the database ‘N/A’ is used to denote ‘not applicable’, and ‘unk’ refers to where data are ‘unknown’.

5.3 Data extraction

5.3.1 Data extraction method for each literature category

Table 4 describes the data extraction method for each literature category.

Table 4: Data extraction methods

Category	Data extraction method
Journal articles	Project researcher and project manager read abstracts to identify those relevant to include before the project researcher carried out full-text screening to extract relevant information and additional references. The project manager also read all of the available full-text publications and checked the data extraction tables.
Guidance and codes of practice	Project researcher used the “CTRL+F” function on a web browser to identify and extract key information. The following terms were used ‘validation’, ‘verification’, ‘ELISA’, ‘PCR’, ‘wet’ ‘dry’ ‘push-through’ ‘changeover’, ‘auto’, ‘CIP’ to navigate the sources. International, non-english, language guidance documents were checked by Campden BRI experts with relevant language skills to confirm relevance to the project. Pre-determined statements on the principles of allergen cleaning validation and verification were decided after initial screening, before extracting whether each guidance document referred to them (for details of the principles see section 6.2 of this report).

Category	Data extraction method
Industry and professional body publications	Project researcher read full text articles and extracted relevant information.
Website pages and other information	Project researcher read full text articles and extracted relevant information.
Book chapters	Project researcher read the book chapters and extracted relevant information.
Webinars	Project researcher selected two webinars, watched the full recordings and extracted relevant information.

Criteria for exclusion/inclusion of journal articles and guidance documents in the final summary tables are provided in Table 5.

Table 5: Inclusion and exclusion criteria for journal articles and guidance documents

Document Type	Inclusion criteria	Exclusion criteria
Journal articles, theses, conference poster	Applied a specific cleaning methodology and tested the efficacy using a relevant, analytical method (for example ELISA, LFD).	Abstract-only articles that made reference to validation but had no specific study details, and were presented at a conference not attended by any member of the project team; Articles validating a specific detection method without applying a cleaning methodology; Articles applying a specific cleaning methodology but neither cleaning nor analysis conducted for allergens;

Document Type	Inclusion criteria	Exclusion criteria
		Articles discussing cleaning methodology in the context of reducing microbiological hazards; General articles that discuss the topic of allergen management, however as no further details on a specific cleaning methodology provided these could not be reported on in the results section.
Guidance documents	Referenced any of the key words and contained extractable information relevant to the topic of 'allergen cleaning' and 'cleaning validation and verification'.	No mention of cleaning to remove food allergens; No mention of cleaning validation.
Industry and professional body publications, website pages and other information, book chapters, webinars	Referenced any of the key words and contained extractable information relevant to the topic of 'allergen cleaning' and 'cleaning validation and verification'.	Articles discussing general allergen-related topics for example allergen-free formulation, PAL without a specific reference to cleaning, testing and sampling (not directly relating to cleaning); Articles discussing hygiene, equipment or machinery but not in the context of allergen cleaning.

5.3.2 Specific cleaning methodologies screening process

From each source, publications were selected for inclusion based on the criteria presented in Table 5 and references made to specific cleaning methodologies were extracted (using the pre-determined categories as described in Section 5.1.1.1), with the full results for each source presented in Appendix 11.10. For guidance documents and codes of practice, the principles of allergen cleaning were determined based on the information extracted. These sources only were selected to investigate the principles as the objective of guidance is to provide recommendations on the various aspects of cleaning, whilst other sources such as articles from industry and professional body publications tend to focus on a specific topic and do not aim to provide comprehensive advice on all areas relevant to cleaning.

5.3.3 Investigating principles of allergen cleaning validation and verification - extraction process for guidance and codes of practice

To investigate and summarise the common principles of allergen cleaning validation and verification, an initial screen of all guidance documents and codes of practice collected from the search was completed to identify key themes and the general principles that are referred to. Guidance documents and codes of practice were selected rather than other sources to investigate principles because, as described above, these literature sources aim to provide comprehensive advice on the various aspects of cleaning. The project researcher and project manager then identified 18 key principles (14 for allergen cleaning validation, four for verification), not specifically called out as principles within the documents but those appearing frequently throughout multiple sources, before carrying out a second review to extract where each document made reference to the principle. Guidance documents and codes of practice that did not refer to Principle 1 (i.e. allergen cleaning validation is required) were excluded from the extraction process. The full results for each source are presented in Appendix 11.11 and 11.12).

5.4 Report structure

The following results section (Section 6: Results) and sub-sections present the information found and extracted by literature type (Journal articles, Guidance and codes of practice, Industry and professional body publications, Websites and other information, Book chapters and Webinars). Each sub-section describes the findings and pulls out

specific considerations that were commonly mentioned by the literature type. The subsequent section (Section 7: Report Summary and Discussion) summarises the information found and discusses it in the context of other literature relevant to the topic of food allergen cleaning. It is recommended to read the results section first (before Section 7) to gain an understanding of the differences between each literature type as the results are not repeated for all sources.

The Appendices include tables, which summarise the information that each source contains. For all sources, tables are provided summarising the extracted information. In addition, for journal articles, an overview for each study is given.

6. Results

6.1 Studies on the efficacy of routine cleaning methodologies for allergen removal published in scientific journal articles and theses

6.1.1 Literature review results overview

Summaries of all selected journal articles and theses (and a conference poster) are provided in Appendix 11.2, which includes details of each study design, the allergens investigated, surface types, cleaning methodology and detection methods included in the studies, as well as a summary of the findings in terms of cleaning efficacy. common

The following paragraphs are based on summary information displayed in Appendices 11.3 - 11.9.

6.1.1.1 Publication types

It is apparent that a limited amount of published peer-reviewed literature exists on carrying out specific allergen cleaning methodologies to investigate the impact on the removal of allergenic proteins. A total of only 23 publications (n=18 journal articles, n=4 theses and n=1 conference poster) were selected in this section of the review as containing sufficient, relevant information to report on (see Appendix 11.3). Of these publications, four of the journal articles and one of the theses were available as abstracts only; as they were either conference proceeding abstracts, a thesis for which a full text version is not available or one article that was in Japanese. It should be noted that six of the references were published prior to the defined search timeframe (2012-2022); they were identified as references of interest as they were cited in the selected publications.

6.1.1.2 Global spread of publications

The global spread of the studies, based on the country of the organisation that the first author is from, was as follows; 12 studies in the United States, two in Japan, two in each of Spain and Canada, and one in each of Germany, New Zealand, Austria, UK and Croatia (see Appendix 11.3). This broadly reflects the countries and regions that are the

source of the greatest global share of scientific publications, as G20 countries produce around 90% of science publications (Schneegans, Lewis and Straza, 2021); G20 or the 'Group of 20' is designated the premier forum for international economic cooperation. Of the studies included in this report only New Zealand is not a G20 country.

6.1.1.3 Number of citations

The number of citations for each reference is included as a metric to summarise the pertinence of any publication in the context of the available literature on allergen cleaning (see Appendix 11.3). The most cited articles are the oldest, i.e. the ones that were published longest ago (i.e. Perry et al., 2004; Jackson et al., 2008 and Röder et al., 2008), which, to a certain extent is unsurprising. This can also be explained as there are not many publications in this field of study, so the few that are there will be commonly cited. In addition, the most cited references contain either information about cleaning to remove allergens in specific scenarios of wide interest (for example Wang, Young and Karl, 2010, who studied cleaning of three processing lines on which battered chicken products (containing wheat in the batter) had been produced, or Ortiz et al. (2018), who surveyed the occurrence of allergens on food contact surfaces from school canteens), or one that is a review of cleaning and other control and validation strategies to prevent allergen cross-contact in food-processing operations (Jackson et al., 2008).

6.1.1.4 Scenarios studied

For categorisation of the studies performed in terms of the different scenarios (food processing or food service) see Appendix 11.4. Of the selected studies, 11 were based on food processing scenarios; one was conducted in a processing facility producing battered chicken products (Wang, Young and Karl, 2010), two on pilot-scale processing lines (Röder et al., 2008 and Zhang, 2014), two on particular pieces of machinery for producing chocolate (Zhang et al., 2018 and Zhang et al., 2019); the remaining six studies were conducted on coupons or parts of a particular surface (Jackson et al., 2008; Spektor, 2009; Jackson and Al-Taher, 2010; Courtney, 2016; Chen et al., 2022). Although some of the surfaces included in such studies could equally be present in food service environments, these studies were categorised as food processing scenarios due to the cleaning methodology employed.

The remaining 12 studies involved food service scenarios; ten of these were performed in, or on samples from, actual food service settings (for example school canteens,

restaurants, hospital surfaces including toys and books), the other two were on either a laminated table surface kept in a hospital office (Watson, Woodrow and Stadnyk, 2013) or coupons (pieces) of surfaces used in both retail and food service (Bedford et al., 2020).

6.1.1.5 Allergens studied

Although a variety of allergens were studied across the literature, this was limited to just six of the 14 food allergens laid down in Annex II to the FIC (milk n=12 studies; peanut n=9 studies; egg n=9 studies; gluten (as a marker for gluten containing cereals) n=7 studies; soy n=3 studies; hazelnut n=1 study), see Appendix 11.5. One study (Kiyota et al., 2017) investigated cleaning to remove orange extract, for which recommended allergen labelling provisions exist in Japan (Ebisawa et al., 2020). This study has been included in this report as orange extract is an example of an adhesive soil, high in sugars. Other factors for inclusion of this reference are that the surfaces studied included materials that are commonly used in food service or domestic settings (polypropylene chopping board, wood chopping board, stainless steel tray and glass dishes) and the detection method used was enzyme-linked immunosorbent assay (ELISA); so, the information adds to the overall research into allergen cleaning.

6.1.1.6 Matrices studied

The selected studies involved several different food matrices or soils, see Appendix 11.6 for details. The most frequently studied matrix was peanut butter (n=6 studies), followed by liquid milk (n=5 studies), milk powder (n=4 studies), peanut flour (n=3 studies), dried egg (n=3 studies), liquid egg (n=2 studies) and soy ‘milk’ and soy flour (n=1 study each). A wide variety of other foods were also included in the studies ranging from chocolate, cookie dough and muffins batter to toast, mayonnaise and battered chicken.

6.1.1.7 Cleaning methodologies studied

A range of cleaning methodologies were included in the selected studies, including wet (n=14), dry (n=6), push-through (n=4), controlled-wet (n=6) and a simulated CIP methodology, see Appendix 11.7 for details. Within each cleaning methodology category, the cleaning protocols were notably varied. For instance, the dry cleaning methods used across different studies included brushing, scraping, vacuuming and dry wiping. Within the controlled-wet category, which includes the use of wipes and cloths, and the wet category, different chemicals were used; in some studies, full details of the chemicals

used were not provided (reference was made merely to detergent, dish detergent or conventional detergent, for example).

6.1.1.8 Surface types studied

Not surprisingly, since it is the most commonly used food contact material in food processing and food service settings, stainless steel was the most frequently studied surface (n=12), followed by plastic (n=9), Teflon (n=3), wood (n=2) and glass (n=1), see Appendix 11.8 for details. A further category of surface type that was studied is utensils (n=8), including pots, pans, plates, spoons, tongs and pastry brushes, for which specific details of the material were not provided.

6.1.1.9 Detection methods used in the studies

The most common detection method used in the selected studies was ELISA (n=12), followed by lateral flow devices (LFDs, n=8) and protein swabs (n=4) see Appendix 11.9 for details. Two studies each utilised adenosine triphosphate (ATP) swabs and visual inspection, although they did so in conjunction with ELISA tests, LFDs and or general protein swabs. It was common to see a combination of detection methods used within each study (n=6 studies); five studies used only LFDs and one study was limited to general protein testing (a colourimetric technique that detects protein residues from any source, so protein from allergic sources as well as non-allergenic sources) only so did not analyse a specific allergenic protein (Aleksić et al., 2020). None of the selected studies used polymerase chain reaction (PCR) for allergen detection.

6.1.2 Efficacy of different cleaning methodologies

Many factors affect the efficacy of cleaning besides merely the cleaning methodology (i.e. dry, wet, controlled wet, push-through), these include: the type of soil to be removed (for example food matrix, such as fats, carbohydrates, proteins; whether the soil has been heated and how long it has been on the surface for), the surfaces to be cleaned; and the cleaning agents and mechanism employed (i.e. time, mechanical energy, thermal energy, chemical energy) (based on Sinner, 1960). One of the requirements of this project is to review the cleaning methodologies available for the 14 food allergens for which labelling is mandatory in the UK, however, as each of the studies selected used a different study design, with different combinations of the above factors, as well as different allergens, it is difficult to extrapolate the effect of one particular aspect of each study to draw

commonalities on the efficacy of specific cleaning methods beyond the context of the individual published study.

An additional complicating factor to consider is the use of different analytical techniques (including ELISA, LFDs, ATP and protein swabs, as well as visual inspection) in the studies to detect residues of allergenic foods following cleaning. These tests all have inherent advantages and disadvantages, the discussion of which is outside the scope of this report but are detailed for example by Walker et al. 2016. In addition, it is challenging to interpret or compare the cleaning efficacy of each approach without knowing the limit of detection (LOD) and/or the limit of quantification (LOQ) of the allergen analytical test method applied. The use of different types of test detecting different analytes, as well as the same type of test from different manufacturers with differing limits, sensitivity, specificity and validation status as evidence of cleaning efficacy therefore affects the ability to draw practical conclusions from the disparate studies.

The following sections therefore summarise the selected study findings based on different cleaning types and highlight where particular issues with any of the above factors or particular allergens affected the cleaning efficacy or analytical results interpretation.

6.1.2.1 Dry cleaning methodologies

Of the six studies involving dry cleaning methodologies, five were conducted for food processing scenarios. Röder et al. (2008) used manual scraping as one of the cleaning methodologies for removing cookie dough containing hazelnuts from simulated pilot plant equipment. Scraping resulted in the highest level of contamination of the next product processed on the ‘cleaned’ equipment seen in the study when compared with other cleaning methodologies.

Jackson and Al-Taher (2010) used high efficiency vacuum to attempt to remove cooked slurries of peanut flour, skim milk powder, whole egg powder, soy flour, soy milk and soy infant formula from various surfaces; this was however unsuccessful as determined by visual inspection, ELISA, ATP or protein swabs. In the same study, the vacuum was able to remove visible unheated dry soils of peanut flour, milk powder, whole egg powder, soy flour and soy infant formula powder from most surfaces, but not milk powder from urethane. Despite surfaces being visibly clean, however, total protein swabs were positive for all soils on all surfaces, whilst positive ELISA results were only seen for

peanut flour, milk powder and whole egg powder on urethane, milk powder and whole egg powder on Teflon and whole egg powder and soy flour on stainless steel.

Results of high sensitivity ATP swabs (Allergiene, Charm Sciences), which are marketed as an allergen-control test that achieve detection comparable to specific allergen methods, however, in some cases differed from the ELISA results. Stainless steel was positive for milk powder and soy infant formula by sensitive ATP test but not by the ELISA, similarly, soy flour was detected on urethane and Teflon by the sensitive ATP test, but not ELISA. Whole egg powder was detected on stainless steel and Teflon by ELISA, but not by the sensitive ATP test. There were more positive results found with the high sensitivity ATP swabs than conventional ATP swabs (Pocketswab, Charm Sciences), likely due to the differing sensitivities of these tests. Three of the conventional ATP results matched the ELISA results, in that milk powder was detected on urethane and Teflon, and soy flour was detected on stainless steel by both methods. However, soy flour and soy infant formula were detected on urethane by the conventional ATP test, but not by ELISA. Of note, at the time of writing this report the marketing information for the high sensitivity ATP test states that it is to be used for wet-cleaned surfaces or rinse waters. The authors comment that ATP swabs may not be applicable to assess the effectiveness of high efficiency vacuum due to high background levels of ATP on dry cleaned food contact surfaces. The conclusion of the study was that the use of high efficacy vacuum may not be effective for removing allergenic food residues from food contact surfaces.

Zhang (2014) investigated scraping with rubber scrapers, equipment for processing cereals bars and muffins, containing non-fat dried milk, which did not effectively remove the soil according to LFD results. In a study by Wells and Jeong (2017) stainless steel coupons were electrostatically coated with soy protein isolate powder; results using LFDs showed a 50% success rate for removal of this soil by vacuuming. Chen et al. (2022) soiled stainless steel coupons with non-fat dried milk and wheat flour, then used a custom experimental rig to brush or scrape the surface. Scraping was found to be significantly less effective than brushing in the removal of powder under all conditions, ultimately however, allergenic residues were consistently detected by specific allergen LFDs following scraping or brushing under most conditions, even as the surfaces appeared visibly clean and passed ATP testing.

A study conducted to assess allergen removal and transfer with wiping and cleaning methods used in retail and food service establishments (Bedford et al., 2020) showed that dry paper wipes and dry terry cloth were not effective at removing peanut powder, peanut butter, non-fat dry milk powder, cream cheese, liquid whole milk, whole egg powder or mayonnaise from stainless steel, plastic or wood surfaces. Detection of allergenic residues was by LFDs, which returned positive results even though some surfaces appeared visually clean. This study also showed that dry wipes contaminated with allergens transferred them to other surfaces.

Results of these studies therefore show that the use of dry cleaning methodologies, although capable in the majority of studies of visually removing dry powder, were not actually able to remove the soil when surfaces were analysed. Cookie and cereal bar dough and muffin batter were not removed by scraping and vacuuming did not remove cooked slurries of allergenic foodstuffs.

6.1.2.2 Controlled wet cleaning methodologies

Six of the selected studies investigated the use of controlled wet cleaning methodologies: two studies were conducted on coupons or pieces of surfaces in a laboratory setting; two were in hospital settings; one was in a school cafeteria and one was in a hospitality kitchen.

Jackson and Al-Taher (2010) used sanitising wipes containing 5.48% alcohol and 175 ppm quaternary ammonium chloride (quat) to effectively remove cooked slurries of peanut flour, skim milk powder, whole egg powder, soy flour, soy milk and soy infant formula from various surfaces, as determined by visual inspection, ELISA, and protein swabs. Conventional ATP swabs, however, detected ATP on surfaces that had been contaminated with soy flour, soy ‘milk’ and soy infant formula, whilst high sensitivity ATP swabs returned positive results for all soils on all surfaces. The researchers commented that ATP swabs may not be applicable due to high background levels of ATP on dry cleaned food contact surfaces.

Bedford et al. (2020) used sanitising alcohol quat wipes (5.48% alcohol and 175 ppm quat) to remove peanut powder, peanut butter, non-fat dry milk powder, cream cheese, liquid whole milk, whole egg powder or mayonnaise from stainless steel, plastic or wood surfaces. Allergen-specific LFD tests were used throughout the study to assess the

efficacy of allergen removal. It was found that using just one wipe left residue of all the allergenic foodstuffs on all the surfaces. Dry milk powder and egg from mayonnaise were removed from all surfaces by the use of two wipes. For the other combinations of soils and surfaces the following returned positive results after two wipes: peanut powder, peanut butter, cream cheese, whole milk and whole egg powder on plastic; peanut butter and whole egg powder on wood; whole egg powder on stainless steel. Peanut butter took four wipes to be removed from plastic, whilst whole egg powder were still detected on plastic after using three wipes (results for four wipes were not provided).

In the same study, wet terry cloth (dish cloth soaked in 50 ppm total chlorine sanitiser solution prepared with bleach) removed peanut powder, low amounts (0.5 g) of cream cheese and mayonnaise from all surfaces as determined by LFD tests. This cleaning method was however not successful in removing peanut butter, non-fat dry milk powder, higher levels (2 g and 4 g) of cream cheese, fluid milk or whole egg powder. Perhaps surprisingly, wet terry cloth (soaked in tap water) was effective at removing peanut powder, 0.5 g of cream cheese and up to 2 g mayonnaise from all surfaces; it did not work for the other food soil and surface combinations in this study.

In addition, the study by Bedford et al. (2020) also investigated transfer of the allergenic foodstuffs used in the rest of the study described above from sanitiser-soaked (2.5 mL bleach added to 3.78L warm tap water (~40 to 45ºC), residual chlorine content 50 ppm) allergen-contaminated terry cloth to clean surfaces (stainless steel, plastic and wood). The cloths were soaked in sanitiser solution for five minutes and were gently squeezed to remove excess sanitiser solution, they were then contaminated with individual allergenic foods (0.05 g of whole egg powder, peanut powder, non-fat dried milk powder, 0.1 g peanut butter, 2.0 g mayonnaise, cream cheese or 1 mL fluid whole milk). The allergen-contaminated cloth was wiped on one surface type for five seconds and then was submerged in sanitiser solution for 15 seconds before being wiped on a second surface of the same composition as the first. This procedure was repeated to wipe two further surfaces of the same type. All surfaces were analysed for the presence of allergen residues using allergen-specific LFD tests. There was no transfer of dry allergenic foods (whole egg powder, peanut powder or non-fat dried milk powder) to some of the second surfaces to be wiped, and no transfer to the third surfaces. Of the wet, paste or sticky allergic foods (mayonnaise, peanut butter, whole milk and cream cheese) only peanut butter was still detected on the third surfaces to be wiped. On the fourth surface to be

wiped, only one faint positive was seen, for peanut butter on stainless steel. The authors concluded that cloth storage in sanitiser solution was shown to minimise allergen transfer between surfaces.

Two studies investigated the use of controlled wet cleaning methodologies in hospital settings using wipes intended for disinfection. In a study by Watson, Woodrow and Stadnyk (2013) peanut butter was applied to a table surface and kept in a hospital office for 110 days. Immediately after cleaning the table using Clorox® disinfecting wipes peanut was not detected using an ELISA test. Watson, Woodrow and Stadnyk (2015) used Clorox® disinfecting wipes and Ultrawipes™ hospital wipes to successfully remove peanut butter from common hospital surfaces (including a laminated plastic table surface, a plastic doll, textured ball and smooth and textured book covers) as demonstrated using an ELISA test.

Perry et al. (2004) used wiping with common household cleaning agents (Formula 409 cleaner, Clorox Company, Oakland, Calif; Lysol sanitising wipes, Reckitt Benckiser, Wayne, NJ; and Target brand cleaner with bleach, Target Corporation, Minneapolis, Minn) and plain water to successfully remove peanut butter from school cafeteria tabletops. Peanut was however detected (using an ELISA test) following wiping with dishwashing liquid. In the same study peanut butter was applied to the hands of volunteers, which was removed according to the results of an ELISA test by the use of commercial hand wipes (“Tidy Tykes” wipes (Pampers, Procter and Gamble); “Wet Ones” antibacterial wipes (Playtex Products, Dover, Del)).

A study conducted in a hospitality kitchen showed that contamination was detected on all surfaces (using protein swabs) that had been wiped with cold then warm water, using the same cloth between wipes (Aleksić et al., 2020). Successive cleaning methodologies in this study were increasingly rigorous; it was not until those procedures involving wiping with warm water, then warm water with detergent (changing the cloth after the first wipe and changing the uniform of the operator after food preparation before cleaning), then the same protocol but also with the operator washing their hands after food preparation before cleaning, were conducted that no contamination was determined on any surface. The employee apron did however show possible contamination in the former of these methodologies.

The selected studies in which controlled wet cleaning has been used suggest that this cleaning methodology is effective at removing allergenic foodstuffs from common food contact surfaces in certain scenarios. It is unclear, however, as to the extent of wiping, the assumption being that surfaces were cleaned until visually clean prior to analysis.

6.1.2.3 Push-through cleaning methodologies

Four of the selected studies used push-through with product not containing allergens or a silicone ‘pig’ (physical object) with the intention of removing allergen containing products from food processing equipment, with varying degrees of success.

Röder et al. (2008) showed that ‘pushing through’ cookie dough without hazelnut after a production run of cookie dough containing 10% hazelnut was ineffective to remove the soil containing hazelnut in a pilot plant, by detection using an ELISA test. Similarly, Zhang (2014) was unsuccessful at removing residues of cereal bars and muffins containing peanut flour, non-fat dry milk and egg powder from pilot scale processing lines using push-through with cereal bar dough or muffin batter not containing those allergenic ingredients; analysis was by ELISA.

In a study involving melted milk chocolate coated into a stainless steel pipe and butterfly valve, cocoa butter at 40ºC was recirculated through the equipment to remove the milk-containing soil (Zhang et al., 2018). Analysis of dark chocolate that then passed through the equipment showed that although milk levels decreased, a total milk ELISA was still detecting milk after approximately 13 kg of dark chocolate had been used to purge the system. In the same study use of a silicone pig to remove the milk chocolate dramatically reduced levels of milk in the initial samples of next product passed through the equipment (dark chocolate). After 13 to 15 kg of dark chocolate had been used to purge the system, ELISA results for the presence of milk in the dark chocolate were below the LOQ (Zhang et al., 2018).

Zhang et al. (2019) also used a flush with cocoa butter at 40ºC to reduce levels of milk carried over from milk chocolate to dark chocolate in a ball mill and horizontal shaft conch. In the same study dark chocolate pushed through a three-roller refiner that had been used for milk chocolate was initially contaminated with up to 2,140 ppm, however, after approximately 3 kg of dark chocolate had been processed measured milk levels were below the ELISA LOQ.

The studies involving push-through cleaning methodologies show that this technique is variously effective, however this seems to be highly dependent on the food matrix or soil to be removed, the push-through material and the equipment being cleaned. Dough and batter type products seem to be difficult to remove using push-through with equivalent non-allergen containing material. Whilst the use of dark chocolate, warm cocoa butter and a silicon pig to remove milk chocolate from processing equipment varied, each method required kilogram quantities of dark chocolate purge to remove the milk chocolate in the pilot-scale studies described. Required volumes of push-through material to achieve allergen removal will depend on the scale of the equipment being cleaned, and possibly also what the material is, these are important considerations around the use of this technique.

6.1.2.4 Wet cleaning methodologies (cleaning chemicals and agents)

Wet cleaning is the most common cleaning methodology used by the food industry (Bagshaw, 2009), this is borne out by the highest number of the selected studies including this technique (n=14).

Some of the selected studies used sequentially more harsh wet cleaning methods, to the extent that some started with water only. Table 6 shows a summary of the findings of several studies that used water only with the intention of removing allergenic soils.

Table 6: Summaries of the results of studies that used water only to remove allergenic food soils

Publication reference	Relevant findings of the study
Jackson et al. (2008)	Water was not effective at removing hot milk soil from stainless steel plates. In contrast, water alone at 62.8ºC and 73.8ºC was effective at removing cold milk soils. Water alone at 62.8ºC was effective at removing peanut butter soils from most of the food contact surfaces studied, but not at ambient temperature.
Röder et al. (2008)	Water at 52ºC along with manual scraping decreased hazelnut cross-contact between cookies containing hazelnut and those that should not, to levels at or below 1 mg/kg hazelnut protein.

Publication reference	Relevant findings of the study
Spektor (2009)	The average reduction of peanut butter, liquid egg and milk by water at 63ºC was 96.5% on abraded and unabraded stainless steel coupons.
Wang, Young and Karl (2010)	Water (40-50ºC) was used to rinse lines on which battered chicken (with wheat flour or wheat starch in the batter) had been produced; gliadin was detected in all swabs of the surface.
Schreder et al. (2013)	In a food service setting, cleaning of work surfaces, utensils or hands and gloves with water only was not sufficient to prevent milk and gluten cross-contact.
Zhang (2014)	Rinsing of pilot-scale processing lines used to produce cereal bars and muffins containing peanut, egg and milk with hot water (54-60ºC) was effective for the cereal bar line but not the muffin line.
Hashimoto, Yoshimitsu and Kiyota (2014)	Food service tableware washed with water only tested positive or weakly positive using LFDs for egg. The quantitative ELISA results showed that allergen levels were around 50 ng/mL after washing with only water.
Kiyota et al. (2017)	Running water at 28ºC was effective at >95% removal of orange extract from stainless steel and glass; however, it was not effective for polypropylene and wood.
Remington et al. (2020)	Brief scrubbing of a wok and saucepan with warm water resulted in no measurable peanut-containing sauce (no peanut specific tests were conducted, measurement of residues was by weighing the equipment before and after cleaning). For utensils rinsed in warm water the level of peanut-containing sauce residue decreased, but was not completely removed.

In many of the studies detailed in Table 6 water alone is not effective in removing allergenic soils from food contact surfaces or hands and gloves, although it does seem to

be capable of reducing the soils. Temperature plays a factor in the efficacy of the use of water alone. Warm or hot water seems to be better at removing some food soils than cold or ambient water, although this too is dependent on the food soil and the surface being cleaned; for example, hot water removed cold milk soils and peanut butter and was effective in cleaning a pilot scale processing line.

In the selected studies a range of cleaning chemicals have been used as part of wet cleaning methodologies. Table 7 shows a summary of the findings of several studies that used chemicals to aid removal of allergenic soils.

Table 7: Summaries of the results of studies that used chemicals in wet cleaning methodologies to remove allergenic food soils

Publication reference	Relevant findings of the study
Jackson et al. (2008)	**Chlorinated alkali** cleaner was able to remove all hot milk residues even when the detergent solution was at ambient temperature. Both **chlorinated alkali** cleaner and **acid detergent** cleaner at 62.8ºC were able to effectively remove all peanut butter residues from the food contact surfaces, but this was not achieved at ambient temperature.
Röder et al. (2008)	Manual scraping plus cleaning with 52ºC **dish detergent** and a final rinse with hot water reduced hazelnut protein on equipment used to produce cookies containing hazelnut to a level at which allergic reactions are unlikely to occur. Comment was made that the detergent didn't additionally decrease hazelnut over water alone.
Spektor (2009)	Use of Juice products Association Type 4 wash plus degreaser and **chlorinated alkaline** plus degreaser resulted in the highest percentage reductions of peanut butter, liquid egg and milk on stainless steel surfaces. The least effective was **acid detergent** plus degreaser, which on average performed worse than water alone.
Wang, Young and Karl (2010)	Foam comprising sodium hydroxide and sodium hypochlorite (**chlorinated alkaline**) and surfactant

Publication reference	Relevant findings of the study
	scrub with a water rinse removed gliadin in the majority of swabs from lines on which battered chicken (with wheat flour or wheat starch in the batter) had been produced. A broad spectrum **sanitiser** followed by a water rinse returned gliadin ELISA results for all swabs of <LOD.
Schreder et al. (2013)	In a food service setting, cleaning of work surfaces, utensils or hands and gloves with water and **detergent** was mostly sufficient to prevent cross-contact, however as LFDs were used there was reference to possible 'hook effect' (where a very high amount of an analyte is present in the sample but the observed value is falsely lowered (Dasgupta and Wahed, 2014)).
Hashimoto, Yoshimitsu and Kiyota (2014)	Food service tableware, that had been in contact with egg, washed with water and **detergent** returned weak positive results in LFD tests. Following an additional water rinse the ELISA results were below the LOQ.
Zhang (2014)	A full cleaning cycle with **alkaline** detergent followed by a **sanitiser** of pilot-scale processing lines used to produce cereal bars and muffins containing peanut, egg and milk was effective at removing allergenic residues.
Kiyota et al. (2017)	Different cookware materials were scrubbed ten times with a urethane sponge scourer containing a household **detergent**, followed by rinsing with running water. This resulted in removal of orange extract from polypropylene, stainless steel and glass, however, orange extract was detected below the LOQ in two of five experiments involving a wood chopping board.
Ortiz et al. (2018)	Wet cleaning using **conventional detergents and cleaning chemicals** was used to clean food contact surfaces in schools; 30% of food contact surfaces in 50 school kitchens were found to be contaminated with allergen residues following cleaning.

Publication reference	Relevant findings of the study
Zhang et al. (2019)	A wet clean involving **detergent**-rinse-air dry of a ball mill and conch used to process milk chocolate resulted in milk levels below the ELISA LOQ for all of the dark chocolate batched produced after the clean.
Galan-Malo et al. (2019)	Usual cleaning by hand or automatic dishwasher with **conventional detergents** was assessed in five out of ten school canteens; washing by hand reduced the allergen contamination rate significantly, particularly for gluten. Higher level of contamination was seen when using an automatic dishwasher, this could be explained by the partial recirculation of water. The other five schools employed an additional cleaning step by using a detergent with **proteases**, which resulted in a significantly reduced occurrence of allergenic residues.
Bedford et al. (2020)	A full cleaning method (wash with **detergent**-rinse-sanitise-air dry) was consistently effective in removal of a range of allergenic foodstuffs from stainless steel, plastic and wood coupons, apart from peanut butter, which was detected on textured plastic and some wood surfaces.

Of the studies included in Table 7 the most frequently used chemical is chlorinated alkaline cleaner (n=4 studies). This chemical was shown to be able to remove all hot milk residues even when at ambient temperature. Peanut butter, however, was not removed at ambient temperature, but it was at 62.8ºC (Jackson et al., 2008). Chlorinated alkaline plus degreaser resulted in the highest percentage reductions of peanut butter, liquid egg and milk on stainless steel surfaces (Spektor, 2009) and the use of foam containing chlorinated alkaline followed by a surfactant scrub and a water rinse mostly removed gliadin from lines processing battered chicken products (Wang, Young and Karl, 2010). In addition, an alkaline detergent used as part of a full clean of processing lines used to produce cereal bars and muffins was effective at removing allergen residues (Zhang, 2014). Chlorinated alkaline and alkaline detergents seem to be effective at removing a

variety of allergenic foodstuffs from several different surface types, however temperature, food soil and the surface being cleaned are also likely to influence its efficacy.

The second most used chemical in the studies was acid detergent (n=2 studies). As with the chlorinated alkaline in the same study, acid detergent cleaner at 62.8ºC was able to remove all peanut butter residues from all food contact surfaces, but not at ambient temperature (Jackson et al., 2008). Acid detergent plus degreaser, however, was found to be the least effective at removing peanut butter, liquid egg and milk from stainless steel surfaces; performing on average worse than water alone (Spektor, 2009). Again, it seems that temperature may affect the efficacy of acid detergent and other factors such as the soil and the surface may impact efficacy.

Sanitisers were mentioned in two studies, however, in one it was used in combination with an alkaline detergent, so it is not possible to comment on its effectiveness (Zhang, 2014). In the other study a broad spectrum sanitiser followed by a water rinse returned gliadin ELISA results for all swabs of <LOD in a battered chicken processing facility (Wang, Young and Karl, 2010). Not included in Table 7 as results relate solely to cleaning hands, Perry et al. (2004) found that peanut butter applied to the hands of volunteers was not removed by antibacterial hand sanitiser from six of the 12 hands sampled, according to the results of ELISA testing; liquid soap and bar soap were effective in this scenario.

The remaining studies in Table 7 do not specify the cleaning chemicals used, referring to them for example as detergent, dish detergent or conventional detergent. The use of ‘detergents’ has varying results. Three studies report successful removal of allergenic soils using ‘detergents’: efficacious removal of milk chocolate from a conch and ball mill (Zhang et al., 2019); efficient removal of hazelnut from equipment used to produce cookies containing hazelnut, when used at 52ºC and in combination with manual scraping and a ‘full clean’ (wash with detergent-rinse-sanitise-air dry) that was capable of removal of a range of allergenic foodstuffs from stainless steel, plastic and wood coupons, apart from peanut butter. The majority of studies though report ineffective cleaning using detergents, for example for food service tableware that had been in contact with egg (Hashimoto, Yoshimitsu and Kiyota, 2014) and in school kitchens (Galan-Malo et al., 2019 and Ortiz et al., 2018).

Galan-Malo et al. (2019) report the successful use of detergent with proteases (enzymes), which significantly reduced the occurrence of allergenic residues in school kitchens.

As a general rule, there is a linear relationship between cleaning efficacy and the temperature of cleaning solutions. Of the selected studies where the temperature of the cleaning solution or water was specified, the range was between 40 and 73.8ºC. It is, however, difficult to extrapolate conclusions on the relationship between temperature and the efficacy of cleaning to remove allergens in these studies, due to the wide variety of other factors involved (type of chemical, soil, surface, detection method).

The use of chemicals to remove a variety of allergenic foodstuffs from a wide range of surfaces in various scenarios has been studied; the results point to the efficacy of chlorinated alkaline, but variable results with acid detergents, sanitisers and conventional detergents. Detergents with enzymes need further investigation to establish efficacy in a range of scenarios. Ultimately, whether particular chemicals perform successfully to remove allergenic foods will depend on the many factors that intrinsically affect cleaning effectiveness.

6.1.2.5 Clean-in-place

Just one of the selected studies looked at a CIP cleaning methodology, all be it in a simulated scenario. Courtney (2016) soiled four food processing surfaces (316 grade stainless steel; high density polyethylene (HDPE); Nylon 6/6; Delrin) with non-fat dried milk and cleaned with four cleaning solutions (commercial caustic (Exelerate CIP, Ecolab – a chlorinated alkaline cleaner); commodity caustic (sodium hydroxide – an alkaline cleaner); acid cleaner; oxidizing sanitiser) separately and then sequentially. It was found that the alkaline and chlorinated alkaline solutions easily removed the milk soil while the acid and sanitising solutions left a soiled surface. When used separately, a chlorinated alkaline solution was observed to outperform an alkaline solution. Stainless steel was most easily cleaned, followed by HDPE and Nylon 6/6.

6.1.3 Efficacy of cleaning methodologies depending on the food matrix

It is not possible to comment on the removal of particular allergens or allergenic proteins per se, as, quite reasonably, none of the selected studies investigated removal of soils of

actual allergen protein as such. Instead, soils containing allergenic foodstuffs, which themselves contain the allergenic proteins are used. Where individual studies include investigations of the cleaning efficacy of removal of different forms of allergenic foods (for example powdered milk and liquid milk or peanut butter and peanut flour) on the same surface type, cleaned using the same cleaning method, it may be possible to draw conclusions as to the effect of matrix on the efficacy of cleaning. Two of the selected studies, within their individual study design, utilised different forms of allergenic foodstuffs and used the same cleaning techniques on the same surfaces.

Jackson and Al-Taher (2010) assessed the efficacy of dry and controlled wet cleaning methods to remove soy flour, soy ‘milk’ and soy infant formula from stainless steel, Teflon and urethane plates. Sanitising wipes were found to be equally effective at removing the different soy soils from all surfaces according to results of visual inspection, ELISA and total protein swabs. ATP tests variously gave positive results, but the study authors have commented that ATP swabs may not be applicable in this scenario due to high background levels of ATP on dry cleaned surfaces.

In the same study, soy flour and soy infant formula were applied to the same surface types, and removal was attempted by high efficiency vacuum. Although the surfaces were visually clean, soy flour was detected by ELISA on stainless steel, but not soy infant formula; positive results for protein swabs were seen, however, for both soil types on stainless steel. On the urethane and Teflon there did not seem to be a discernible difference between removal of the different soy soils. The results suggest that, in this instance, soy infant formula was more easily removed from stainless steel than soy flour.

Bedford et al. (2020) applied powdered, wet or sticky and paste forms of foods containing allergens to stainless steel, textured plastic and maple wood; cleaning was by various dry and controlled wet methods. Differences were seen between removal of different peanut soils using terry cloth soaked in tap water and terry cloth soaked in sanitiser solution, which were able to effectively remove peanut powder, but not peanut butter from all surfaces. Peanut butter also required more alcohol quat wipes for removal (3 or 4 versus 2 or 3) than peanut flour.

It was also shown in the same study that terry cloth soaked with water was able to remove low amounts (0.5 g) of cream cheese from all surfaces, but non-fat dried milk

powder and fluid whole milk were not removed. Higher amounts of cream cheese (4 g), however, were not removed using the same cleaning method.

When Bedford et al. (2020) investigated different forms of egg (whole egg powder and mayonnaise) it was found that terry cloth soaked with water was less effective at removal of the whole egg powder than mayonnaise. The same trend was seen with terry cloth soaked in sanitiser. It was also observed that more alcohol quat wipes were needed to remove the whole egg powder than the mayonnaise.

In summary, the study by Bedford et al. (2020) shows that, peanut butter seems to be more difficult to remove than peanut flour; milk powder and fluid milk were more difficult to remove than low (but not high) levels of cream cheese; and whole egg powder was more difficult to remove than mayonnaise.

6.1.4 Efficacy of cleaning methods depending on the surface

Where individual studies include investigations of the same form of allergenic food on different surfaces, that are cleaned in the same way, it may be possible to draw conclusions as to the effect of surface on the efficacy of cleaning.

Of the relevant selected studies, it was found that milk powder was not visibly removed from a urethane surface by vacuuming, whereas it was from stainless steel and Teflon (Jackson and Al-Taher, 2010). In a study by Courtney (2016) it was noted that plastic surfaces developed various amounts of surface roughening throughout the experiment which could harbour milk protein soils, while the stainless steel surface was consistently cleaned. Similarly, Bedford et al. (2020) commented that in the conditions they studied, allergenic foods seemed to be more difficult to remove from a textured plastic surface than stainless steel or wood.

Kiyota et al. (2017) found orange residue more difficult to remove from polypropylene and wooden chopping boards than stainless steel or glass surfaces.

Chen et al. (2022) found that surface roughness did not significantly affect cleaning outcomes by scraping or brushing for removal of wheat flour and non-fat dried milk from stainless steel coupons. It should be noted that this study found that allergenic residues were consistently detected.

In an investigation of food contact surfaces in school canteens, Galan-Malo et al. (2019) found that of the materials studied (Teflon, stainless steel and plastic) none showed a significant impact on the number of utensils remaining contaminated with allergen residues after cleaning. Only the utensils made of Teflon show a clear trend to be contaminated with gluten, although comment was made that this result should be confirmed by analysing a higher number of utensils.

From these studies it seems that allergenic foodstuffs could be effectively removed from stainless steel in the majority of circumstances. It appears to be more difficult to remove allergenic foods from plastic surfaces, especially where these are textured or become textured through use.

6.1.5 Findings relating to detection methods

Of the selected studies, seven used combinations of different detection methods, however, only five of these provided enough information for comparisons to be made between the different methods used. Visual inspection has been included as a detection method as well as ELISA, LFDs, ATP and protein swabs. Table 8 provides a summary of the five studies in which the results of different detection methods could be compared.

Table 8: Summaries of the results of studies that used different detection methods to evaluate efficacy of cleaning for allergen removal

Publication reference	Relevant findings of the study
Spektor (2009)	Although surfaces were visually clean, positive ELISA results were generated.
Wang, Young and Karl (2010)	In trials comparing ATP and protein, when detecting residues in a battered chicken processing facility, ATP bioluminescence was found in this study to be an effective surrogate indicator of residual gliadin (by ELISA).
Jackson and Al-Taher (2010)	ELISA and protein swabs were equally effective tools for detecting food residue in the dry cleaning scenarios but did not always agree with visual inspection. Both conventional and high sensitivity ATP swabs may not

Publication reference	Relevant findings of the study
	be applicable due to high background levels of ATP on dry cleaned food contact surfaces.
Courtney (2016)	Throughout the study, some visually clean surfaces yielded positive LFD results.
Chen et al. (2022)	Allergenic residues were consistently detected by LFDs following scraping or brushing under most conditions, even as the surfaces appeared visibly clean and passed ATP testing.

The studies represented in Table 8 demonstrate that there is disparity between the results of analysis using different detection methods. Notably, visually clean surfaces often yielded positive results using analytical methodology (Spektor, 2009; Jackson and Al-Taher, 2010, Courtney, 2016; Chen et al, 2022).

Results of ELISA analysis agreed with those of protein swabs in dry cleaning scenarios (Jackson and Al-Taher, 2010).

Results for ATP were shown to not agree with LFDs (Chen et al, 2022) and were not applicable to dry cleaned food contact surfaces due to high background levels of ATP (Jackson and Al-Taher, 2010). In a study by Wang, Young and Karl (2010) involving production of battered chicken, however, ATP tests were found to be useful substitutes for detecting residues by gliadin ELISA.

The lack of agreement between some of the detection methods points to the need to select such methods carefully, based on the specific situation, and to use a combination of methods, particularly in addition to visual inspection, to test for cleaning efficacy. In particular, visual inspection and ATP testing should not be the only detection methods relied upon, as visually clean surfaces (and those that display ‘negative’ ATP results) may still harbour detectable allergen residues. It may be appropriate to use surrogate methods, such as total protein detection, when conducting verification and monitoring activities, as long as those tests, with their associated LOD and LOQ have been proven valid for this purpose in the validation study, for example by comparison with allergen-specific methods where applicable.

6.1.6 Results overall summary

The selected studies display a high level of disparity with most references investigating the effect of a specific cleaning method or methods on reducing contamination of a specific allergenic food (different matrices), in a particular context (for example food processing or food service) and therefore involving different surface types. The scarcity of similarity between the studies means that data on the reproducibility of the results in different settings or contexts is lacking. Ultimately, the findings are difficult to extrapolate to all allergenic foodstuffs and the efficacy of the cleaning method is highly context-dependent. Nonetheless, the 23 studies identified through the screening process provided findings relevant to the review, most of which used a clearly detailed systematic approach to evaluate the efficacy of allergen cleaning.

Although the ability to draw definite conclusions on the efficacy of cleaning methodologies is limited by the number of published studies in this area, some general findings include:

- Wet cleaning, including controlled wet cleaning, has greater efficacy in terms of allergenic soil removal than dry cleaning methods; dry cleaning was rarely effective in the selected studies.
- Push-through cleaning is variously effective; however, this seems to be highly dependent on the food matrix or soil to be removed, the push-through material and the equipment being cleaned.
- Chlorinated alkaline seems to be more effective than acid detergent for removing allergenic foodstuffs.
- The use of cleaning formulations that include enzymes show potential for removal of allergenic food soils.
- Cleaning efficacy can be affected by food matrix and surface type.
- Visual inspection and ATP testing should not be the only detection methods relied upon, as visually clean surfaces (and those that display ‘negative’ ATP results) may still harbour detectable allergen residues.
- Analytical methods should be selected carefully and validated for use.
- Analysis for detection of total protein or other surrogate tests may be useful for verification and monitoring activities, as long as their use has been proven acceptable in the cleaning validation study, for example by comparison with allergen-specific methods where applicable.

6.2 Guidance and codes of practice

6.2.1 Global spread of guidance

The total number of guidance and code of practice documents relating to food allergens from around the world found using the search strategy described in Section 5.1.1 was 38. After screening these documents for information on cleaning, validation, and verification, beyond the mere mention that these are required, the final number of selected documents was 28. The documents in which there is additional information on cleaning, are from nine regions, based on the region where the document was published and where it is therefore applicable for use (see Appendix 11.10). Seven documents were published by organisations in the European Union, seven in the United States, three in the United Kingdom, three in Canada, two in Australia, and one in each of Brazil, Japan, New Zealand and Spain. An additional three guidance documents in the final sample were applicable in a broader 'global' context, which included those from commercial standards organisations (such as BRCGS and Safe Quality Food Institute (SQFI)) and the internationally recognised Codex Alimentarius (Food and Agriculture of the United Nations (FAO)/World Health Organisation (WHO).

6.2.2 Basic principles of cleaning

The following basic principles of cleaning are discussed throughout this report but, within guidance as in the other literature sources, are not clearly separated from sections describing specific cleaning methodologies (for example wet, dry etc.). Two guidance documents (European Hygienic Engineering and Design Group (EHEDG), 2021a and Campden BRI, 2020b), which are either focussed on, or contain a section on, the basic principles of cleaning were therefore selected as they provide detailed descriptions of the principles; these are summarised in this section.

6.2.2.1 Hygenic design

The hygienic design of equipment is an important consideration in controlling the safety and quality of any products made (Campden BRI, 2020b), including for example the hygienic design of joints, fasteners, internal angles, bearing and shaft seals, drainage, controls and doors, covers and panels. Hygienic design should be considered a prerequisite, in that there should be easy access to all surfaces, and/or equipment can be

easily dismantled to enable effective cleaning (European Hygienic Engineering and Design Group, 2021a). In addition, equipment contact surface materials must be compatible with recommended cleaning agents and disinfectants, including their concentrations, temperatures, contact time and pH (EHEDG, 2021a). Consideration should also be given to the finish of the surface, effectively its roughness, as rougher surfaces can deteriorate more rapidly with age and wear (Campden BRI, 2020b). Welding should be smooth and continuous, with no overlapping joints (Campden BRI, 2020b). It is pointed out that although hygienically designed equipment may initially be more expensive, in the long-term it is more cost-effective as cleaning costs and cleaning time will be reduced (Campden BRI, 2020b).

6.2.2.2 Components of the cleaning and disinfection programme

A combination of four fundamental parameters is employed in cleaning and disinfection programmes (below bullet points are based on information from EHEDG, 2021a and Campden BRI, 2020b):

- **Mechanical or kinetic energy** – used for physical removal of soils, for example physical or manual labour such as scraping and brushing, automated scrubbing, pressure jet washing or turbulence for example flow rates in CIP.
- **Chemical energy** – through the application of detergents that break down the soil to make it easier to remove and suspend in solution, so it can be rinsed away. In chemical disinfection, the disinfectant disrupts the normal functioning of any microorganisms that remain on the surface after cleaning, which ultimately kills them.
- **Thermal energy** – in general the higher the temperature of the cleaning solution, the more effective the clean, however, some soils can become more difficult to remove if high temperatures are used (in particular proteins can be denatured and become more tenacious). Depending on the equipment, the soil and the cleaning agent used, temperatures from ambient up to 85ºC are routinely utilised, although higher temperatures (for example 100-140ºC) are used for example during alkaline cleaning parts of UHT plants.
- **Time** – for cleaning processes using mechanical, chemical and thermal energies, generally, the longer the time period employed, the more efficient the process. The

cleaning agent contact time required for effective cleaning depends on the characteristics of the soil, amount of soil present, production length etc.

6.2.2.3 Water quality

Water used in cleaning regimes can dramatically impact the efficacy of cleaning (Campden BRI, 2020b). Water can used without additional chemicals for rinsing, but may be used in a blend with cleaning chemicals (EHEDG, 2021a). It is a universal solvent for all types of soils and carries chemicals, energy and mechanical action to the soils (EHEDG, 2021a). Water used for cleaning surfaces in food businesses should be potable, i.e. microbiologically fit for human consumption, have been properly treated by a water treatment plant and be monitored regularly for the presence of harmful chemicals and microorganisms (Campden BRI, 2020b). It is also important to consider the hardness of water for cleaning, i.e. the level of calcium carbonate ($CaCO_3$) it contains, as too soft water (for example 0 mg/L $CaCO_3$ total hardness) can lead to pitting and corroding (EHEDG, 2021a). The quality of water can also dictate what chemical products are used for cleaning as soft water can cause issues with foam control when using detergents, whilst hard water may require higher concentrations of detergents to be effective, which may increase detergent costs, and the need for regular/periodic descales (Campden BRI, 2020b).

6.2.2.4 Principal stages in the cleaning and disinfection programme

The sequence of events in the cleaning and disinfection programme should be carefully considered to maximise removal of contamination and reduce the risk of re-contamination (Campden BRI, 2020b). The following definitions are from Campden BRI (2020b):

- **Cleaning** refers to the complete removal of soil from surfaces, leaving them visually clean, so that subsequent disinfection will be effective.

- **Disinfection** is the reduction of microorganisms to a level that will not lead to contamination or spoilage of foods and is not harmful to health. It is not possible to eliminate all microorganisms in an open environment.

Typical standard cleaning protocols are described by EHEDG (2021a). FBOs often engage cleaning chemical suppliers to help with the design and implementation of cleaning and disinfection programmes, including the writing of cleaning schedules,

ultimately however, the development of a hygiene management system (including cleaning and disinfection programmes) is the responsibility of the FBO (Campden BRI, 2020b).

An example of the principal stages of an open plant, wet cleaning procedure is outlined in the below list based on European Hygienic Engineering and Design Group, 2021a and Campden BRI, 2020; the list is very much an outline, with examples of considerations at each stage provided, and is not intended as guidance, but rather as an illustrative example of some of the stages in an example cleaning and disinfection programme:

1. **Prepare the area to be cleaned** – for example switch off electrical equipment, isolate water-sensitive components, dismantle equipment (if required), remove raw materials, utensils and packaging from the area or cover it to prevent contamination with water and chemicals, use appropriate personal protective equipment, place warning signs.
2. **Remove gross soil from production equipment** – this should be carried out whether using wet or dry-cleaning techniques and involves manually removing loosely adhered soils and placing them in a suitable waste container, using equipment such as disposable cloths, scrapers and brushes.
3. **Pre-rinse** – working from top to bottom, pre-rinse all equipment and adjacent wall surfaces with water. Key considerations are the quality of the water, water temperature, pressure, flow and the application technique, which should not spread contamination.
4. **Clean** – the use of mechanical energy, cleaning agent and temperature to remove adhered soils from surfaces and dismantled parts. The cleaning methodology (i.e. wet, dry, push-through, CIP) used will depend on the soil and environment.
5. **Rinse** – using potable water to remove remaining product debris and cleaning agents that may affect the food product and subsequent disinfection.
6. **Monitoring and/or verification of the cleaning** – it is vital to check that the validated cleaning protocol has been completed effectively. Monitoring involves the use of methods including, most importantly, visual inspection, as well as analysis that can provide results in a timeframe that enables correction of any detected inadequacy of the cleaning (for example ATP swabs, general protein swabs, allergen LFDs). Verification is the use of methods, in addition to

monitoring, which determine whether the validated decontamination procedure has been conducted effectively and/or are still effective. Analytical techniques used in verification may be those that can be used on-site and generate results quickly (including for example ATP swabs, general protein swabs, allergen LFDs) or tests in which results can take longer (such as microbial sampling and analysis, allergen plate ELISA tests) and that can be used for trend analysis.

7. **Disinfection and reassembly as required** - disinfection should only be conducted on visually clean surfaces; it should be remembered that disinfectants and sanitisers alone are not effective at removing allergenic food soils as their purpose is to reduce the level of microorganisms. Equipment that has been dismantled for cleaning will need to be reassembled.
8. **Prepare the area for hand back to production** – remove any coverings that have been used to prevent contamination, clean and disinfect all cleaning equipment and PPE and complete final verification checks (for example microbiological swabbing, due diligence documents/sign off).

Not all cleaning and disinfection steps will necessarily be required (EHEDG, 2021a), conversely, addition steps may be needed (for example fogging or gassing to decontaminate the air, further rinses) depending on the design of the object to be cleaned and the expected level of cleanliness.

It is important on an on-going basis to encourage staff to operate good housekeeping and clean-as-you go practices and to have procedures in place for dealing with spillages (Campden BRI, 2020b).

The cleaning programme should be documented on a cleaning instruction card or standard operating procedure (SOP), and this should be trained out to all personnel who are involved with the cleaning (EHEDG, 2021a).

6.2.3 Cleaning methodologies specifically mentioned

The guidance and code of practice documents were screened as described in section 5.3.2. The overriding principle that cleaning should be applied in any part of the food handling, manufacturing or preparation and storage environment where allergenic protein may have been in contact, and which could result in allergen cross-contact, was detailed throughout the selected documents. Just less than half of the guidance documents found

(18/38) referenced a specific cleaning methodology, highlighting the lack of detailed guidance on this topic. There was scarce specific mention of controlled wet cleaning throughout the documents. Guidance published within the EU, UK and US mentions the following cleaning methodologies; dry, wet, push-through and CIP. Guidance from Canada mentions three of the four (not including push-through), and guidance from Australia and New Zealand does not mention any particular methodology.

It should be noted that the majority of guidance documents focus on food processing environments; food service is rarely specifically mentioned, with the exception of Codex Alimentarius (2020a), which contains particular guidance for this sector and retail in addition to manufacturing.

Wet cleaning is the methodology most referred to within guidance documents and codes of practice (n=16), which is not surprising considering it is the most widely used method by industry (Bagshaw, 2009), followed by references in the guidance to dry (n=12), CIP (n=9) and push-through (n=8). Table 9 shows the number and percentage of documents that reference specific cleaning methodologies.

Table 9: Number and percentage of the guidance documents that reference a specific cleaning methodology

Method	Number	Percentage
Wet	16	89
Dry	12	67
CIP	9	50
Push-through	8	44

The following sub-sections summarise the information relating to different specific cleaning methodologies as detailed in the guidance documents.

6.2.3.1 Dry cleaning

Dry cleaning is conducted without the use of water or chemical detergents; this technique uses physical equipment (for example brushes, dustpans, vacuums) to remove food soils

from contaminated surfaces. The method is often used in instances where water should be avoided, either due to the equipment design or product type, and is limited to the production of dry foods (US Food and Drug Administration (US FDA), 2022), where no sticky, glutinous allergen residues are present (Alberta Agriculture and Rural Development (AFREA), 2014). Although the use of brushes and dustpans is referred to in some guidance, FoodDrinkEurope (FDE, 2022) and AFREA (2014) state a preference to use filtered vacuum systems, as the use of brushes can lead to allergens becoming airborne, which can then contaminate non-allergenic products.

ASSIFONTE (who represents the European processed cheese sector, 2018) gives specific recommendations on the material of brushes (not to be made of bristle or wood but rather plastic for example polypropylene or high-density nylon), buckets (similar materials to brushes or stainless steel) and cleaning cloths, which it is stated should be avoided and instead disposable paper towels used. Where plastic equipment is used, it is recommended that it is replaced at a regular, defined interval. Colour coding equipment can prove advantageous for dry cleaning, as it can allow equipment to be specifically designated for certain allergens to minimise cross-contact (FDE, 2022).

Discouraged in many guidance documents is the use of compressed air, as it may spread allergenic proteins and (re)contaminate adjacent equipment or clean areas and could introduce other microbiological, physical (foreign bodies) or chemical risks; therefore, use should be limited to contained areas (EHEDG, 2021a). If compressed air is to be used due to practical considerations (for example equipment design), precautions should be taken to contain food residues (Codex Alimentarius, 2022a).

Unlike wet cleaning however, AFREA (2014) recommends that a step-by-step procedure is not required and instead the method should be to start high and work down to lower levels.

6.2.3.2 Push-through

Push-through involves ‘pushing’ an inert material (for example flour, sugar, salt, starch), using a physical object (‘pig’) or foodstuff that does not contain allergenic proteins through the production process to remove any contamination and is considered a type of ‘dry’ cleaning method (EHEDG, 2021a). The objective of ‘push-through’ is to reduce the level of allergen cross-contact without the need to dismantle equipment, which may not always be feasible. Use of the method should be supported by a risk assessment to

ensure the method is appropriate to reduce the allergenic protein of concern (Peanut and Tree Nut Processers Association (PTNPA), 2020). After the 'push-through' process, the material used should be treated using the same controls as for the original allergen (FDE, 2022). The method has been described as more effective when used in combination with other cleaning methodologies (FDE, 2022).

As allergen residues are likely to remain, even after the 'push-through' procedure, the method is not comparable with wet cleaning and more so aims to reduce the allergenic protein of concern to an acceptable level rather than completely remove it (EHEDG, 2021). Therefore, it is recommended that collected data should indicate a decline in the level of the allergen to the pre-determined acceptable level (Campden BRI, 2013).

The context will affect the nature of the quantity and 'flushing' material required (FDE, 2022) and a 'validated' quantity should be used (EHEDG, 2021a). The process could also be limited by the nature of the ''flushing'' material used, as high concentrations of substances such as sugar or salt for example may interfere with analytical methods (Campden BRI, 2013). It is important to establish the amount/volume of 'push-through' material that is needed in advance, including how many 'flushes' are needed to reduce the allergenic protein to an acceptable level, these are factors that should be considered as part of a validation study (PTNPA, 2020; US Department of Agriculture, Food Safety and Inspection Service (USDA FSIS, 2022). It is recommended by Codex Alimentarius (2020a) that this validation study should include testing the first product produced after 'push-through' to evidence allergen removal.

FDE (2022) states that the 'flushing' material should be 'pushed' through any part of the manufacturing environment where allergenic protein may have been in contact and could have resulted in cross-contact (including for example raw material addition points and packaging machinery), comment is made that 'flushing' the primary process (for example the main mixer) only is unlikely to be sufficient.

6.2.3.3 Wet cleaning

Wet cleaning is often referred to as the best/preferred cleaning option, where its use is practical and does not introduce a microbiological risk into the processing/food service environment (FDE, 2022). Dairy Food Safety Victoria (DFSV, 2018) states that although soils containing allergenic proteins can be difficult to remove, the best mechanism is by physical cleaning followed by rinsing and washing with cleaning agents. The use of

physical equipment (often associated with dry cleaning for example brooms and brushes) is not recommended by AFREA (2014) for wet cleaning as it can “promote microbial growth”, and it is industry best practice that where tools are used, they should be cleaned after carrying out the cleaning protocol. Ultimately, the cleaning procedure must be capable of removing all contaminations, and the rinsing stage should be sufficient to flush the system (FDE, 2022).

Centers for Disease Control and Prevention (CDC, 2013) guidelines on managing food allergies in schools and early care and education programs states that cleaning with water only will not be sufficient on its own to remove food allergens. Alternatively, FARRP (no date) recommends using full wet cleaning to remove food allergen residues, in the context of a food processing environment.

Generally, wet cleaning refers to the application of a chemical detergent at a defined concentration and temperature, followed by mechanical action, or may include prolonged rinsing with water (EHEDG, 2021a). These factors are also referenced within Farmhouse and Artisan Cheese & Dairy Producers European Network (FACE, 2018) guidance outlining good hygiene practices for cheese and dairy products under the TACT (Time, Action, Concentration, Temperature) acronym, where the recommended protocol for cleaning is given as rinsing in warm water, followed by application of acidic/alkaline cleaning or rinsing in hot water and then further rinsing before drying, with particular care given to ensure sufficient mechanical action and contact time.

Few specific examples are provided within guidance documents; those that are given include high-pressure detergent sprayers and low or line-pressure detergent foamers (US FDA, 2022). Concerns were raised regarding the use of high-pressure water hoses that have the potential to aerosolise food and cause cross-contact during the cleaning process (Codex Alimentarius, 2020a), and instead low-pressure hoses were recommended (Food Allergy Canada (FAC), 2022). USDA FSIS (2022) states that procedures should be in place when using high-pressure water hoses to ensure that any potentially affected areas are adequately cleaned to prevent cross-contact.

Wet cleaning can be advantageous due the range of cleaning agents that are available to enhance the efficacy of the cleaning procedure (for example bulk chemicals like sodium hydroxide and nitric acid as well as complex, formulated cleaning products) (EHEDG, 2021a). Although chemicals can assist with wet cleaning, the use of chlorinated or highly

alkaline detergents could raise the potential for reactions (for example production of toxic fumes) to occur between cleaning products (AFREA, 2014). Appropriate chemical concentrations and any potential cross-reactions must therefore be carefully considered. AFREA (2014) recommends using the chemical's Material Safety Data Sheet to inform procedures, and if there is doubt, issues should be discussed with the chemical supplier. In addition, the use of chemicals introduces the potential for cross-contact of product with such chemicals, which could ultimately affect the product's safety.

The use of chemical detergents alone may not be sufficient to remove the allergenic protein of concern on heavily soiled surfaces and pre-soaking or scrubbing may be required (US FDA, 2022). The cleaning procedure would need to take into account the surface that is to be cleaned. Due to the large variety of commercial cleaning agents available, the different conditions under which the cleaning agents work best and the processing/food service contexts they are used in, it was also suggested that it is not possible to recommend a single universal cleaning agent that would be applicable for all situations (US FDA, 2022).

Choosing an appropriate detergent depends on the biochemical properties of the agent and the foodstuff. ASSIFONTE (2018), EHEDG (2021a) and FACE (2018) distinguish between cleaning procedures to remove certain soil types. The guidance states that alkaline detergents (containing wetting agents) are normally used for the removal of organic material whilst acids are used to facilitate the removal of inorganic soils.

It is widely accepted that the efficacy of cleaning is improved by increasing the temperature of the water or cleaning chemical solution being used, this is due to increased chemical reaction rates, the increased solubility of some soils (in particular fats and oils at temperatures above their melting point) and reduction in strength of the bonds between the soil and the surface (Campden BRI, 2020b). However, if temperatures exceed 50 to 60ºC, some soils, such as proteins, can be denatured and become more tenacious or 'baked on' (Campden BRI, 2020b). As a general rule, there is a linear relationship between cleaning efficacy and cleaning chemical temperature. So, for every 10ºC rise in temperature the reaction rate approximately doubles, i.e. the time required for cleaning to be completed reduces as the temperature increases (Campden BRI, 2020b).

6.2.3.4 Clean-in-place

CIP methodology involves the use of a mechanical system to automatically apply a rinsing procedure with a detergent solution, without the need for constant supervision. The methodology may use computerised control points to monitor the cleaning process and ensure that the temperature, time and detergent application is appropriately controlled, but may also use manual methods to control the system; further guidelines to develop a CIP system are provided by AFREA (2014) and is also referenced by EHEDG (2021a). ASSIFONTE (2018) recommends the continuous recording of CIP system parameters including the temperature, time, concentration and flow rate.

Limitations of CIP include the risk of cross-contact where CIP solution is collected for reuse (PTNPA, 2020), and non-applicability to the cleaning of some equipment (for example slicers, mixers) that should be cleaned manually (US FDA, 2022).

Automation of cleaning can prove beneficial, but when using such processes, due to potential cross-contact between cleaning procedures, it is recognised that cleaning validation is required in order to reduce the risk (USDA FSIS, 2022). Codex Alimentarius (2020a) also highlights the importance of verification (for example testing rinse samples or swabs) to check the on-going efficacy of the CIP system in removing allergens.

6.2.4 Principles of allergen cleaning validation

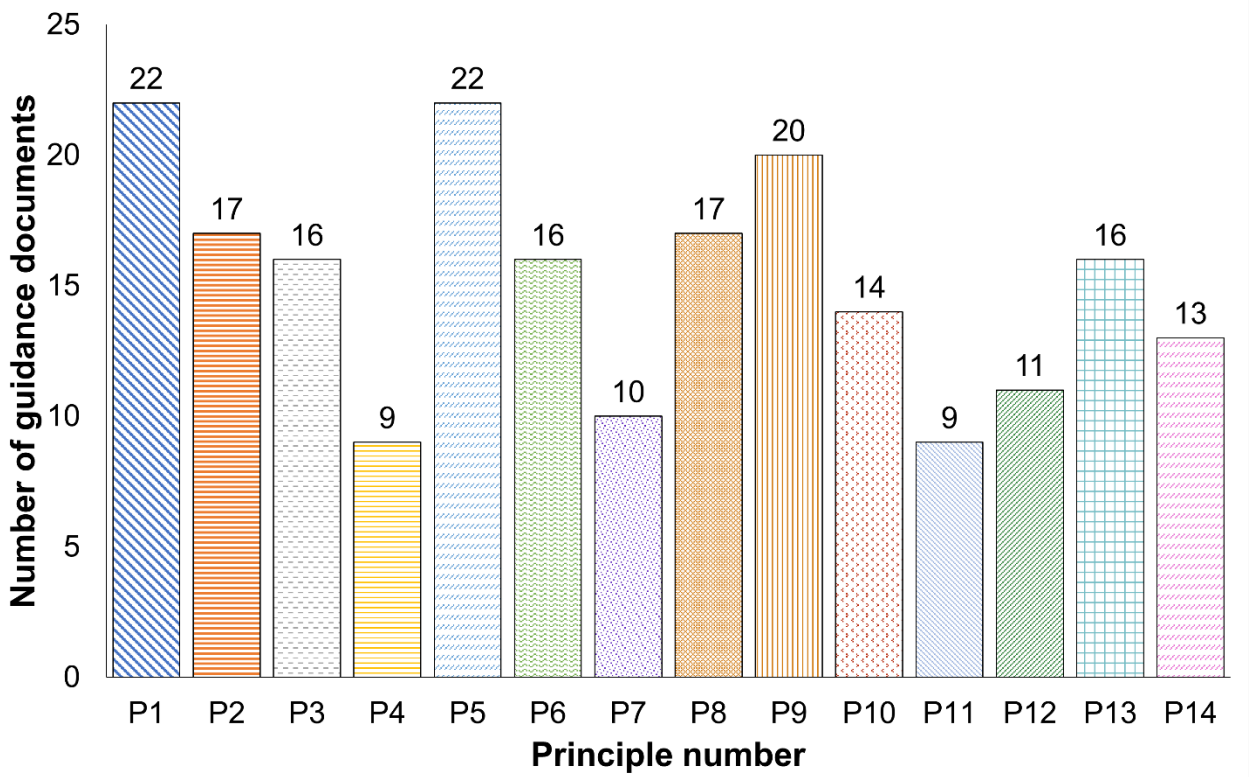
Guidance and code of practice documents were screened as described in Section 5.3.3 to establish principles of validation, i.e. the process of assuring that a defined cleaning procedure is capable of effectively and reproducibly reducing or removing allergenic food from specific food processing equipment thereby preventing or minimising allergen cross-contact. Additional objectives of the validation study are to confirm the verification and monitoring checks are sufficient/effective to determine whether a control measure is or has been operating as intended, and to ensure the appropriate analytical tests are used for these checks.

A set of 14 Principles were proposed based upon the allergen cross-contact risk management guidance and published literature identified and reviewed. The 14 proposed principles established from the guidance are listed in Table 10; Figure 1 displays the number of documents that include each principle.

Table 10: Proposed principles of validation of cleaning for allergen removal as established from selected guidance and code of practice documents

Principle	Description
1	Validation of cleaning to remove allergens is required
2	Cleaning procedures should be defined and thoroughly documented
3	Consider the physical form of the allergen
4	Validation should consider a 'worse-case scenario'
5	Validation should involve appropriate allergen analysis, where feasible and appropriate
6	Validation should include checks for visibly clean
7	Validation should demonstrate that cleaning is effective on multiple separate production runs
8	Re-validation of cleaning procedures should be conducted periodically and if significant changes take place
9	Appropriate sampling/swabbing procedures should be determined
10	Focus sampling on hard-to-clean areas that may trap product residues
11	Include positive controls when sampling
12	Select an appropriate analytical method
13	Analytical methods should be validated
14	Analytical results should meet acceptable criteria

Figure 1: Graph of the principles of cleaning validation for allergen removal as established from published guidance and the number of guidance documents that include them



Out of the total number of guidance documents found (n=38), 22 included Principle 1 (allergen cleaning validation is required) and were therefore further screened for other advice on validation and verification. Nine of the documents included ≥12 of the 14 principles, with two documents covering all principles (International Life Sciences Institute (ILSI-Europe), 2022; Neogen, 2016), see Appendix 11.11 for details of the principles covered by each document.

As well as Principle 1, which was the deciding criteria as to whether to include the document in further screening, Principle 5 (validation should involve allergen analysis) was observed in all guidance documents (100%, n=22), however, there was recognition that this may not be feasible or appropriate in all circumstances (for example Codex Alimentarius, 2020a). Principle 9 (appropriate sampling/swabbing procedures should be determined) was the next most referenced (91%, n=20), highlighting that these are widely accepted principles for allergen cleaning validation. It was also widely recognised (by 77% of the guidance documents) that allergen cleaning procedures should be defined and thoroughly documented (Principle 2) and re-validated periodically (several mention at least annually) or if significant changes take place (Principle 8).

The principles least often referred to, in that they were mentioned in less than 50% of the documents, were Principle 4 (validation should be completed for a 'worse-case-scenario'), Principle 7 (demonstrate that cleaning is effective following at least three separate, production runs) and Principle 11 (include positive controls when sampling).

The principles are ordered broadly into groups as follows: Principle 2 on the cleaning regime, 3-8 on the validation, 9-11 on sampling; and 12-14 on analysis.

The following sections include information from the guidance and code of practice documents on the principles described in Table 10. It is not feasible to repeat all the guidance provided here, so top-line information is given as well as reference to any areas of disparity between the advice supplied by the different documents.

6.2.4.1 Principle 2: the cleaning regime

Principle 2 - Cleaning procedures should be defined and thoroughly documented: The need for clear documentation detailing cleaning procedures was commonly referenced (77%, n=17), and was often cited as a first step to be completed in advance of carrying out an allergen cleaning validation study. Documentation is used to provide evidence of the cleaning procedure to be followed, and in relation to the validation, to record the capability of a specific cleaning methodology in the manufacturing/food service context. Some key content to include in such documentation is covered by EHEDG (2021b) and Neogen (2016), a standardised approach to what information should be recorded, however, is lacking.

6.2.4.2 Principles 3 - 8: the validation study

Principle 3 - Consider the physical form of the allergen: This principle was referenced in 73% of the guidance documents, often in the context of a 'worse-case scenario' when deciding when, and on what, to conduct the validation (see Principle 4 below). Some guidance provides additional considerations on sampling and the form of the allergen, particularly with regard to finished product testing and considerations around the homo/heterogeneity of samples collected (see section 6.2.4.3). It is recommended by Codex Alimentarius (2020a) that the validation process should be specific to the allergen, process and product matrix combination.

Principle 4 - Validation should consider a 'worst-case' scenario: The premise of targeting a 'worst-case' scenario for the cleaning validation is that if cleaning is efficacious in this situation, then it should also be effective in 'less bad' scenarios.

A limited proportion (41%) of the documents specifically call out the need for a 'worst-case scenario', and within these the terminology is variously used in different contexts to those described here, for example with regard to sampling from hard-to-clean areas (see Principle 10) or considerations of the physical form of the allergen (see Principle 3).

Although what constitutes a 'worst-case scenario' in terms of the cleaning validation exercise is not strictly defined in most guidance documents, there is general agreement among the few that do provide examples, for instance it is suggested to include:

- The allergenic food matrix that is the most complicated/challenging to clean (for example sticky materials, particulates) i.e. the most strongly adhered soil.
- The most difficult to clean equipment.
- The recipe with highest concentration of the allergen.
- The production schedule with highest number of consecutive formulations containing the allergen of concern.

It is noted within the EHEDG (2021b) guidance, that it may be several months or longer before the worst-case scenarios are truly identified.

Principle 5 – Validation should involve appropriate allergen analysis, where feasible and appropriate: Analysis for detection of allergens is recognised as important for allergen cleaning validation by all of the selected guidance documents and codes of practice. Codex Alimentarius (2020a), however, recognise that an analytical testing program may not be feasible or appropriate in all circumstances.

Although not solely relating to cleaning validation, coverage of different analytical techniques in the guidance documents is as follows: ELISA was the most referenced detection method (n=16); followed by PCR (n=14); LFD (n=13); ATP and protein swabs (n=11); and mass spectrometry (n=8).

It is pointed out by FDE (2022) that allergen analysis alone is not sufficient for allergen management, and by Campden BRI (2013) that when validating or verifying an allergen management plan, sole reliance should not be placed on allergen testing. Some guidance documents refer specifically to other sources for information on analytical

testing (for example Australian Food and Grocery Council (AFGC), 2021, references the Allergen Bureau website). Also referenced in multiple documents is the recommendation to carry out analytical testing only after a ‘visibly clean’ standard has been achieved (see Principle 6 for further information).

Principle 6 – Validation should include checks for visibly clean: Of the selected documents 73% (n=16) make specific mention of checking for visual clean as part of a validation study. When referring to ‘visibly clean’ within the principle, this is to describe the appropriateness of a visual check to confirm that allergens are not present. However, surfaces should be at least visibly clean before carrying out analytical testing to ensure analytical testing is not being carried out on surfaces that clearly contain allergenic soils. Campden BRI (2013) points out that the presence of visible residues remaining on surfaces following a clean suggests a failure to adequately clean.

Where ’visibly clean’ is commented on, there are some conflicting views regarding its importance as part of an allergen cleaning validation; however, most tend to agree that visual inspection should be used in combination with appropriate additional analyses as an endpoint of acceptability. For example, DFSV (2018) states that visual inspections are important for verification but avoids using the same statement in the section where validation is discussed. FDE (2022) and Neogen (2016) positively include visual inspection in a typical validation procedure as well as quantitative analytical testing. With reference to food service, Codex Alimentarius (2020a) states that equipment, utensils, containers, and preparation areas should be adequately cleaned, at a minimum to visually clean.

Principle 7 - Demonstrate that cleaning is effective on multiple separate production runs: Principle 7 was referenced in less than half of the guidance documents (45%, n=10), indicating a lack of specific guidance on the repeatability of results necessary for validation purposes. Where it is referenced, it is made clear that there is a need for multiple (often three) acceptable results to confirm the cleaning method applied is capable of achieving the required result, i.e. during three separate production runs (EHEDG, 2021b; FDE, 2022; PTNPA, 2018).

Principle 8 - Re-validation of cleaning procedures should be conducted periodically and if significant changes take place: There is widespread consensus on

the need for periodic re-validation (77%, n=17), at least annually or if significant changes occur in the process such as:

- New products introduced.
- New ingredients used.
- New equipment installed.
- New production line rate/speed of operation or configuration.
- Change to scheduling or cleaning protocols.
- Significant personnel changes.
- Change to line configuration.

6.2.4.3 Principles 9 - 11: sampling

Principle 9 – Appropriate sampling/swabbing procedures should be determined: The need for appropriate sampling procedures was recommended by a majority of the guidance documents (91%).

When devising a sampling plan, several of the guidance documents state that this should be determined by considering the equipment and product to be sampled and should be established using a risk-based approach to maximise the probability of detecting contamination (EHEDG, 2021b; ILSI-Europe, 2022). This should include the sampling of equipment where food build-up is likely (Neogen, 2016). FAC (2022) recognise that as sampling plans are context-dependent and relate to the specific allergenic protein, food matrix and manufacturing operation, no standard approach has been developed by standardisation bodies.

In terms of numbers of samples, the AFGC guidance (2021) states that Acceptable Quality Limit (AQL) statistical sampling could be a useful approach. Some widely adopted sampling procedures, as suggested by ILSI-Europe (2022), include the ‘Square root of N+1’ or ‘Cubed root of N’ rule (where N = number of packaged units) (Muralimanohar and Jaianand, 2011); it is recognised that these do not have an underlying basis in statistical sampling theory but have been widely adopted.

DFSV (2018) reference specific recommendations for sampling final products including: as a guide, take a minimum of five samples; the number of samples should be representative; consider size of production run and homo/heterogeneity of the product. Campden BRI (2009) recommends taking at least three samples; for example, the first

three non-allergen products down the line following cleaning after a run of allergen containing product. Whilst FDE (2022) states that depending upon product type and situations (for example held-up areas down the line) the number of samples and times when samples are taken may vary.

It is acknowledged that there can be issues with heterogeneously distributed contamination as the sampling plan may not capture the allergen of concern (ILSI-Europe, 2022). FDE (2022) guidance states that in such a situation, analytical testing might not provide reliable data; therefore, visual inspection and confirmation that the 'visibly clean' standard is met (no product residue or particulates) should be considered as the only pass criteria for a successful validation study. It was also suggested that medium to high heterogeneity can be dealt with by increasing the random sampling rate (ILSI-Europe, 2022). The PTNPA (2018) guidance emphasises the difficulty of collecting a statistically significant sample for finished products, and states that swabbing equipment may provide a more suitable option for testing.

On the other hand, homogenous samples (for example free-flowing powder or liquid) may only require a small number of samples to be representative (ILSI-Europe, 2022).

Different sample types are described, and some of the guidance documents refer specifically to the need for testing of the production environment (i.e. swabbing of surfaces, rinse or wash waters, push-through material, air) in combination with the final product, i.e. to check for cross-contact. Utilising both production environment and product sample types is considered important, as although swabs may be positive, tested products may meet acceptable criteria (FDE, 2022). In addition, Campden BRI (2013) state that swabbing should not be used in isolation from testing other sample types; swabbing should be combined with product and other environmental sampling. ILSI-Europe (2022) state that swabbing is to be considered as "semi-quantitative" as there is no "direct correlation" between allergenic protein detected in swab solutions and concentration in the final product.

For evaluating environmental swab results, Neogen (2016) recommends the use of a green/yellow/red scoring system, whereby green highlights high confidence that results meet expectations, yellow that additional cleaning is necessary (it may also demonstrate that progress has been made) and red that results are not acceptable. Acceptability is

defined in the guidance as below the LOD, and for anything above it is stated that it should be treated as a positive result.

Principle 10 – Focus sampling on hard-to-clean areas that may trap product residues: This principle is mentioned in 64% of the documents. The emphasis here is on sampling of hard-to-clean areas as part of the validation of the cleaning process, rather than focussing cleaning on these areas. FDE (2022) suggest that swabs should be taken from locations representative of product contact points and that 'worst-case scenario' locations should be targeted, for example difficult to clean, rough or pitted surfaces, welds, bends or anywhere that product could 'hang up' and be released later during production.

Principle 11 – Include positive controls when sampling: The selected guidance does not often recommend the use of positive controls as part of the allergen cleaning validation process (41%, n=9). Positive controls are, however, recognised as important to ensure that the selected method detects the allergen(s) of interest when they are known to be present (Campden BRI, 2013; Neogen, 2016). Guidance from USDA FSIS (2022) suggests that swabs obtained during pre-cleaning could serve as a positive control. In addition, the need for 'negative controls' is also mentioned by FAC (2022), Campden BRI (2009) and ILSI (2022) to guarantee the analytical technique is usable in the context of the allergen cleaning procedure to be validated, as well as to help with interpretation of results.

With regard to design of the validation study and generation of appropriate control samples, guidance commonly states that product containing the target test allergen should first be run down the line, or be handled, prepared or processed using the piece of equipment to be cleaned. Samples should be taken at this stage to act as positive controls. The cleaning regime should then be applied, following which environmental samples should be collected. Then a similar product, without the presence of the target test allergen, should be run down the line, handled, prepared or processed, and samples of this taken to check for the presence of cross-contact. Flow diagrams depicting this sequence of events are provided for example by Campden BRI (2009) and FDE (2022), whilst ILSI (2022) provide a narrative description.

6.2.4.4 Principles 12 – 14: analysis

Principle 12 – Select an appropriate analytical method: Most of the selected documents are limited to descriptions of analytical methods, rather than providing clear recommendations. Codex Alimentarius (2020a) makes a general recommendation to use "allergen-specific" testing. Some of the documents indicate that consideration should be given to a method's sensitivity, selectivity, specificity and reproducibility (for example FDE, 2022; EHEDG, 2021b).

Half of the selected guidance documents (n=11) specifically state that, for allergen cleaning validation, ELISA testing should be carried out rather than LFDs or other detection methods, as ELISAs are quantitative and more sensitive than other tests (Campden BRI, 2020a). AFREA (2014), DFSV (2018) and Neogen (2021) specifically call out that protein and ATP swabs are not acceptable for validating the removal of allergens and should only be used for verification when calibrated with a validated cleaning procedure. In addition, FDE (2022) state that ATP and protein assays are not specific for allergens as they detect general contamination with biological material / proteins, which are not necessarily the allergens of concern, but can indicate level of cleaning capability. Further to this, ILSI-Europe (2022) state that while ATP tests are effective indicators of sanitation, they have limited value for allergen testing as ATP is not a protein and is found in all organic matter. Therefore, there is no way to distinguish between ATP from an allergenic food (Neogen, 2016).

Principle 13 – Analytical tests should be validated: It is widely understood (73%, n=16) that the food matrix and how the product has been processed can impact the detection of allergens and could result in false negatives. False positive results may also be generated due to cross-reactivity, for example, which may be misinterpreted. Therefore, tests should be validated for each individual food matrix (for example ILSI-Europe, 2022; FDE, 2022). Validating the specific matrix provides evidence that the test is effective and can be confidently used to accurately evaluate the efficacy of cleaning procedures.

It is important to note that this requirement to validate analytical tests does not just relate to those being conducted by an accredited analytical laboratory, but also to on-site tests such as LFDs. ILSI-Europe (2022) state this requirement for proper validation of LFDs and the importance of blanks and positive controls being analysed. The PTNPA (2018)

point out that LFDs may read a false negative due to allergen protein saturation and therefore a three-line test, i.e. one that alerts the user to an overload, is recommended.

Principle 14 – Analytical results should meet acceptable criteria: Often pieces of guidance specify that an acceptable criteria or result is required (59%, n=13), but they do not stipulate what these criteria actually are. For example, evidence is required to prove allergen removal, or reduction to an acceptable level (SFQI, 2012).

Defining the acceptable level should be carried out before validation to understand what application of the cleaning protocol needs to achieve (BRCGS, 2022). FDE (2022) state that in the absence of operational action limits for the specific allergen, all test results should be less than the LOQ of the specific validated, quantitative test method. Limits may also be referred to in the context of HACCP critical limits (AFREA, 2014). It is pointed out that if acceptable limits are not met, cleaning efficacy should be further investigated (EHEDG, 2021a).

At the time of conducting this review, there is work being conducted and discussions being held nationally and internationally about the use of allergen threshold levels to inform allergen risk management for foods, primarily in the context of PAL. For further details refer to outputs from Ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens (as published on the FAO website) and ILSI-Europe (2022).

6.2.5 Principles of allergen cleaning verification

Whilst validation is about assessing the capability of a cleaning regime to effectively remove or reduce food allergen contamination, verification involves the application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure is or has been operating as intended (Codex Alimentarius, 2020b).

The need for verification to ensure that the validated clean is being conducted correctly and continues to be effective was referenced in all (n=22) of the guidance documents, as well as the need for allergen analysis to aid with this process, where practicable and appropriate (86%, n=19), see Appendix 11.12.

A majority, but not all, of the documents reviewed referred specifically to the need to check that surfaces are visibly clean when carrying out verification procedures (82%, n=18). This number is similar to those that recommend the use of visual inspection for validation purposes (73%, n=16); for validation, however, visual inspection is mostly referred to as appropriate only in combination with allergen specific tests (for example ELISA).

Even though there is widespread agreement on the principles for verification, similar to validation, the need to select an appropriate method for specific circumstances (for example the use of LFDs for verification rather than ELISA tests as they can provide a quick result on site without the need to send off samples for further analytical testing (EHEDG, 2021b)) was suggested by only eight documents (36%). Table 11 details the principles of verification of cleaning for allergen removal, along with the number and percentage of guidance documents that refer to them.

Table 11: Principles of verification of cleaning for allergen removal as established from selected guidance and codes of practice documents, along with the number and percentage of documents that refer to each principle

Principle	Description	Number	Percentage
1	Allergen cleaning verification is appropriate to check efficacy of cleaning	22	100
2	Verification should include checks for visual clean	18	82
3	Allergen analysis is appropriate for verification, where practicable and appropriate	19	86
4	Select the appropriate analytical method (i.e. LFD rather than ELISA)	8	36

6.3 Industry and professional body publications

6.3.1 Literature review results overview

Of 30 industry and professional body articles identified from the search, 15 were excluded as they were not relevant to the topic of the literature review (for example covered allergen detection methods only). Out of 15 articles included in the final sample, 13 mention a specific cleaning methodology, of which, 10 reference wet cleaning, 11 refer to dry cleaning, four mention push-through and two reference CIP (See Appendix 11.13). In addition, 11 of the 15 comment on allergen cleaning validation and seven mention verification. The global spread of the industry and professional body publications covered two regions, nine from the United States, and six from the United Kingdom, however the organisations of the first authors have a different global spread, with 6 from the United States, seven from the United Kingdom, and one of each from Germany and New Zealand. The articles mostly refer to allergen cleaning in the context of food processing environments and there was no information specifically referencing food service operations.

6.3.2 Cleaning methodologies specifically described

6.3.2.1 Dry cleaning

Overview

Dry cleaning (n=11) was described in a similar amount of industry/professional body publications as wet cleaning (n=10). The point is made that not all processing environments are suitable for using wet cleaning methodologies to remove allergens, due to the potential to introduce microbiological risk, but caution should still be exercised when working with dry powder products/ingredients as they are more likely to be transferred (and therefore cause cross-contact) than non-volatile liquids (Littleton, Walker and Ward, 2021). Nonetheless, there are options available that can be applied without the need for introducing an amount of water that could prove hazardous, including push-though, dry cleaning using physical equipment, modified dry cleaning using wipes or brushes, and alternative methods including dry steam or dry ice (Haley and Brouillette, 2018). It was suggested that dry cleaning is appropriate for dry allergens that contain little/no oil (Lopez and Morales, 2015).

Brushing and vacuuming are usually given as examples of methods for dry cleaning, and it was stated that in the processing environment, tools need to be accessible and usable (i.e. not broken) to help operators properly carry out any cleaning procedures required through the day (Demetrakakes, 2022). Accessibility is also important to encourage the use of physical equipment for dry cleaning. It was mentioned that not all allergens can be removed by dry cleaning processes and to prevent cross-contact, scrubbing surfaces by hand is required, which may be a time-consuming process (for example “if powder is caked onto a mixer’s paddles and interior surfaces”, Demetrakakes, 2022).

Within one article, Haley and Brouillette (2018) report on the range of dedicated equipment used to minimise cleaning and the order of preference for cleaning dry facilities (“> push/flush [most preferable] > dry clean > dry clean with chemicals > clean in place > controlled wet cleaning out of place (part washer) > assisted cleaning system > controlled wet cleaning in place > flood cleaning [least preferable]”) (Haley and Brouillette, 2018).

Colour coding of equipment

Colour-coding equipment was described as an important technique to help reduce cross-contact, and is beneficial due to its ease of adoption, low cost (Teng, 2013) and ability to support tool traceability to help with preventing product recalls when issues have been identified (Kochak, 2016). Distinctive colours are often chosen and there is the option to apply secondary colour coding using rubber bands, for example to identify different attachments for vacuums (Smith, 2019). It was suggested that “regulatory pressures” in the US led to an increased popularity in the use of colour-coding of equipment by manufacturers and it was advised that its use should be determined only after defining the zones and associated colours of the manufacturing environment (Teng, 2013).

Discouragement of the use of compressed air

It was often identified that the use of compressed-air hoses should be discouraged; the aim of dry cleaning should be to “remove soil, not just displace it” (Haley and Brouillette, 2018). It is stated that its controlled use is still possible in manufacturing contexts, but it is recommended that soils should first be eliminated, and other tools that could be more effective (for example vacuums) have been disregarded.

Dry steam

Gill (2020) reported on the efficacy of dry steam for allergen cleaning, stating that traditional wet cleaning methods can be resource-intensive (for example the amount of water used, and the energy required to heat water). As dry steam cleaning uses less water and energy, and can ensure that belts are dry after cleaning, it may be a useful cleaning method for some producers and, for one particular manufacturing context, it was found that almond, peanut, sesame and soya fell below 5 ppm after its application (Gill, 2020). It was also found that productivity increased due to the reduced downtimes between batches. Other purported benefits include the need for minimal supervision, the potential for continuous or periodic operation, and the ability to use dry steam without chemicals or detergents. The method was also referenced by Haley and Brouillette (2018), but it was highlighted that such techniques simply move the food soil rather than remove it, meaning that the displaced residue would then need to be collected before resuming operations.

6.3.2.2 Push-through

Although mentioned in a limited number of industry/professional body articles (n=4), cleaning by push-through was still recognised as a potential cleaning option that may be essential in some cases (Zerva, 2015). Push-through is particularly relevant in instances where equipment is enclosed and not easily accessible to carry out other cleaning methodologies (Lopez and Morales, 2015). Haley and Brouillette (2018) provide an example benefit of push-through in that it can use inexpensive ingredients or a “dummy” product without expending expensive ingredients. It was clearly stated that the amount of push-through used must be validated through testing, but even if the method can reduce allergen contamination to acceptable levels, it may do so without eliminating microbiological risk, which could be a concern (Lopez and Morales, 2015). Such methods can lead to product waste but purged material could potentially be reused in other product formulations, as long as the allergenic content is identified, and labelling implications are considered.

6.3.2.3 Wet cleaning

Wet cleaning was commonly referred to within industry/professional body articles (n=10). Some articles describe the general process for carrying out wet cleaning and the benefits and limitations are frequently discussed; these are summarised below.

For a new production day, cleaning equipment with water and testing for allergenic proteins can be helpful to aid with removal of any product build-up (Schaffner, 2020) and high-pressure cleaning may provide a quick and effective means to effectively clean (Brown, 2019). However, Demetrakakes (2022) explains that wet cleaning is not an option for all processing environments, for example where the migration of moisture into some final products must be avoided. It is also pointed out that some equipment simply cannot be wet-cleaned as it may trap water, have electrical components that could be damaged or is made of materials that can corrode (Haley and Brouillette, 2018). Furthermore, inappropriate application of a wet cleaning procedure may introduce microbiological and physical risks. Selection of the appropriate system is therefore key; the article by Brown (2019) was the only one to specifically recommend taking into account the ingress protection rating (i.e. how well a piece of equipment is protected against water ingress) and the reject unit (i.e. that anything that is taken apart to be cleaned should be “easily detached, but quickly and securely reattached”) to ensure the equipment is suitable for the cleaning procedure.

For procedures involving certain wet cleaning methods (for example foaming and rinses), to remove water after use, drainage is required (Haley and Brouillette, 2018). Without appropriate systems to remove the water, the amount of time saved by using wet cleaning may be counterbalanced by the additional efforts to remove the water, and a ‘modified wet cleaning’ procedure may be more appropriate (for example removal of gross soils using controlled amount of water using a bucket and brush or wipe, Haley and Brouillette, 2018).

The need for cleaning chemicals is commented on when referring to wet cleaning, and examples given include sodium hypochlorite and hydrogen peroxide (Demetrakakes, 2022). Although sanitisers are widely understood to have antimicrobial properties, application of these alone is not sufficient to remove allergenic proteins (Lopez and Morales, 2015). Neutral detergents were noted to be “particularly effective for manual cleaning operations applied via brush or cloth” (Littleton, Walker and Ward, 2021). It was also stated that the cleaning solution selected should be used at an optimal temperature, which takes into account the biochemical properties of the components (for example “too cool and fats/oils will not be solubilised, too hot and the debris may be baked onto the surfaces making it hard to remove”, Littleton, Walker and Ward, 2021).

One industry/professional body article (Easter, 2015) details a pilot plant study that measured residues of a ready meal slurry (containing egg, wheat (gluten), soya, peanut and milk) that had been applied to stainless steel sheets, which were cleaned by detergent and disinfectant using an industrial power spray. Samples were collected at four stages of the clean (stage 1: before drying, stage 2: after pre-rinse, stage 3: after detergent and rinse, stage 4: after disinfectant and rinse) and analysed using ELISAs for gluten and peanut, as well as a range of other specific (lateral flow device, LFD) and non-specific (ATP and protein) tests. Results of the study seemed to show that residues were still detected by gluten ELISA and ATP test after the full clean. Gluten LFDs, the peanut ELISA and casein LFDs all seemed to be less sensitive, in that they no longer detected residues in the stage 4 samples. Results for the other tests were again less sensitive, showing reduction in detection of residues at earlier sampling stages. Of note, the egg LFD did not provide any meaningful results in this study. The authors conclude the results show that good cleaning can remove all food residues, including its allergenic components, to levels at or below the LOD of the tests, and that a combination of analytical detection methods can provide a greater assurance of cleanliness.

6.3.2.4 Clean-in-place

CIP methodology is only referred to within two industry/professional body articles, with most of the key considerations described below from the article by Demetrakakes (2022). Although recognised as a useful tool, needing minimal supervision to properly execute, it should not be viewed as a “panacea” to solve allergen cross-contact, and does not guarantee allergen removal. For CIP systems, issues may arise with certain equipment, including heat exchangers, separators, evaporators, valve clusters and gaskets. Care should be taken to maintain CIP equipment to ensure it is able to carry out its function correctly, and it should be suited to the equipment/process it is used for cleaning.

Demetrakakes (2022) also states that often the installation of “inadequate or improper” cleaning equipment may create further issues, such as clogs in spray balls or in-line strainers and leaking pumps, which may unnecessarily extend the time required to clean appropriately and compromising efficacy of the process. Accessibility was also raised as an issue as equipment components may be difficult to reach (for example spray balls in tanks), and potentially require equipment disassembly, limiting the number of inspections that are completed. There may be further issues with contamination of allergenic proteins when the equipment for cleaning is used for multiple product lines, however, risks can be

minimised if efficacy of the process has been validated and is operated correctly (Littleton, Walker and Ward, 2021).

6.3.3 Key considerations described by industry and professional body publications

6.3.3.1 General overview

Allergen cleaning, including validation and verification, is widely acknowledged in industry and professional body publications as essential in reducing allergen, and also microbiological, cross-contact. Similarities exist between the methods of cleaning and chemicals used for eliminating both microbiological and allergenic hazards, yet the approach to validation and verification is different (Schaffner, 2020). Cleaning protocols should be carefully planned based on the equipment, allergenic protein of concern and surfaces to be cleaned, dedicating enough time to guarantee effective implementation, which includes the inspection of all equipment before and after use (Kochak, 2016). Littleton, Walker and Ward (2021) and Haley and Brouillette (2018) both provide diagrams summarising key steps for cleaning methodologies (wet and dry respectively). It has been suggested that, as each processing environment is unique, no international standards for any method to measure the efficacy of cleaning methodologies have been published (Easter, 2015 with reference to Jackson, 2008).

For bakeries, Haley and Brouillette (2018) suggest that cleaning is often not the “root cause” of allergen-related recalls, but this should not lead to complacency and the use of allergen cleaning validation, as well as the testing of surfaces was still recognised as important. It was also stated that industry divergence exists, particularly in the method for verification of sanitation methods alongside techniques used for environmental monitoring.

Four types of allergen cleaning are described by Littleton, Walker and Ward (2021), including: dry cleaning; deep cleaning; inter-product ‘changeover’ cleans and automated cleans, all of which were identified to have common factors that must be considered when implementing allergen control measures. Alternatively, in the context of the confectionery industry, cleaning is described as physical (for example scrapers), chemical (i.e. cleaning with hot water with or without sanitiser) and biological (for example ultraviolet light) by Franzmeier (2019). Sanitiser was not recommended for

confectionery equipment due to the potential adverse effect it may have on the equipment's components.

6.3.3.2 Common principles for cleaning validation

References to common principles for allergen cleaning validation were often made in industry and professional body publications including but not limited to, focussing on a 'worst-case scenario' (for example highest allergenic load), selecting an appropriate analytical test (for example those targeted to detection of allergens, for example ELISA), the need for positive controls and documentation. It was noted by Littleton, Walker and Ward (2021) that documentation should include sampling procedures and further highlighted that using multiple samples is important "as a single test result is often relatively meaningless".

Baumert and Taylor (2013) reference common global food safety initiatives (for example BRCGS, SQFI) and highlight that specific approaches are not provided for allergen cleaning validation. Recommendations were made to carefully interpret testing results; although swabs for environmental samples may not correlate with allergenic residues in the final product, it is pointed out that caution should be taken to ensure any cross-contact is reduced to an acceptable level (Baumert and Taylor, 2013).

6.3.3.3 Surfaces

Surface properties, such as absorbency and smoothness affect the adhesion of allergenic proteins to surfaces and validation should be carried out for the different surfaces that are being cleaned (Lopez and Morales, 2015). Different combinations of method, soil and surface type should be validated individually as the food matrix (for example liquid, powder) can also affect the ability to remove allergenic proteins (Lopez and Morales, 2015); an example of a record including cleaning method, surface and soil combinations is provided within the article.

Littleton, Walker and Ward (2021) provide a hierarchy of "cleanability" of different types of food contact surface, with the easiest surface to clean being stainless steel followed by aluminium, hard plastic, soft plastic or rubber and then cloth and wood.

Although stainless steel surfaces have a higher cleanability due to the material's texture, mesh conveyor belts and poorly welded parts can still present issues (Zerva, 2015). New plastic surfaces can be easily cleaned, however, after continued use the material may

become damaged and is more likely to harbour allergenic residues and become cross-contaminated. Most difficult to clean are fabric surfaces, and the use of dedicated cleaning tools (for example cloths) for specific equipment should be considered, although it was acknowledged that this is not always possible (Zerva, 2015).

6.3.3.4 Equipment design and accessibility

It is important that suitable cleaning equipment is used to ensure that product build-up, which could lead to subsequent cross-contact, does not occur (Littleton, Walker and Ward, 2021). Accessibility of equipment for cleaning is therefore key and is often referred to within industry and professional body publications. In the past, equipment was not always designed to take into account the need for cleaning, and had elements such as “crevices, recesses, protrusions” that could lead to the build-up of allergenic residues (Demetrakakes, 2022). Modern food processing equipment, however, “is designed to be relatively easy to clean” (Demetrakakes, 2022); examples of appropriately design equipment to ensure accessibility are provided in the articles from Haley and Brouillette (2018), Brown (2019) and Franzmeier (2019). Having parts of equipment that can be easily removed allows for more effective cleaning of individual components, but it was noted that when removed, dedicated equipment for transporting parts to a separate location for washing should be used (Franzmeier, 2019). While important, it was accepted that is it not always possible for all equipment to have a high level of accessibility without compromising the function, simplicity or ease of use.

“Non-smooth areas” (for example rough welds, die-cut rollers, mesh belts) may be difficult to remove allergenic residues from and the cleaning methodology should take equipment properties into account (Lopez and Morales, 2015). An equipment design checklist was suggested as a potential tool to identify any difficult-to-clean areas (Haley and Brouillette, 2018). Examples of equipment where product residues are likely to build up, described as “hot spots”, include rollers, scrapers, elbows, tensions and product guides (Demetrakakes, 2022). Gravity metal detection systems can also be problematic for some food matrices (for example powders, particulates) due to the collection of product residues potentially containing allergenic proteins (Brown, 2019). Making sure that equipment has smooth surfaces without grooves was further discussed in the article by Franzmeier (2019), with one example given in the context of stainless-steel bearings with special hygienic seals that are often used by the industry.

6.3.3.5 Visual inspection

According to an article by Schaffner (2020), the US FDA requires that shared equipment be “visually clean” when producing a foodstuff not containing allergens after one that does, but Schaffner (2020) argues that companies should go beyond a “visual clean” for allergen cleaning verification, a point also made by Demetrakakes (2022). Although visual inspection may be a quick and simple tool for monitoring the efficacy of cleaning, small amounts of contamination will be difficult to recognise (Littleton, Walker and Ward, 2021). There may also be issues with wet-cleaned surfaces as they are more likely to look clean upon visual inspection but, by the time of the next production run, the residue may only then be visible to the operator (Schaffner, 2020). Visual inspection was listed as a minimum requirement by Lopez and Morales (2015) but should be carried out only in combination with analytical testing after product changeover. However, for allergenic proteins that do not have a developed test, it was stated that visual examination with ATP results must be relied upon. Nonetheless, as proteins are not alive they do not contain ATP, an area may appear clean but could still be contaminated with food allergens (Ridler, 2022).

6.4 Website and other information

6.4.1 Literature review results overview

Website information found for this section of the report (n=24) was formatted in a variety of ways, including as standard webpage articles (in the form of text only or short videos) or single author blogs. Search results included website pages from three categories of sources: those found on government, authority and agency webpages (n=5), organisation webpages (n=5) and analytical test kit companies, cleaning chemical and equipment suppliers and analytical laboratory webpages (n=13). Two of the articles were identified via LinkedIn, one of which was a blog article with a single author with no associated organisation. See Appendix 11.14 for further details.

Further literature fell outside of the previously described categories and took the form of presentation slides or company-published information (for example white papers and reports). Due to the disparate nature of this literature and the low quantity found from the search (n=7), the information to describe is limited, but what was found has been included within this section of the review.

6.4.2 Information on cleaning methodologies

Only general information on cleaning, without specific reference to cleaning methodologies, was provided by many of the government, authority and agency websites, for example by the Singapore Food Agency (2021); this site did however mention that procedures to monitor the efficacy of cleaning procedures should be in place. These procedures were specified to include relevant swabbing of surfaces after cleaning or testing CIP rinse water, alongside the need for equipment disassembly to manually clean hard-to-reach areas.

Useful guides for managing allergens in catering environments are provided by the FSA and Food Safety Authority of Ireland (FSAI), which suggest checking the cleaning of equipment, however these sources do not provide references to cleaning methodologies or a requirement for allergen cleaning validation.

One article published by the Canadian Food Inspection Agency (2022) discusses the need for preventive controls to avoid allergen cross-contact (for example cleaning, sanitation and inspection of equipment) and specifically calls out the importance of considering the physical form of the allergen (for example paste, particulate, powder, liquid), its solubility (for example water or lipid-based), concentration (for example high or low), any application of heat during processing, the surface material, the length of the processing run, the potential for the build-up of food material, and the type of cleaning method.

This requirement to base the cleaning regime on the specific circumstances is reiterated on many of the other websites; Campden BRI (2020a), for example, states that when deciding on cleaning methodology, each situation should be considered on a case-by-case basis. It is stated that the aim of cleaning is to effectively remove debris from the material surface, and not to destroy or denature the allergenic residue.

Romer Labs (2019a) states that the allergen management system “rises or falls” depending on the quality of the cleaning procedure, and any methodologies should be consistently validated to confirm the efficacy.

Emport LLC (2015) refers to the lack of “agreed-upon rules” for cleaning contaminated surfaces and for determining whether they have been cleaned to an acceptable level,

suggesting a combination of cleaning methods may be a better approach than the use of only one.

Some sources go further than such general information, for example, the Allergen Bureau of Australia and New Zealand (2023) has published a step-by-step guide to allergen management, which presents information in a similar format to guidance documents such as FDE (2022). Outlined within are three components that make up an effective cleaning approach and include: a cleaning program (documented and validated cleaning procedures that are continually reviewed); a cleaning schedule (methodology and frequency of cleaning program as well as responsible persons) and a cleaning matrix (sets out the order of the cleaning program; an example is provided on the website page).

Diversey (2021) and Biocel (2022) list essential information for standard sanitisation operating procedures (SSOP) such as: equipment description and surface/area to be cleaned; list of tools to be used and where to find them; instructions for self-inspection and specifics for the TACT variables.

Several websites provide specific advice relating to particular scenarios. For example, prior to carrying out “in-depth cleaning”, efforts should be made to reduce as much product residue as possible to prevent the spread of any that has built up (AIB International, 2022). Physical action (for example scrubbing) is recommended before the use of cleaning agents, as detergents/chemicals will not achieve this effect alone.

In addition, when deciding on the cleaning methodology, the form of the allergen is important (for example paste and particulates are usually more difficult to clean than liquids) and the principle that those present in the same form can usually be managed and monitored together (Romer Labs, 2019b).

Properties of the foodstuff or soil (for example number of components in the formulation) need to be taken into account as this will affect the ease of removal, and understanding how it will react to specific treatments (for example denaturing) will allow identification of the most suitable cleaning methodology (Hygiena, 2021).

6.4.2.1 Dry cleaning

Dry cleaning was defined as “cleaning without water”, by the Canadian Food Inspection Agency (2022), and its use appropriate in the production of foods with a low water activity

but not where “wet, sticky or gummy” residues are produced. On this website, dry cleaning is said to involve use of tools such as: compressed air (controlled use); grit or CO_2 blasting; pre-moistened (alcohol) wipes; vacuum; dry steam; brushing and push-through or ‘flushing’ (Canadian Food Inspection Agency, 2022).

Hygiena (2021) state that dry cleaning utilises mechanical energy using physical equipment (for example vacuum, brush, scraping, wiping, product flushes) and that these methods must be validated, documented and continuously verified. Using such techniques, it is possible to help prevent the spread of allergens, and filtered vacuum systems are more efficient for allergen removal (Emport LLC, 2015). A general rule provided is that any method that can spread material (for example compressed air) should be avoided (Romer Labs, 2020a), and only used as a “last resort” where necessary (AIB International, 2022). This is a common concern among the sources with the Allergen Bureau (2023) referring not just to the use of compressed air, but also to high-pressure hoses in wet cleaning applications as sources of potential cross-contact.

Another dry cleaning method mentioned is the use of a scraper, and for allergen removal, it is recommended by Biocel (2022) to apply scraping before carrying out a full clean.

Terminology in use differs between the different sources, with some including controlled wet methods in discussion of dry cleaning. Diversey (2021), for example, states that in dry environments surfaces may be sprayed with a cleaning solution followed by wipe down after five minutes, which can help manage allergens. It was stated by Biocel (2022) that wet cloths/wipes are more effective than dry wipes. Within dry cleaning environments, removable subcomponents of pieces of equipment can also be cleaned separately in a controlled wet environment (for example a washroom) (Rochester Midland Corporation, 2021).

Christeyns (2020) states that the first step in dry cleaning is often the removal of gross debris using scrapers or brushes, followed by the application of a detergent in a ‘controlled wet’ cleaning procedure; if disinfectant is applied this often results in a microbiologically clean, dry surface due to the fact that disinfectant is often alcohol-based and would therefore evaporate.

In addition, ‘flushing’ is also recognised as helpful in allergen removal from hard-to-reach areas (Emport LLC) and is discussed in the context of dry cleaning by Hygiena (2021).

Of note is the advice that a thorough inspection should always be carried out after cleaning and that equipment used to conduct cleaning needs to be properly cleaned after use (AIB International, 2022).

6.4.2.2 Controlled wet cleaning

There was little mention of controlled wet cleaning methodologies to remove food allergens in the website articles found, although some included this in discussions of dry cleaning or cleaning in dry environments.

Food Allergy Research & Education (FARE) advise that frequently touched surfaces and those that come into contact with food, so classrooms and other similar environments, should be cleaned and sanitised with water or other cleaning agents. It was also recommended that the use of soap and water is appropriate for handwashing as the application of water or hand sanitiser alone is ineffective for food allergen removal. The Food Allergy & Anaphylaxis Connection Team (FAACT) provide some information on accidental exposure and suggest avoiding wiping utensils immediately after use when they have been in contact with an allergen, a practice that was recognised as common in sandwich shops. It was also suggested that various surfaces (for example airline seats, tray tables, desks) should be vigorously wiped with wipes wetted with a chemical detergent (for example, Clorox®, Lysol®), or by the application of a “spray-on detergent” (for example Formula 409®, Fantastic®, Windex® Multi-Surface).

6.4.2.3 Wet cleaning

Wet cleaning was again often recognised as the “best” or “ideal” option for allergen cleaning where practicable without introducing microbiological risk, with Diversey (2021) and Biocel (2022) both highlighting foam cleaning as particularly effective. Also emphasised, by these articles and others, was the need to avoid high pressure due to possible aerosolization and potential allergen spread.

Hygiena (2021) discusses wet cleaning in the context of the three types of energy (mechanical, thermal, chemical) that can be applied when using this cleaning methodology. The same parameters are also described by Uğurcan (2022), with descriptions for each, alongside a figure displaying how the different factors vary between manual cleaning, cleaning-out-of-place (COP) and CIP cleaning. Mechanical energy for example being scrubbing, water turbulence and high-pressure water jets;

thermal energy relating to warm water or hot CIP washes and chemical energy being cleaning chemicals or detergents. Hygiena (2021) also states that it is important to consider the cleaning objective as this will play a role in the choice of cleaning methodology; this source distinguishes between complete removal of the allergen versus ensuring a visually clean standard is achieved.

Others discuss similar factors that need to be considered when developing a cleaning protocol including temperature, chemical properties and concentration of the cleaning agent, mechanical interaction between cleaning agent and the surface, and the time taken to carry out the cleaning procedure (Romer Labs, 2020a; Hygiena, 2021), or describe using the 'TACT' acronym (temperature, agitation, concentration, and time, for example Diversey, 2021).

The Canadian Food Inspection Agency (2022) recommended wet cleaning to clean "doughy or sticky residues", but state that this method should only be used in contexts that allow for the use of water. Accessibility was mentioned, with the need to disassemble equipment in some cases and clean by hand. It was stated that cleaning with water only is insufficient, and chemicals/detergents should be used, particularly chlorinated detergents, which it is stated are more effective at removing proteins; although alkaline or caustic agents, with hydrogen peroxide and enzymes, were also described as effective.

For COP, equipment must be dismantled and washed individually (Biocel, 2022; Canadian Food Inspection Agency, 2020). If production equipment is not used for a long period after cleaning (for example hours), it should be isolated and covered with poly sheeting (Rochester Midland Corporation, 2021).

AIB International (2022) state that when using water, thorough rinsing should be carried out to remove visible residues. Inexperienced operators may assume that spraying water and applying chemicals is sufficient, but it was suggested that this method takes a long time and is ineffective (AIB International, 2022).

Water alone has been described as being poor for eliminating proteins (for example food allergens), though additional agents (for example detergents, proteases, chlorinated alkali detergents) can be used in combination with water to increase the efficacy of the clean, (Romer Labs, 2020a). Chlorinated alkaline solution was suggested as appropriate to remove the protein fraction that contains allergens of concern (Rochester Midland Corporation, 2021). This was corroborated by Diversey (2021), who state that one of the

most effective compositions for removing protein from stainless steel surfaces is a chlorinated alkaline detergent (typical solution concentration: 0.1-1.0% sodium hydroxide or potassium hydroxide; 60-1000 ppm sodium hypochlorite; hard water sequestrants and surfactants) and Jackson (2017) who rate chlorinated alkaline detergents as excellent at removing protein.

It was stated that sanitisers do not remove allergenic proteins, but it is recommended to store cloths in a sanitiser solution between uses to reduce allergen transfer across surfaces (Biocel, 2022).

6.4.2.4 Cleaning-in-place

It was noted that CIP cleaning is often used in dairy, brewing and beverage processing environments, as well as for the production of ready meals, soups and sauces (Christeyns, 2020).

The potential for automatic CIP or semi-automation (COP) is said to be an advantage, but it is noted that caution should be taken to assess the processing equipment for “evidence of pitting or rough welds” that may harbour allergen residues (Canadian Food Inspection Agency). Limitations of CIP include the potential need for specialised equipment, such as tanks and piping (Christeyns, 2020).

For CIP cleaning, specifics are provided including chemical agent compositions for example “maintain >60 ppm titratable sodium hypochlorite in the wash cycle”, or “flush with 150 ppm peracetic acid and rinse if required” (Diversey, 2021).

Jackson (2017) presented a study involving pilot-scale high-temperature short-time (HTST) processing of non-fat milk with cleaning using different concentrations of chlorinated alkaline detergent, at different temperatures and flow rates. Following cleaning, a “simulated apple juice” was passed through the equipment and tested for milk; only the two “harshest” cleaning procedures resulted in no detectable milk in the next product processed. Comment was made that wet cleaning methods that use chlorinated alkaline detergents tend to be effective at allergen removal, but methods need to be evaluated for efficacy.

Chemical suppliers were highlighted as important to aid decisions made on cleaning methodologies. It was suggested that in general, an increase of 10ºC in a detergent solution, doubles the rate of chemical reactions involved in cleaning (Uğurcan, 2022).

6.4.3 Key considerations described by website articles

6.4.3.1 Cleaning validation and verification

Validation and verification are recognised as two distinct activities that are key to ensure allergen cleaning is effective (Food & Allergy Consulting & Testing Services, 2022). The Allergen Bureau (2023) describe some common principles of cleaning validation and verification including the need for visual inspections, inspection of areas where product build-up is likely, the use of analysis to provide documented evidence that a cleaning methodology is effective, the requirement for multiple samples and the need for continuous verification (for example using rapid allergen test strips or swabs, ATP and visual standards). Although the need for visual inspection was referenced, it was stated that “visually clean equipment may still harbour allergenic proteins” and validation is required, a point again raised in the article from Gloves by web (2016). Also emphasised is the fact that microbiologically clean does not necessarily mean clean from allergenic protein. This was corroborated in a presentation by Jackson (2017) to the Codex Committee on Food Hygiene (CCFH) in which it is outlined that microbiologically clean does not mean allergen clean.

Howlett (2016) describes the need for cleaning validation procedures, presents examples of statistical analysis, and includes key information that needs to be considered and documented (for example standard operating procedures, cleaning chemical properties, equipment design). Also mentioned is the fact that similar cleaning procedures do not require an individual validation, and use of a “worst case” is acceptable. Both Howlett (2016) and Reading Scientific Services Ltd (RSSL, 2022) refer to the use of analytical techniques such as ELISA for the detection of proteins and PCR for detection of DNA in the validation of cleaning.

The Allergen Bureau (2023) further state that validated cleaning programs may eliminate cross-contact but for some manufacturing environments this may be significantly more difficult (for example in chocolate or dry-blend production).

AIB International (2022) state that periodic validation of the cleaning method using allergen testing is required, and any positive results should lead to re-validation. It was noted that neither quality management standard organisations nor government bodies provide specific details for how often allergen cleaning validation needs to take place, and therefore the decision should be made by the individual business (Rochester

Midland Corporation, 2021). Verification frequency was recognised as depending on the number of changeovers per day and per week and depends on the risk assessment of the food produced. In addition, for checking the efficacy of cleaning, a post-cleaning inspection should be carried out, ideally by a different person to whomever carried out the clean, using a flashlight, and with enough time dedicated to carry out a thorough check (AIB International, 2022). Christeyns (2020), point to the need to ensure that obvious “trap areas” such as rollers, scraper bars and ledges are identified and checked for visual clean.

Hygiena (2022) provide short videos on their website discussing key principles of allergen cleaning validation, verification and allergen testing methods, which are those often described within guidance documents and other website articles from the Allergen Bureau (2023), Romer Labs (2019a) and Canadian Food Inspection Agency (2022) for example. Such principles include using a ‘worst-case scenario’, focussing sampling on difficult to clean areas, re-validation after significant changes and the need for visual inspection (i.e. ‘physical audits’) in combination with analytical testing. Evidence is described as necessary for proving the efficacy of cleaning methodologies and can be ascertained by carrying out validation and continuous verification.

It is pointed out by The Acheson Group (TAG, 2016) that quantitative tests are most often used during the validation process and qualitative tests, often called screening tests, are used most often for verification and routine monitoring.

Food Safety Standard App (2023) state in an article on LinkedIn that setting up a cleaning protocol and checking efficacy a limited number of times is not enough to validate a cleaning methodology, as variation can occur (for example employees, chemicals). It is said that validation can be conducted statistically using a “capability study”.

6.4.3.2 Processing equipment design, surface material and accessibility

The Allergen Bureau (2023) indicate that key considerations for the purchase of new equipment are the “cleanability” and potential for residue accumulation (for example build-up in pipework, equipment such as pumps, mixers and homogenizers, conveyors, airborne dust, utensils). When cleaning to remove allergens, the process should begin with a physical clean and may require equipment disassembly. Food Safety Experts

(2017) makes a specific reference to EHEDG certified equipment, as easy to clean and capable of minimising the risk of remaining allergens after cleaning.

Equipment that functions by using movement for example product belts and rollers should also be carefully considered (AIB International, 2022). While the cleaning of moving equipment in the position where it has stopped is important, it should also be cleaned following repositioning to ensure no residues are missed. Although not discussed frequently, it was recognised as crucial that adequate lighting is used in all areas where cleaning procedures are undertaken, so that operators are confident that residues that are difficult to see are removed (AIB International, 2022).

Some common surfaces used in food processing environments include polyethylene, polycarbonate, ultra-high molecular weight polyethylene (UHMW), polyvinyl chloride (PVC), vinyl, rubber, glass, wood and cloth and material properties can impact the likelihood for allergenic protein accumulation (Diversey, 2021). Surface roughness/smoothness and material absorbency affect allergen removal, which is also impacted by the foodstuff characteristics, including the food matrix and allergenic load. It was noted that allergens are difficult to remove from textured plastic surfaces (Diversey, 2021). RSSL (2022) state that stainless steel is deemed easiest to clean and cloth or wood the hardest due to their relative porosities; in between these, there are surfaces such as aluminium, hard plastic, soft plastics and rubber.

Accessibility is cited as being important and equipment design needs to be carefully considered, accounting for any time commitment required for dismantling before cleaning (Hygiena, 2021). Identification of any “hot spots” for example rollers, scrapers, elbows, tensioners and product guides, where product build-up is likely, is therefore essential to ensure all residues are removed (AIB International, 2022). Any post-cleaning inspection should be carried out by someone who is aware of these “hot spots” (AIB International, 2022). Visual inspection is recommended after equipment disassembly, and once the visually clean standard is achieved, after applying the cleaning methodology, allergen testing can provide evidence for validation (Biocel, 2022).

6.4.3.3 Cleaning equipment design

Regarding cleaning equipment, it was recognised in a paper (Smith, 2015) and presentation by the same author (Smith, 2016) that there is not much guidance on hygienically designed cleaning equipment such as brushes, with few manufacturers

producing hygienically designed tools, even though it is a key requirement in the BRCGS. Examples of equipment are provided throughout the paper and presentation, and EHEDG hygienic design principles (EHEDG, 2018) are referred to.

6.4.3.4 Cost implications

A webpage article from Uğurcan (2022) was one of the only sources found throughout the entire review to discuss the cost of cleaning; where cleaning was described as “often accepted as a necessary tool which does not add value to a product directly”. It was also stated that the cost of cleaning is regularly measured by the food industry. The cost considerations described include labour and supervision, water supply, treatment and purchase, chemicals, water heating, downtime, cleaning equipment, corrosion, effluent and monitoring.

Labour and supervision were identified as the predominant factor affecting the cost of cleaning and were claimed to account for “over 60% of the total cleaning budget whether resourced under contract or in-house”. Cost pressures were described as often leading to cuts in the budget for labour, even though it may save time and costs in the short term, the long-term indirect costs for example reduction in shelf-life, increased complaints and product recalls, may ultimately lead to a financial loss. After labour and supervision, the most significant costs come from the variable costs of water and cleaning chemicals used. It was stated by Uğurcan (2022) that “most of the time, the aim is to obtain a balance consistent with cost, efficacy and food safety”.

6.5 Book chapters

6.5.1 Literature review results overview

From the searches undertaken, 15 book chapters relevant to food allergens were found. Three of them, however, were excluded from this review as they did not discuss methods of cleaning to remove food allergens, or their validation and verification.

Of the remaining 12 selected book chapters, six had authors associated with organisations, businesses, or universities in the US, four from the UK, one from Canada, one from Germany, and one from Belgium and the Netherlands. These included 11 that specifically discussed methods of cleaning to remove food allergens and 11 that

described the validation and verification of these methods (See Appendix 11.15). For the place of publication of the book chapters, seven were from the US and five from the UK.

6.5.2 Information on cleaning methodologies

Within the book chapters that described cleaning to remove food allergens, its use was described in relation to the prevention of cross-contact between food products, mitigating unintended presence of allergens and accurate allergen declaration. Marriott, Schilling and Gravani (2018) particularly highlighted allergen sanitation as the first line of defence in preventing allergen cross-contact within the food business. Eight of the sources identified that the removal of allergenic soil or debris (containing allergenic proteins) is the aim of effective allergen cleaning (Stone, Jantschke and Stevenson, 2009; Burrows, 2010; Stone and Yeung, 2010; Cochrane and Skrypec, 2014; Nikoleiski, 2015; Eisenberg and Delaney, 2018; Jackson, 2018; Marriott, Schilling and Gravani, 2018).

These same eight sources particularly examined the different methods of cleaning to remove food allergens and identified that the methods and frequency of allergen cleaning will differ depending on the allergenic soils and the type of food production operation (Stone, Jantschke and Stevenson, 2009; Burrows, 2010; Stone and Yeung, 2010; Cochrane and Skrypec, 2014; Nikoleiski, 2015; Eisenberg and Delaney, 2018; Jackson, 2018; Marriott, Schilling and Gravani, 2018).

6.5.2.1 Factors affecting efficacy of cleaning for allergen removal

The book chapter by Jackson (2018) considered many variables that can influence the effectiveness of allergen cleaning such as: the physical form of the allergen soil (for example pastes can be more difficult to remove than powders and liquids); the chemical composition of the soil (for example protein-based soils are generally the most difficult to remove, particularly if they have been heated); the concentration of the allergen in a food soil (for example higher concentrations of allergen in the food soil will often require a more intensive cleaning procedure); the age of soil (for example the longer the soil is in contact with a food-contact surface, the more difficult it is to remove). Also included was reference to the effect of processing on food soils (for example heating may result in denaturing of proteins, making them more difficult to remove from some surfaces or longer processing runs cause more soil to build up on equipment surfaces, requiring more extensive cleaning procedures).

Further considerations regarding the effectiveness of methods to remove allergenic soils relate the type of surface to be cleaned, for example: its composition (for example cloth and metal can be hard to clean) and texture (for example smooth easier to clean than rough or with defects) (Stone and Yeung, 2010; Jackson, 2018). In addition, the hygienic design and the age of equipment can affect cleaning effectiveness (for example older equipment can be harder to clean as it can be scratched or have defects) (Stone and Yeung, 2010; Jackson, 2018). This was also specifically considered in work conducted by the Anaphylaxis Campaign and Reading Scientific Services Limited (RSSL) in 2006, documented within the book chapter by Gowland (2010), identifying for example that proteins of peanut and hazelnut are highly tenacious even after rigorous application of chemical and mechanical treatments; that milk proteins are slightly easier to remove; that for the removal of nut protein automatic washing is generally better than manual bowl washing; that used chopping boards and those made of wood are extremely difficult to get clean and that detergents are mildly better than hot water alone at removing allergens bound in high fat matrices. Furthermore, this work also identified the capacity for the people carrying out the cleaning or the equipment used for cleaning to be a vector of allergen contamination, for example it was described that high levels of contamination were taken up and transferred through the use of sponges and cloths (Gowland, 2010).

The soil characteristics of allergenic foods were identified as being of importance to the efficiency of cleaning, with proteins being described as the most difficult soil to remove, especially those which have been heated, have become denatured and have adhered to complex surfaces of equipment (Eisenberg and Delaney, 2018; Jackson, 2018; Nikoleiski, 2015).

6.5.2.2 Dry cleaning

Dry cleaning was specifically discussed in six of the book chapters (Stone, Jantschke and Stevenson, 2009; Burrows, 2010; Stone and Yeung, 2010; Nikoleiski, 2015; Jackson, 2018; Schilling and Gravani, 2018). Where dry cleaning methods are applied to remove allergen soil, using utensils and other equipment, it was stated that they should be dedicated and identifiable for allergen cleaning regimes only or themselves cleaned between uses by a robust allergen cleaning programme in a separate location to the processing environment (Stone, Jantschke and Stevenson, 2009; Burrows, 2010; Stone and Yeung, 2010; Nikoleiski, 2015; Jackson, 2018; Schilling and Gravani, 2018).

It was stated that compressed air should not be advised for use within allergen cleaning as it will generate the risk of airborne allergen contamination (Stone, Jantschke and Stevenson, 2009; Stone and Yeung, 2010; Nikoleiski, 2015; Jackson, 2018). Vacuum cleaning though is said to be one of the most effective methods of choice for the removal of dry and loose materials, but this method is not very effective at removing dried or adhered soils and vacuum cleaners would need to be dedicated to a use and an area within the facility as to not spread allergen contamination (Stone, Jantschke and Stevenson, 2009; Stone and Yeung, 2010; Nikoleiski, 2015; Jackson, 2018). Scraping was identified as producing inconsistent results due to the effects of variation in the tools and strength of the employee performing the clean as well as depending on the type of allergenic soil being removed (Stone and Yeung, 2010). Dry ice cleaning was deemed a very effective method in cases where soil adheres strongly to surfaces (Jackson, 2018).

6.5.2.3 Push-through

Food allergen cleaning using push-though, ‘flushing’ or purging was documented in six of the selected book chapters (Stone, Jantschke and Stevenson, 2009; Stone and Yeung, 2010; Nikoleiski, 2015; Moerman and Mager, 2016; Jackson, 2018; Marriott, Schilling and Gravani, 2018).

Materials that have an abrasive nature, including dense particles such as grain-like (for example rice grains) or crystal-like (for example salt, sugar, starch) foods, can be used to purge food residues such as allergens from product contact surfaces in equipment (Stone, Jantschke and Stevenson, 2009; Stone and Yeung, 2010; Nikoleiski, 2015; Moerman and Mager, 2016; Jackson, 2018; Marriott, Schilling and Gravani, 2018). This method can be applied either with dry or wet ‘flushing’ material, which does not contain the allergen of concern (Nikoleiski, 2015).

‘Pigs’ can be used to remove debris within pipes though they should be dedicated to allergen or non-allergen cleaning and are usually followed by ‘flushing’ to remove the loosened debris (Stone, Jantschke and Stevenson, 2009; Moerman and Mager, 2016; Jackson, 2018). Product sequencing itself can be considered as a type of ‘flushing’ protocol (Nikoleiski, 2015). Methods have also been identified using dry ice pellets, sodium bicarbonate and grit to blast off baked on or hard residues from delicate surfaces (Moerman and Mager, 2016; Jackson, 2018). However, these methods do not work as effectively for soft or elastic soils as they do not capture the debris removed and so can

disperse the soil, potentially causing allergen contamination (Moerman and Mager, 2016; Jackson, 2018).

6.5.2.4 Wet cleaning

Eight of the selected book chapters considered wet cleaning methods for the removal of allergenic soils (Stone, Jantschke and Stevenson, 2009; Burrows, 2010; Gowland, 2010; Stone and Yeung, 2010; Nikoleiski, 2015; Eisenberg and Delaney, 2018; Jackson, 2018; Marriott, Schilling and Gravani, 2018).

Factors affecting the effectiveness of wet cleaning for the removal of allergens were considered to include the correct time exposure to adequately wet and remove the soil, the required action to loosen soil and dislodge biofilms, the application of the appropriate cleaning chemical(s) in the correct concentrations and the use of the cleaning solution at the optimal temperature (Stone, Jantschke and Stevenson, 2009; Gowland, 2010; Stone and Yeung, 2010; Nikoleiski, 2015; Jackson, 2018).

Cleaning to remove allergens using foam methods was deemed effective, though it was pointed out that the correct contact time is required or there will not be adequate time for the detergent to react properly to remove the soil; in addition, thorough rinsing should follow (Nikoleiski, 2015; Jackson, 2018). In contrast high pressure methods of allergen cleaning were not favoured as they can spread allergen contamination through the facility if they are not operated properly (Nikoleiski, 2015; Jackson, 2018).

When manual wet cleaning methods are used it was stated that consideration should be given as to the selection, maintenance and dedication to allergen cleaning of utensils and other equipment so as to not themselves become a vector of allergen contamination (Gowland, 2010; Jackson, 2018).

CIP and COP systems were considered by three of the sources (Stone and Yeung, 2010; Nikoleiski, 2015; Jackson, 2018). It was recommended that where these methods are used, a single use system design is implemented, as the reuse of detergent may carry over allergenic food proteins and recontaminate the plant. The need to inspect filters and strainers in such automatic cleaning systems and, if necessary, manual cleaning of allergic debris before and following allergen cleaning cycles was also highlighted (Stone and Yeung, 2010; Nikoleiski, 2015; Jackson, 2018).

In terms of cleaning chemicals, four sources specifically considered the different constituents of soils of an allergenic food matrix and the best mechanisms and detergents for their removal (Stone and Yeung, 2010; Nikoleiski, 2015; Eisenberg and Delaney, 2018; Jackson, 2018). The following paragraph describes the consensus of approaches covered by these four sources.

Regarding cleaning to remove carbohydrate soils (for example sugar and starch) it was stated that alkaline detergents (for example sodium hydroxide or potassium hydroxide), which may contain a solvent and surfactant, are effective. The most successful chemicals at removing proteins (for example milk protein and egg protein) were said to be chlorinated or strong alkaline, which can be used in combination with a booster or oxidiser (for example peroxide) or proteolytic enzymes (for example proteases). Soil containing fats was considered best removed by alkaline detergents that could also contain a solvent, surfactant or emulsifier (for example phosphates). Allergenic soil containing inorganic materials (for example milk stone or salt) was characterised as being best removed by detergents or chemicals containing acids (for example phosphoric or nitric).

The same four book chapters (Stone and Yeung, 2010; Nikoleiski, 2015; Eisenberg and Delaney, 2018; Jackson, 2018) highlighted that the use of disinfectants or sanitisers alone would not be adequate to remove allergens or soil containing them.

6.5.3 Key considerations described by book chapters

6.5.3.1 Cleaning validation

The validation of allergen cleaning methods or procedures was discussed in seven of the selected book chapters (Stone, Jantschke and Stevenson, 2009; Stone and Yeung, 2010; Cochrane and Skrypec, 2014; Nikoleiski, 2015; Crevel, 2016; Jackson, 2018; Marriott, Schilling and Gravani, 2018).

It was specifically stated that allergen cleaning should be demonstrated as appropriate and effective as part of validation (Stone, Jantschke and Stevenson, 2009; Stone and Yeung, 2010; Cochrane and Skrypec, 2014; Nikoleiski, 2015; Crevel, 2016; Jackson, 2018; Marriott, Schilling and Gravani, 2018) and that validation should be completed to confirm that allergen cleaning regimes and changeover practices are capable of removing the allergen to prevent allergen contamination (Stone, Jantschke and

Stevenson, 2009; Stone and Yeung, 2010; Cochrane and Skrypec, 2014; Nikoleiski, 2015; Jackson, 2018).

Of the included studies, three identified that as part of an allergen cleaning validation the ‘worst-case scenario’ should be chosen as the basis of the validation study (for example cleaning following the production of the product recipe that is the most difficult to clean and that contains the highest concentration of the allergen used, followed by production of a product recipe, which does not contain the allergen, to show that the cleaning between is capable of mitigating the cross-contact risk) (Stone and Yeung, 2010; Cochrane and Skrypec, 2014; Nikoleiski, 2015).

It was considered by three studies that allergen cleaning procedures should be developed and validated before production happens and should consider multiple factors (for example length of production run, amount of ingredients, processing temperatures, scheduling of the process, detergent types, concentrations, cleaning methods, time, cleaning temperatures) and demonstrate efficacy against these (Stone and Yeung, 2010; Cochrane and Skrypec, 2014; Jackson, 2018). Further to this, it was highlighted that different lines or types of production need to be assessed individually, depending on the design of equipment, process, the product, the changeover and their impact on allergen cleaning regimes (Stone, Jantschke and Stevenson, 2009; Stone and Yeung, 2010; Cochrane and Skrypec, 2014; Nikoleiski, 2015; Jackson, 2018).

It was also considered that allergen validations should include and focus on hard-to-clean equipment (for example dead ends, pumps, valves and sensors) (Stone, Jantschke and Stevenson, 2009; Stone and Yeung, 2010; Cochrane and Skrypec, 2014; Nikoleiski, 2015; Jackson, 2018).

Of the book chapters identified five stated that a visual validation should be conducted to ensure the cleaning methods are capable of removing all visible residues of allergenic soil, which is then followed by an analytical validation to ensure complete removal of all allergenic soil by the cleaning methods (Stone, Jantschke and Stevenson, 2009; Stone and Yeung, 2010; Cochrane and Skrypec, 2014; Nikoleiski, 2015; Jackson, 2018).

The importance of wholly and accurately documenting the food allergen cleaning validation as evidence of capability was explained (Stone, Jantschke and Stevenson, 2009; Stone and Yeung, 2010; Cochrane and Skrypec, 2014; Nikoleiski, 2015; Jackson, 2018). In addition, the need for the allergen cleaning validation (or re-validation) to be

repeated on a regular basis or when there are any changes to the included factors that will affect the allergen cleaning was highlighted (Stone, Jantschke and Stevenson, 2009; Stone and Yeung, 2010; Cochrane and Skrypec, 2014; Nikoleiski, 2015; Marriott, Schilling and Gravani, 2018; Jackson, 2018).

6.5.3.2 Analysis for allergen cleaning validation

There were six book chapters that specifically considered analytical testing as part of a food allergen cleaning validation (Stone, Jantschke and Stevenson, 2009; Stone and Yeung, 2010; Cochrane and Skrypec, 2014; Nikoleiski, 2015; Marriott, Schilling and Gravani, 2018; Jackson, 2018).

It was identified by Marriott, Schilling and Gravani (2018) that the sensitivity of the selected method must be such that the level of detection needed is met and that the analytical method used must be able to detect the allergen being tested for (Jackson, 2018).

The consensus of two of the book chapters was that ATP was not to be used as part of testing for allergen cleaning validation as it does not have the required sensitivity and is not specific to allergens (Jackson, 2018; Stone, Jantschke and Stevenson, 2009). A further chapter by Cochrane and Skrypec (2014) documented that as well as being non-specific to allergens, ATP results can be hard to interpret with negative results not confirming a lack of allergen post clean.

Quantitative analytical lab testing using ELISA for allergen validation was recommended (Stone and Yeung, 2010; Cochrane and Skrypec, 2014; Nikoleiski, 2015; Jackson, 2018; Marriott, Schilling and Gravani, 2018). However, limitations of this technique have been outlined, for example, it does require a separate kit for each allergen, which can be expensive, and depending on the processing of the product (for example heat-treated, hydrolysed proteins and fermented products) this analytical method does not always work as it should (Cochrane and Skrypec, 2014; Jackson, 2018; Marriott, Schilling and Gravani, 2018).

LFDs or strip tests for the validation of allergen cleaning were identified as being easy to conduct, inexpensive and rapid, with processing facility application since instrumentation is not required (Jackson, 2018; Marriott, Schilling and Gravani, 2018). Cochrane and Skrypec (2014) also documented that LFDs or strip tests are simple to use, however it

was identified that they only provide qualitative or semi-quantitative results at best and do share the limitations of other analytical ELISA methods.

Use of the PCR methods for allergen cleaning validations was also described. This method was stated to be a fast and inexpensive test to identify DNA of allergenic foodstuffs as an indirect detection method (i.e. it does not detect what people are allergic to, which are proteins) (Cochrane and Skrypec, 2014; Jackson, 2018; Marriott, Schilling and Gravani, 2018). However, PCR can fail to detect some food allergens because it cannot identify the presence of those that have been indicated to contain lesser amounts or no DNA (for example egg whites and milk) (Marriott, Schilling and Gravani, 2018).

Another method that was described by three of the book chapters, was liquid chromatography-mass spectrometry (LC-MS), which was identified as more accurate through the direct detection of food allergen components instead of indirect detection through DNA (PCR) or antibodies (ELISA) and can test for multiple allergens at once (multiplex) (Cochrane and Skrypec, 2014; Jackson, 2018; Marriott, Schilling and Gravani, 2018). However, the limitation of this method is that the equipment is costly, but it can still be accessed through testing laboratories (Jackson, 2018; Marriott, Schilling and Gravani, 2018).

Marriott, Schilling and Gravani (2018) identified the use of biosensors (for example surface plasma resonance (SPR)-based biosensors) and flow cytometry assays as increasingly accepted tools for allergen detection as part of validation of allergen cleaning. Flow cytometry assays were described as able to provide simultaneous detection of multiple allergens from small sample amounts in seconds, with lower equipment costs than biosensors, but with similar labour requirements to ELISA methods (Marriott, Schilling and Gravani, 2018).

6.5.3.3 Sampling for allergen cleaning validation

Of the selected book chapters, six considered sampling as a key component of a food allergen cleaning validation study (Stone, Jantschke and Stevenson, 2009; Stone and Yeung, 2010; Cochrane and Skrypec, 2014; Nikoleiski, 2015; Jackson, 2018; Marriott, Schilling and Gravani, 2018).

Samples collected as part of an allergen cleaning validation study should be taken to maximise the probability of detecting any contamination; the sampling plan must

therefore consider factors such as the physical nature of contaminants, the level of processing, the amount of protein in the recipe and the design of the production plant (Stone, Jantschke and Stevenson, 2009; Stone and Yeung, 2010; Cochrane and Skrypec, 2014; Nikoleiski, 2015; Jackson, 2018). These sources also stated that samples must be representative.

It was found that three book chapters highlighted that the types of samples collected will depend on the cleaning method applied; for example, for wet cleaning, surface and equipment swabbing, testing of rinse waters or product (for example finished product or 'flushing' materials) should be considered (Cochrane and Skrypec, 2014; Nikoleiski, 2015; Jackson, 2018). Whereas in the case of dry-cleaning regimes, testing of 'flush' materials and finished product is recommended. It was identified that samples should only be taken from a line that has passed a physical validation, as any analytical testing of visually unclean surfaces will just confirm what has been identified visually (Stone, Jantschke and Stevenson, 2009; Stone and Yeung, 2010; Cochrane and Skrypec, 2014; Nikoleiski, 2015; Jackson, 2018).

6.5.3.4 Cleaning verification

The verification of cleaning methods or procedures for food allergen removal was discussed in ten of the selected book chapters; verification must be carried out to confirm that the validated cleaning procedures continue to remain to be effective (Stone, Jantschke and Stevenson, 2009; Gowland, 2010; Stone and Yeung, 2010; Cochrane and Skrypec, 2014; Nikoleiski, 2015; Crevel, 2016; Holah, West and McHardy, 2016; Eisenberg and Delaney, 2018; Jackson, 2018; Marriott, Schilling and Gravani, 2018).

6.5.3.5 Analysis for allergen detection and cleaning verification

The most common method for allergen cleaning verification discussed by eight chapters was visual inspection or audit (Stone, Jantschke and Stevenson, 2009; Gowland, 2010; Stone and Yeung, 2010; Nikoleiski, 2015; Holah, West and McHardy, 2016; Eisenberg and Delaney, 2018; Jackson, 2018; Marriott, Schilling and Gravani, 2018). However, Nikoleiski (2015) did suggest that visual inspections as part of a verification protocol for CIP installations may be impractical and on-going verification or monitoring of the specific critical cleaning parameters would be instead required.

Analytical detection methods for verification of food allergen cleaning were discussed and general information was presented relating to allergen detection in scenarios not relating to validation or verification of cleaning. Different immunological methods were mentioned: LFDs (Stone, Jantschke and Stevenson, 2009; Nikoleiski, 2015; Crevel, 2016; Jackson, 2018; Marriott, Schilling and Gravani, 2018) and plate ELISA testing (Stone, Jantschke and Stevenson, 2009; Crevel, 2016; Jackson, 2018; Marriott, Schilling and Gravani, 2018). In addition, it was highlighted by Stone and Yeung (2010) that any devices or analytical methods used for verification, such as test kits and ATP meters, should be appropriately calibrated to those used for validation with a calibration record being documented and maintained.

PCR was discussed (Crevel, 2016; Jackson, 2018; Marriott, Schilling and Gravani, 2018). Mass spectrometry was also mentioned, though it was noted that this method requires considerable capital resources and a very high level of technical expertise, which can limit its application to research or non-routine uses (Crevel, 2016; Jackson, 2018; Marriott, Schilling and Gravani, 2018). The use of biosensors and flow cytometry was described by Marriott, Schilling and Gravani (2018) for use in the detection and verification of allergen cleaning methods.

Methods detecting ATP were identified for use as a marker to verify or monitor the general cleanliness and removal of soil by cleaning methods, but not allergen cleaning specifically (Stone, Jantschke and Stevenson, 2009; Stone and Yeung, 2010; Holah, West and McHardy, 2016). It was also suggested by Crevel (2016) that detection of the allergenic protein may not be necessary in some instances and instead a marker molecule (for example lactose in milk), which is always found in a known ratio to the allergic proteins and for which a sensitive and robust analytical method is available, could instead be used.

The selected book chapters then seem to suggest that a wide range of analytical techniques are appropriate for both validation and verification of cleaning to remove food allergens.

6.6 Webinars

6.6.1 Literature review results overview

From the search, six webinars were identified with titles indicating that they cover allergen management (including cleaning) and/or cleaning validation and verification (see Appendix 11.16 for details). Due to the scope and time limitations of the current review, a comprehensive overview of all webinar content was not possible; therefore, two were selected to be watched in full and were chosen on the basis that they cover different regions (one from South Africa and another from the UK) and different topics (one on allergen cleaning and another on validation and verification).

6.6.2 The role of cleaning in the management of allergens (Littleton, 2020)

The first webinar selected was entitled 'The Role of Cleaning in the Management of Allergens' delivered by Peter Littleton for Anaphylaxis Campaign in 2020 and was aligned with the publication of the white paper by Christeyns (2020), referenced in Section 6.4. The webinar described the factors that need to be considered when selecting an appropriate cleaning methodology. It was identified that more research is needed on the science behind allergen cleaning, but the large number of factors (for example different food matrices, recipes, allergenic proteins, cleaning methods, detergents etc.) that affect a specific clean mean there are practical challenges. The factors that affect cleaning methodology selection and application were described as applicable to other contexts for example food service, where the common goal of removing debris is the same.

Equipment design was highlighted as a key issue due to its potential to harbour allergen residues. It was noted that equipment is often designed for a specific objective such as efficient processing, engineering ease or hygienic design in terms of microbiological safety, which may impact the efficacy of allergen removal. Some equipment was recognised as easier to clean (for example table surfaces), but this is not always the case for food processing equipment, which can be difficult to dismantle and ensure that all food contact surfaces are cleaned. Common problems were mentioned as well as the potential for equipment to accumulate residues, for example equipment having hard-to-reach areas. Lack of time to properly carry out cleaning, insufficient training and lack of attention to detail were also mentioned. Brushes, scrapers and scourers can accumulate

allergens, and therefore they should be appropriately colour-coded and washed between uses. For equipment, it may be possible to “engineer out” areas where accumulation is likely (for example conveyors can be easily separated for cleaning), but it is also important to evaluate any new equipment thoroughly and determining it’s cleanability.

“Cleanability” was referred to, with factors that affect the selection of a cleaning methodology including form of the foodstuff (i.e. solid, liquid, powder) and porosity/texture of the surface. Stainless steel was described as the easiest to clean (because of its surface properties for example smoothness and the wide range of chemicals that can be applied) followed by aluminium, hard plastic (corrosion may lead to “scoring” and allergen harbourage), soft plastic and rubber (use can lead to “trapping areas”) and cloth and wood (cloth conveyor belts acknowledged as particularly tricky to remove, clean and insert back into place). The importance of considering the food matrix was mentioned, as allergenic proteins are not often present individually, but are in a matrix often with other constituents, such as fats and oils.

The different cleaning methods were listed as manual (for example bucket, brush, disposable wipe), foam/gel (for example detergent application using a pressure gun) and automated (for example CIP, tray wash, robotics) and factors affecting each methodology were discussed. Manual cleaning was emphasised as an important tool that may take a greater amount of time but can often achieve the desired cleaning outcome, with the application of warm solutions, which allow the chemical agents to work at a faster rate, generally more effective. Foam cleaning can be used to clean surfaces faster, but surfaces may still require manual agitation after application. Automatic options can be effective, but there are concerns with allergenic residue carry over. In all cases, the importance of carrying out validation (with ELISAs) and verification (with rapid tests for example LFDs) activities was emphasised. Different detergent types were also outlined, where it was made clear that alkaline and neutral solutions are more suited for allergen removal. It was stated that it is quite likely that a microbiological clean would be suitable for an allergen clean, but it was stressed that validation and verification is necessary, particularly as disinfectants won’t interact with or be effective at removing allergens.

6.6.3 Validation vs. verification in a food factory (van Zijl, 2021)

The second webinar selected was entitled 'Validation vs Verification in a Food Factory Webinar' delivered for Hygiena by Comaine van Zijl for Food & Allergy Consulting & Testing Services in 2021. The webinar highlighted that South Africa has quite stringent legislation on food allergens, specifically a mandatory requirement for PAL and therefore the control of cross-contact is recognised as important.

Validation was described as, "proof that applying an allergen cleaning procedure works prior to commercial manufacturing or when introducing a new allergen (otherwise annually), and verification as demonstrating that the cleaning procedure is carried out correctly, continues to be effective and is continuously monitored after every clean."

Validation requires a rigorous physical audit, including equipment dismantling, and is supported by appropriate testing (for example testing product, environmental swabs, rinse water and 'flushing' samples quantitatively by ELISA, real-time polymerase chain reaction (rtPCR) or LC-MS). It is important to consider areas that are likely to be missed when operators are under time pressures and a 'worst-case scenario' should be used. Verification includes testing surfaces, rinse water and where feasible, the product. Protein swabs are limited to environmental samples which can also be tested with LFDs (and products to an extent).

Taking three consecutive samples to show repeatability was stated to be best practice, and examples were given as to what to do in the following scenarios:

- If after the first run the rinse water is clear but the finished product is not, it is likely that something has been missed in the risk assessment (for example equipment "hot spot", contaminated ingredient).
- If the first run is clear on both samples but not on the second, this indicates that either the cleaning protocol or the sampling plan were not carried out correctly.

Rather than simply repeating results, it was recommended to evaluate where any issues may be coming from, to determine whether the sampling strategy or cleaning methodology need modifying.

During the validation activity, it is important to start to formulate cleaning verification documentation, recording key details (for example swabbing procedures, testing methods), with photographs, and take the opportunity to check verification test kits.

It was stated that it is hard to assess the likelihood of allergen removal based on the allergen only, as cleaning efficiency depends on the foodstuff, how the product interacts with the surfaces and what processing steps are involved. Some allergen forms are easier to remove (for example roasted peanuts) using manual techniques, but those in a “sticky” form (for example peanut butter) can be much more difficult, particularly after having undergone heat treatment or further processing.

7. Report Summary and Discussion

This section of the report provides a summary and discussion of the findings presented in Section 6 (Results). For full details of the studies and literature it is recommended that Section 6 is read before this section to enable a contextual point of reference and better understanding.

7.1 Strengths and limitations of the literature review

This report provides a comprehensive review that takes into account a wide range of different literature types at an international level. The sources comprised literature from 18 geographical regions and also included some that were applicable to a global context. The review both consolidates the available published scientific literature and takes a detailed approach to extract the key principles from guidance documents. In addition, guidance and codes of practice, industry and professional body publications, website pages and other sources were captured to ensure viewpoints from industry bodies and professionals as well as governmental and non-governmental organisations were included. Although a single scientific literature database was used, FSTA was selected to complete an extensive search of the literature and to ensure that the results were from high-quality food-related peer-reviewed articles.

Sources were categorised based on the structure and format of the literature source but not ranked due to the fundamental differences (for example audience, presentation etc.) between each category. The number of citations was provided for studies published in journal articles and theses, where possible, to give an indication as to the prominence of each article amongst the current studies included in literature published in scientific journals on the topic of allergen cleaning. For other types of literature, no relevant figures could be given to signify article prominence within the literature.

The report was limited to the topic of allergen cleaning methodologies, validation and verification of cleaning only, which provided a basis for the article exclusion criteria. Although frequently discussed in the articles selected, the capability of various allergen detection methods available to support validation and verification activities were not explored in great detail (for example strengths and limitations).

The literature search was not limited to a single allergen and included those that are required to be mandatorily declared when intentionally present in food in the UK (retained Regulation (EU) No 1169/2011). Due to time constraints, the literature search was limited to literature published post-2012, but other relevant sources were captured where possible via citation tracking, a process that was conducted to source additional studies referenced in journal articles only. Although the results were predominantly English language sources, Campden BRI's internal international expertise was used to capture relevant non-English language guidance documents and the relevant information was extracted where necessary. All sources underwent a thorough screening and extraction process by two individuals to ensure that only those articles specific to the requested review were included in the report.

It has been 15 years since the previous comprehensive study on the topic of allergen cleaning was published by Jackson et al. (2008). In the meantime, numerous guidance documents have been issued on cleaning to remove food allergens, as well as its validation and verification, and there are ongoing conversations internationally around the issues with allergen cross-contact and the need for harmonisation of PAL. The current report provides researchers, policymakers and industry with a detailed overview of international literature on the subject of cleaning for food allergen removal and provides a solid foundation on which to base future research study designs, develop guidance and subsequent industry practice.

7.2 Comparison between information from different literature sources

Detailed comparisons of cleaning methodologies between literature types were not possible due to wide range of variables included in published studies, as well as the lack of specific methodologies tested outside of published studies in journal articles. Nonetheless, it was clear that each literature type had a general focus, which are summarised below.

Each study detailed in journal articles selected for inclusion was based on a defined investigation of a specific situation. On the other hand, guidance documents described general principles and lacked specific details on the efficacy of methodologies. This finding was expected due to the general consensus found across most literature types that cleaning should take place on a case-by-case basis and is dependent on many

factors such as the properties of the foodstuff produced, the food processing or food service environment and factors affecting the efficacy of the cleaning methodology.

The overarching principles extracted from guidance documents on allergen cleaning validation and verification (and the requirement to carry out such activities) were repeated across the majority of literature types. The basic principles of cleaning, however, were detailed in general guidance on cleaning, but were rarely mentioned in documents specific to food allergens. This lack of detail around cleaning to remove allergens in most sources is likely due to there being no one method for effective allergen removal.

Within industry and professional body publications, there was a focus on practical considerations, particularly the accessibility of equipment (including surface properties) alongside some additional considerations not always covered in guidance, such as the use of dry steam for cleaning. Website pages were presented in a variety of formats (guidance-like webpages, blog articles and government information webpages), some of which covered principles whilst others provided details on some cleaning methodologies, although this was limited to descriptive information about the cleaning protocol. As described in the report, those sources categorised as ‘other information’ were of a disparate nature and therefore could not be evaluated under a single description. Book chapters provided general overviews on the topic and referenced results demonstrating the efficacy of some cleaning methodologies but did not give information beyond that covered by the journal articles that were cited.

7.3 Cleaning to remove food allergens

7.3.1 Importance of cleaning to remove food allergens

One way that cross-contact can occur in food processing and food service environments is when allergenic foodstuffs are handled, prepared or processed on surfaces or equipment or using utensils that are not then cleaned appropriately before preparation of a food product that does not contain those allergenic ingredients, or even any allergenic ingredients. Cross-contact can also occur when allergenic foodstuffs spillage occurs in food handling, storage and transport environments that is not cleaned up appropriately. Such contamination raises concerns around consumer safety for allergic individuals and FBOs alike. Therefore, cleaning is a critical step in preventing contamination or re-contamination of products; physical, chemical and biological cleanliness is a prerequisite

for food safety (Schmitt and Moerman, 2016). It should be remembered that there is a legal responsibility placed on FBOs to produce safe food under the general food law retained Regulation (EC) No. 178/2002.

Cleaning to remove or reduce allergens to an acceptable level is therefore instrumental to the production of safe food. Cleaning is defined by Codex Alimentarius General Principles of Food Hygiene (2020b) as ‘the removal of soil, food residues, dirt, grease or other objectionable matter’ and it is stated that controls to prevent cross-contact from foods containing allergens to other foods should be implemented, for example by effective cleaning between foods with different allergen profiles. Codex Alimentarius Code of Practice on Food Allergen Management for Food Business Operators (2020a) includes recommendations on the management of food allergens by outlining a harmonised approach across the food chain based on general hygiene requirements. The document talks about the need in retail and food service for equipment, utensils, containers and preparation areas to be adequately cleaned (at a minimum visually clean) immediately after the preparation, storage, and dispensing of foods to prevent allergen cross-contact. Whilst in food manufacturing the advice is to develop cleaning procedures designed to remove food allergens to the extent possible. It is stated that such procedures should specify the equipment, utensil, or area of the establishment to be cleaned; the tools and cleaning materials to be used; the sequence of steps to be followed; any disassembly required; the monitoring activities; and any actions to be taken if the procedures have not been followed or if food residues have not been adequately removed.

Following adoption of the global principles laid down by Codex Alimentarius (2020a), the European Union has introduced Commission Regulation (EU) 2021/382, which amends the Annexes to the EU version of the general hygiene Regulation (EC) No 852/2004. The amendments introduce for all FBOs (including primary production) the legal requirement for good hygiene practices to prevent or limit the presence of substances causing allergies or intolerances in equipment, conveyances and/or containers used for the harvesting, processing, handling, transport or storage of foodstuffs. It is stated that such equipment ‘should be cleaned and checked at least for the absence of any visible debris’, if being used in the production of both allergenic and non-allergenic foods.

Other than in the EU, globally there is a lack of specific national or regional legislation relating to allergen management in general or cleaning in particular; guidance in some

countries refers to Codex Alimentarius (2020a), for example Singapore, or the aforementioned EU legislation.

The importance of cleaning is also emphasised by commercial food management standards (for example Global Food Safety Initiative (GFSI) recognised standards such as BRCGS and FSSC 22000), which state that applying an appropriate cleaning procedure is often necessary to reduce issues caused by cross-contact. The development of numerous guidance documents internationally that address cleaning also give weight to its importance.

In the context of cleaning to remove allergens, it is vital to understand that cleaning in this specific circumstance is about removing food soils. Unlike microorganisms, allergens are proteins (i.e. biochemicals), and therefore cannot be 'killed' or necessarily made non-allergenic by cleaning. What classifies as 'microbiologically clean' then does not strictly correlate to 'allergen clean'.

7.3.2 Food service and food processing environments

This study found that the majority of information on cleaning for allergen removal, particularly in guidance, is targeted at food processing rather than food service environments. Over half of the journal articles, however, involved food service scenarios and some information for caterers was found on website pages. Advice and requirements were though skewed towards the use of cleaning methodologies and analysis for validation and verification, that whilst applicable in food processing environments would not be feasible for food service businesses.

With regard to the use of cleaning in food allergen management in different sizes of business, Jackson et al. (2008) referred to studies by US FDA (2006) and Taylor et al. (2006). It was reported that large food production facilities are more likely than small facilities to use cleaning protocols and production scheduling, with 76% using shared equipment (US FDA, 2006). In addition, it was found that 77% of manufacturers include cleaning and sanitation as part of their allergen control plan highlighting its implementation across the food processing industry (Taylor et al., 2006). Subsequently, FSAI (2012) found that food manufacturing businesses generally use scheduling when producing foods that contain allergens, either at the end of the day or before applying a thorough cleaning protocol. Of those that were audited, none used separate production lines and therefore relied heavily on cleaning procedures to control cross-contact.

Interestingly, four out of 12 businesses did not carry out any allergen testing, although the majority tested either the equipment or the final product (one business tested both).

When forming policies, guidance, or even legislation, it is important to consider the practicability of the advice or requirements for different sizes of business and also the different sectors in which such businesses operate.

7.3.3 Basic principles of cleaning

Basic principles of cleaning were not defined in the literature that specifically relates to food allergens, however, as evidenced throughout this report, there was much discussion around the considerations concerning these principles. General guidance on cleaning does provide detailed descriptions of the basic principles including aspects such as hygienic design (of equipment, environment and cleaning equipment), components of the cleaning and disinfection programme (the four fundamental parameters of mechanical or kinetic energy, chemical energy, thermal energy or time), water quality and principal stages in the cleaning and disinfection programme.

It should be remembered that cleaning is not just about allergen removal, it is also used for purposes such as: to remove the majority of the microorganisms present; to remove materials that may conflict with labelling claims or consumer choice preferences for example vegetarian or vegan, Halal or Kosher; to remove materials that could lead to foreign body contamination; to extend the life of, and prevent damage to equipment and services; to provide a safe and clean environment for employees; and, to protect the reputation of a brand by providing a consistent and suitable production/food handling environment (Campden BRI, 2020b). Cleaning and disinfection are undertaken to remove microorganisms and materials conducive to microbial growth, which reduces the risk of contamination by pathogens and by reducing spoilage organisms, maintains the quality of the product and may extend its shelf-life (Campden BRI, 2020b).

Cleaning and disinfection must be designed using a risk-based approach and on a sound technological basis and should be regarded as part of the manufacturing/preparation process. The procedures must be validated by generating and documenting evidence that the cleaning is capable of achieving the desired risk management outcome. There should be written procedures, training provided to those involved and sufficient time allocated for the procedures to be carried out repeatedly and correctly.

7.3.4 Summary of findings from the published literature on cleaning to remove food allergens

The overall finding from the literature described in this study is that cleaning methodologies should be selected on a case-by-case basis depending on the context in which they are to be applied. There are many factors to consider (including for example food matrix, surface, environment, equipment accessibility, cleaning chemical characteristics, concentration and temperature etc.) that make it difficult, and arguably impossible, to suggest one particular method that will effectively clean in all scenarios. As pointed out by Jackson et al. (2008) 'no single wet-cleaning protocol is ideal for all situations', this could be further expanded to 'no single cleaning protocol is effective in all circumstances.'

Published studies within the literature on cleaning to remove food allergens are highly variable and context-dependent, and this is a reflection of the statements above on the many factors that need to be considered. Fryer and Asteriadou (2009) identify that data on the efficacy of cleaning is usually held by individual food manufacturers. As this wealth of information is not available in the public domain it is necessary to try and derive some general meaning from the information that is available. The following sections provide broad deductions on different factors affecting cleaning efficacy for allergen removal from the published literature.

7.3.4.1 Surfaces

The 'cleanability' of surfaces was presented in a hierarchy in multiple sources where it was agreed that stainless steel is generally the easiest surface to clean, whilst wood and cloth are the most difficult (for example Littleton, Walker and Ward, 2021; RSSL, 2022). However, despite the surface material, equipment accessibility, hygienic design and hard-to-reach areas where product build-up can occur still need to be considered. It is also important to inspect equipment, as surfaces can erode and deteriorate over time leading to the potential for residues of allergenic foodstuffs to stick to previously cleanable areas.

7.3.4.2 Soil or matrix type

The physical form of the allergen to be removed (for example solid, liquid, paste, particulate, or powder, aerosol) affects the efficacy of the clean. Although sticky paste residues are often recognised as more difficult to clean than dry residues, this can

depend on the cleaning methodology applied and surface being cleaned. From the studies reported in section 6.1 it is not possible to state which allergen is most difficult to remove, as the form of the allergenic food has such an influence on cleanability. None of the selected studies investigated removal of soils of actual allergen protein as such, but this is not unexpected and would likely not yield results applicable to real-world scenarios.

Proteins have been described as typically the most difficult to remove of the constituents that make up food soils (the other food soil types being fat, carbohydrate and minerals) (EHEDG, 2021a; Jackson, 2018). Although allergens are proteins, it should be considered what the overall matrix containing the protein is when deciding how it should be cleaned, as food soils often contain the different constituents in differing quantities. It is also recognised that processing, in particular heat, can make food soils more difficult to remove (Fryer and Asteriadou (2009); with particular reference to proteins, this is due to their denaturation and consequent adherence to the surface. How long the soil has been in situ, effectively its age, can also affect how easy or difficult it is to remove; with older soils being more difficult to clean (Schmidt, 2018). In addition, build-up of soil and biofilm formation can affect its ease of cleanability (Schmidt, 2018). The nature of the soil should therefore be considered when selecting a cleaning methodology (Jackson et al., 2008).

7.3.4.3 Equipment and environment

The type of equipment being cleaned and the environment in which it is being used can dictate what cleaning methodology is applicable. For example, an automated CIP clean may be possible in some cases, such as piping systems, but not others (for example a mixer). Equipment may not always be accessible and push-through may therefore need to be considered, where feasible. Equipment being used in dry environments cannot be cleaned using water, as this may introduce the potential for microbial growth or affect the quality of the product.

In a food service kitchen, there may be some equipment that cannot be cleaned in an automatic dishwasher, due to its size or the presence of electrical components for example. Different equipment in different environments will determine what cleaning methodology is applicable and appropriate.

7.3.4.4 Cleaning methodology

As already stated, some cleaning methodologies are more suitable for particular purposes than others, but, as to be expected, all have their limitations beyond when and where they can be used. It is recommended throughout the literature that the method of cleaning is designed using a risk-based approach. This section outlines the findings of the review in relation to different cleaning methodologies.

Dry cleaning

Throughout this review it was found to be stated that dry cleaning has limited efficacy for allergen removal, even in cases where surfaces may appear to be visually clean. These findings emphasise the point that appropriate validation is required to understand the capability of cleaning methodologies for the intended purpose. Some guidance specifically states that filtered vacuum systems are preferred over scraping and brushing, but even vacuuming may not be sufficiently effective for allergen removal, hence the need for validation. Dry cleaning techniques may be complemented by the application of a detergent using a ‘controlled wet’ procedure (i.e. use of a commercial ‘wet wipe’, or a cloth, which may be ‘wetted’ with a specific cleaning chemical or antibacterial solution, to clean a surface in a controlled manner), which was found to be effective in some published studies (for example Jackson and Al-Taher, 2010 and Bedford et al., 2020).

There was general agreement throughout the literature that equipment that displaces allergen residues rather than removes them (for example compressed air) should be avoided.

Push-through

As documented in this report, information on push-through is limited, again likely due to the highly context-dependent circumstances under which such procedures are undertaken. The production of chocolate was identified in multiple sources as an example where this type of cleaning method can be effective at allergen reduction. Evidence provided by journal articles notes the variable efficacy of the method and dependence on multiple factors including the food soil or matrix, the push-through material and the equipment; therefore, validation should be carried out for each individual scenario. Again, the use of dry cleaning could be complemented by other cleaning methodologies to increase the efficacy where feasible.

Wet cleaning

Wet cleaning is often referred to as the ‘best’ cleaning method for allergen removal in guidance and grey literature. This point is corroborated by the journal articles referenced in the report, which found a greater efficacy of wet cleaning methodologies (including controlled wet cleaning) compared to dry, although water alone was found to be insufficient. As with cleaning methodologies in general, the overriding finding was that wet cleaning should be selected on a case-by-case basis.

Wet cleaning involves application of a “solution of a chemical product in water at a certain temperature, for the required time necessary to dissolve or loosen soil deposits, and the mechanical action of the cleaning fluid aids in the removal these residues” (EHEDG, 2021a). Sinner’s circle was developed in 1960 (Sinner, 1960), which outlines the four factors that contribute to the efficacy of cleaning methodologies and includes: chemistry (detergent properties); heat application (temperature); mechanical force (impact or shear stress) and detergent contact time (and concentration). A similar expression of the factors is as the acronym, TACT; which stands for temperature, action, concentration and time. This acronym has been further extended to incorporate ‘coverage’ (TACCT) (Tamime, 2008). In the current review, some sources simply list factors affecting the efficacy of a cleaning methodology (particularly for wet cleaning), whilst others describe Sinner’s circle or use the ‘TACT’ acronym. It can be difficult to determine the weight (or relative significance) of each parameter for the particular cleaning context (EHEDG, 2021a). As stated, particularly in Section 6.1.2, it is challenging to interpret the results of disparate studies from peer-reviewed journal articles and use these to come up with guidance, due to the sheer number of variables involved in the different studies. Some comment can though be made on the efficacy of different cleaning formulation chemicals and other key components.

Widely recommended in most literature types in this review is the use of cleaning agents (for example chemicals or detergents, with or without the presence of enzymes) as part of a wet cleaning procedure (or controlled wet in some cases). Information varies throughout the literature from simply stating the overall factors that impact the efficacy to specific advice on what chemical or detergent to use and under what conditions, although specific information is uncommon.

From the literature in this review general principles as to the most efficient chemicals for removal of different soils can be obtained and are summarised in basic terms in Table 12.

Table 122: Summary of the effectiveness of different cleaning materials for removal of different soil types

Soil type	Effective cleaning chemicals for removal of soil type
Carbohydrate	Alkaline, amylases and other carbohydrate-degrading enzymes
Protein	Alkaline or chlorinated alkaline, proteases
Fat	Alkaline with or without surfactants, lipases
Inorganic materials	Acid

Indeed, the most effective cleaning chemical for allergen removal, as evidenced by the selected studies in journal articles (Section 6.1.2.4), was chlorinated alkaline. Acid detergents were found to be variously effective, often depending on the temperature of the cleaning chemical.

Jackson (2018) comments that the use of alkaline plus oxidiser (for example sodium hydroxide in combination with sodium hypochlorite or peroxide) is excellent at removing protein soils, as these chemicals can partially hydrolyse and solubilise proteins. If more general literature around cleaning in food processing and handling is consulted it is found for example that a ‘rule of thumb’ is provided by Schmidt (2018); i.e. that alkaline cleaners dissolve acid soils and food wastes, whilst acid cleaners dissolve alkaline soils (minerals). In fact, acid cleaners are known to precipitate protein, which can make such soils more difficult to remove. Schmidt (2018) goes on to say that removal of many soils and biofilms require ‘more sophisticated’ chemicals containing oxidising agents (such as chlorinated detergents).

It is interesting to note that whilst Galan-Malo et al. (2019) found that use of a detergent with proteases resulted in a significantly reduced occurrence of allergenic residues, Jackson (2018) states that the length of time needed for enzymes to be effective limits their use, as the contact time required may take from a few minutes to several hours.

There is scant mention of the use of enzymes in cleaning throughout the selected literature. EHEDG (2021a) states that “as enzymes are proteins, they can themselves induce allergic reactions when inhaled and thus may pose a risk for operators, therefore a suitable risk assessment should be carried out before their use”. Campden BRI (2020b) points out that cleaning products containing enzymes are especially susceptible to heat degradation.

It is clear that some chemicals are generally not effective in food allergen removal; disinfectants and sanitisers may be used in cleaning operations to reduce the level of microorganisms, however, they alone are not effective at removing allergenic food soils (Jackson, 2018).

In addition, some chemicals are not suitable for certain surfaces or circumstances, for example acid and highly alkaline cleaners can damage aluminium surfaces, rendering them ‘non-cleanable’ (Schmidt, 2018). Chlorinated alkaline is not recommended for use in CIP as the "in use temperature" will cause the chlorine to be vented, which is itself corrosive to stainless steel (N Blitz 2023, personal communication, 13 March).

Again, the choice of cleaning chemical will depend on the soil to be removed and it should be remembered that although allergens are proteins, consideration should be given to the matrix containing the protein when deciding how it should be cleaned.

The use of commercial dishwashers in food service scenarios was included in studies investigating the efficacy of cleaning in school canteen kitchens (Galan-Malo et al., 2019 and Ortiz et al., 2018) where cleaning was found not to be effective for all utensils. Information on allergic reactions occurring during the study described by Ortiz et al. (2018) were also reported (Ortiz-Menéndez et al., 2019); there was a significant relationship between episodes of food reaction (not requiring epinephrine) and positive egg LFD results, suggesting that the presence of egg traces in the school kitchens may have contributed to the appearance of these reactions. A case study conducted by Arrowsmith, Ng, Clarke and Brown (2009, Campden BRI Research Summary Sheet (2009-42) Cleaning validation for removal of allergens: comparison of ELISA or dipstick tests, not published in the public domain) demonstrated plates on which fried eggs had been served in a food service establishment, were still found to have a residue of egg white protein after dishwashing when tested using an ELISA, but were negative using an LFD for egg.

In addition, washing by hand in food service environments was included in few studies (for example Galan-Malo et al. (2019); Schembri (2017); Ortiz et al. (2018)) and was found to be variously effective. A case study conducted by Arrowsmith, Ng, Pettit and Brown (Campden BRI Research Summary Sheet (2009-50) Efficacy of cleaning and management controls for allergens in catering establishments, not published in the public domain) showed that a sponge used to clean a pan that had contained poached eggs tested positive for egg using an ELISA test for egg. When the same sponge was used to clean a tray that had been used to cook bacon, swabs of the tray were positive for egg. The sponge tested positive for egg after it had been used for manual cleaning throughout an eight-hour shift.

More work is needed, therefore, to elucidate the efficacy of cleaning to remove allergens, in different forms and matrices, from a variety of surfaces by commercial dishwashers and washing by hand.

7.3.4.5 Laundry and hands

Clothing and hands are potential sources of cross-contact in food processing and food service environments and yet few literature sources described the need for appropriate handwashing and laundering techniques to reduce cross-contact, nor did much of the published literature measure the efficacy of such techniques. Where it is discussed, findings show that water alone is not sufficient for allergen removal.

Two of the journal articles reported on in this review (Schreder et al., 2013 and Aleksić et al., 2020) respectively found that cleaning work surfaces, tools or hands and gloves with detergent or soap is sufficient to prevent cross-contact and that cleaning of hands in combination with replacement of protective clothing and the most stringent cleaning regime was also effective. Whilst Perry et al. (2004) found that peanut butter applied to the hands of volunteers was effectively removed by liquid soap and bar soap.

Arrowsmith and Brown (2006, Campden BRI Research Summary Sheet (No. 2006-69) Laundering to remove allergens from protective clothing worn in food factories, not published in the public domain) conducted a case-study to determine whether laundering is effective at removing allergens from protective clothing, and to examine whether protective clothing could become contaminated with allergens in the laundry. Results demonstrated that protective clothing worn in two food manufacturing environments, one dealing with nuts, the other with prawns, has the potential to be contaminated with

allergens to a significant level. However, laundering removed allergens from the overalls in the study described. In the specific scenarios studied, the laundry was not a source of cross-contact of protective clothing; however, it was advised that testing of protective clothing for allergen residues following laundering should be considered as part of the validation of allergen control measures in food handling environments.

The studies described demonstrate that the influence of protective clothing, its laundering and washing of hands must not be excluded from future studies into cleaning efficacy where relevant.

7.3.4.6 Cleaning equipment

It is pointed out that the use of equipment (such as brushes, scrapers, brooms and vacuums) can support effective cleaning, particularly in dry environments where water cannot be used, but such equipment can itself be a potential source of allergen cross-contact (Littleton, Walker and Ward, 2021). Where possible, the use of dedicated cleaning equipment is encouraged to minimise cross-contact and the benefits of having different coloured equipment for certain allergens are explained (Teng, 2013; Smith, 2019; FDE 2022). In addition, it is recommended that hygienic design of cleaning equipment is important but is not always considered (Smith, 2015; Smith, 2016; Smith, 2019).

7.3.4.7 Costs

Cost considerations were rarely discussed in the literature reviewed, despite the recognition that cleaning and change-over procedures are recognised as a key factor for allergen management, with an annual cost estimate per company of $1M to $2.5M, based on small companies (those with earnings of ≤$500 million annually) and large companies (those with earnings of >$500 million annually) (Gupta et al., 2017). Factors that affect the cost include those relating to the cleaning methodology, such as labour and supervision, chemicals, water heating and cleaning equipment. It was described that 60% of the cost is for appropriate labour and supervision (Uğurcan, 2022), whilst detergents and cleaning solutions have a low contribution to cost (5%) but have a large impact on efficacy (Holah, 2014).

Colour coding of equipment to more easily prevent and manage cross-contact was described as a low cost initiative (Teng, 2013).

Based on the information extracted throughout the report, the below bullet points summarise some of the factors that may affect the cost of the cleaning methodology selected:

- Wet cleaning: the need for appropriate cleaning agents; chemical expertise; water; energy; training to ensure equipment is used effectively and procedures are carried out appropriately.
- CIP: purchase and operation of specialised equipment as well as the same considerations as for wet cleaning; although reduced labour and supervision required.
- Dry cleaning: physical equipment (considering any additional premium for colour-coded equipment); equipment maintenance; potential additional labour costs compared to other methodologies; potential risks due to issues with cross-contact.
- Push-through: flushing material and the quantity required; costs (and reduced productivity/increased downtime) to carry out validation studies.

7.3.4.8 Inconsistent terminology

Throughout the literature, terminology is not always used consistently. For example, sometimes push-through is included under the definition of dry cleaning. Controlled wet cleaning is not always highlighted as a separate cleaning methodology and is sometimes also grouped with dry cleaning due to carefully controlled application of water or a cleaning agent before wiping. Some sources refer to the operational modes of cleaning i.e. mechanical, foam or gel, automated (CIP) which have also been categorised as either dry cleaning, deep cleaning, inter-product ‘changeover’ cleans or automated cleaning. Others group on the basis of the cleaning energy required i.e. mechanical, thermal or chemical, or even on the basis of physical (for example scrapers), chemical (for example cleaning with hot water or detergent) or biological (for example ultraviolet light).

In addition, there are nuances between use of the terms ‘cross-contact’ and ‘cross-contamination’. The term ‘cross-contact’ is used internationally and is defined by Codex Alimentarius (2020a) as occurring “when an allergenic food, or ingredient, is unintentionally incorporated into another food that is not intended to contain that allergenic food”. WHO (2006) explain that ‘cross-contamination’ refers to “the introduction of microorganisms or disease agents from raw food into ready-to-eat food making it unsafe”. In some places the terms are used interchangeably, or ‘cross-contamination’ is

qualified by stating ‘allergen cross-contamination’ (for example, Government of Canada, 2019). A consensus on use of the terms would aid harmonisation of understanding.

The terms ‘validation’ and ‘verification’ are also not widely understood and therefore need definition, see Section 7.4 for further information.

7.4 Validation and verification of cleaning for allergen removal

Effective cleaning is widely accepted, as part of a wider allergen control plan, as one of the best strategies for preventing or minimising allergen cross-contact in food processing and food service environments, particularly where lines, equipment, utensils or areas are used to prepare foods with different recipes, without allergens or containing different allergens. This use of cleaning as a control measure, defined as ‘any action and activity that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level’ (Codex Alimentarius, 2020b), is therefore well established.

Legislation (retained Regulation (EC) No 852/2004 on food hygiene) lays down various principles relating to food hygiene, including that primary responsibility for food safety is borne by the FBO. In addition, the legislation underpins the requirement that FBOs shall put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles. Codex Alimementarius General Principles of Food Hygiene (Codex Alimentarius, 2020b) lays down the HACCP principles by international consensus; of relevance is principle 3 ‘the requirement to establish validated critical limits.’ Principle 3 then goes on to state that, “criteria often used include minimum and/or maximum values for critical parameters associated with the control measure such as measurements of temperature, time, moisture level, pH, aw, available chlorine, contact time, conveyor belt speed, viscosity, conductance, flow rate, or, where appropriate, parameters that can be observed, such as a pump setting.” Many of these variables have been documented specifically previously in this text.

This then also relates to principle 6 ‘validate the HACCP plan and then establish procedures for verification to confirm that the HACCP system is working as intended.’ This includes CCPs, critical limits and control measures. It could be considered that while allergen management may not typically be a CCP to an FBO, it could certainly be a control measure, thus requiring validation.

Validation and verification are, therefore, inherent principles of HACCP. These activities are explained further in Codex Alimentarius Guidelines for the Validation of Food Safety Control Measures (2008) and are incorporated into GFSI-benchmarked standards including for example BRCGS.

However, it is rarely the case that the hazards associated with allergens can be controlled at a particular step in the manufacturing process. Control of such 'generic' or site-wide hazards, i.e. those that may impact many steps of the process and are not specific to a particular process step, is therefore achieved by good manufacturing practices. Allergens must therefore be considered as part of the FSMS (European Commission, 2022).

It is important to consider the definitions of validation and verification to truly understand the activities involved in each, as there is sometimes misinterpretation of the terminology; the following definitions are from Codex Alimentarius (2020b):

- Validation of control measures: Obtaining evidence that a control measure or combination of control measures, if properly implemented, is capable of controlling the hazard to a specified outcome.
- Verification: The application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure is or has been operating as intended.

Another term that is often used, but misconstrued is also defined (Codex Alimentarius, 2020b):

- Monitoring: The act of conducting a planned sequence of observations or measurements of control parameters to assess whether a control measure is under control.

With specific reference to food allergens, the Codex Alimentarius Code of Practice on Food Allergen Management for Food Business Operators (2020a) states that "the validation process should be specific to the allergen, process and product matrix combination. Cleaning processes should be verified through visual observation (checking that equipment is visibly clean) and, where feasible and appropriate, through an analytical testing program." It is pointed out by Schmitt and Moerman (2016), however,

that cleaning validation is not necessarily required for potentially non-critical cleaning of floors, walls and the outside of equipment, unless required by hazard evaluation.

7.4.1 Summary of findings from the published literature on validation and verification of cleaning for allergen removal

Other than Jackson (2008), peer-reviewed journal articles did not detail principles for validation and verification of cleaning to remove food allergens. Most information in this area was provided in guidance documents, where 61% of the selected sources stated that validation of allergen control measures is required. Of those, 33% referred to the majority of principles of validation as established from the selected sources. Verification was discussed in all but one of the documents that detailed cleaning validation. Industry and professional body publications mentioned validation and verification with reference to cleaning for allergen removal, but unsurprisingly based on the length and detail of the articles only topline information was available on the whole. Websites and other information sources (such as white papers and presentation slides on the internet) either didn't mention validation and verification, mentioned it briefly or were focussed on it as the main topic of the source. Similarly, book chapters and webinars either provided limited information beyond the requirement for validation and verification or were specifically focussed on this area.

There did not seem to be discernible differences between guidance from different areas of the world.

7.4.1.1 Principles of validation and verification of cleaning to remove allergens

Jackson et al. (2008) remarked on a lack of consensus on the principles of validation and verification of cleaning to remove food allergens at that time. Subsequently, and not specifically relating to allergens, the food industry has seen international consensus on the validation of food safety control measures in guidance from Codex Alimentarius (2008), peer-reviewed literature (for example Schmitt and Moerman, 2016) and guidance, such as 'Cleaning Validation, Monitoring and Verification' (EHEDG, 2021b), which is based on the recommendations of guidance from the pharmaceutical industry. The general principles of validation and verification then are well established.

Specifically relating to food allergens, this review found various sources of information and general agreement between them in terms of the principles of validation and verification of cleaning to remove food allergens that were mentioned; however, only two of the guidance documents detailed all the principles established in this review. It remains then that consistency of the extent of advice on the principles in relation to validation and verification of food allergen cleaning is lacking.

The food industry would benefit from consensus and consistency in guidance relating to both validation and verification of cleaning for allergen removal.

7.4.1.2 Visual inspection

One area among the literature where there was divergence was around the use of visual inspection in validation and verification of cleaning to remove food allergens. Some references only mentioned checking for visually clean for verification, not validation. Generally though there was agreement that where visual inspection is used it should be in combination with appropriate analytical testing.

It is clear that visually soiled surfaces following a clean suggest a failure to adequately remove the food soil, meaning that the likelihood allergenic proteins are present increases. But it was reported in some of the journal articles that, even when surfaces seem to be visually clean, analytical tests can still detect the presence of allergenic food soils. Visually clean then should be the first objective in any cleaning regime, but there is also a need for analysis of environmental samples (such as swabs of surfaces, rinse waters, flush-through material, where relevant) and product samples to fully understand the capability and on-going efficacy of the cleaning regime where appropriate and feasible.

7.4.1.3 Analytical detection of food allergens in cleaning validation and verification

The lack of the use of allergen analysis, particularly by SMEs is evidenced in a report for the FSA (FSA, 2022). It was found that overall, allergen testing by SMEs as part of risk analysis process was minimal. There was some testing of pathogens and particularly cleaning validation for microorganisms for manufacturers. There were two examples of an allergen being tested to validate a free from claim in the study. There were no examples of allergen cross-contact being tested to support the use of PAL, either as cleaning validation or a product test.

In addition, Jackson et al. (2008) reported on a survey that had been undertaken by the US FDA in 2001 (link no longer available). The survey was carried out on businesses that had had previous issues with allergen cross-contact and found that only 4% utilised analytical testing to verify cleaning, highlighting an association with the use of allergen detection methods and reduced contamination. The percentage compared to overall industry figures was reported to be vastly different, as a report from the Institute of Food Technologists (IFT) (also reported by Jackson et al. (2008)) found that than 85% of companies validated cleaning programs and 71% conducted analytical testing to verify that the cleaning programs were effective. Of concern considering the findings of this current literature review is the result that at the time visual inspection was the most common verification method for the majority of companies (100% of small companies, 90% medium, 93% large) despite a lack of evidence supporting it's effectiveness. The second most popular method was ELISA testing, although this was carried out by a much smaller number of companies (15% of small companies, 38% medium, 52% large). A more recent survey of Canadian food processors by Dominguez et al. (2022) found that 81% confirmed cleaning procedures using allergen-specific swabs, followed by 75% using ATP and/or general protein swabs, and 75% using visually clean inspections. Results suggest that there has been a shift away from visual inspection as the main method of detection to more allergen-specific techniques, although geographical differences and regulatory contexts may also contribute to the perceived difference.

When discussing analytical methods for detection of food allergens many sources provided general information on how the methods work. Some made comment on the use of particular methods in specific circumstances, for example Jackson and Al-Taher (2010) talked about the importance of using visual inspection in combination with either ELISA or total protein swabs for detecting the presence of allergenic food residues after dry cleaning equipment surfaces. From the journal articles lack of agreement between results from different methods was evidenced. The findings show that it is important to select test methods carefully, to consider their inherent benefits and limitations, and what is most applicable to the specific situation. Use of a combination of tests is encouraged (for example Chen et al. (2022)) and frequently imparted is the advice to validate tests for their intended purpose, especially for the specific samples collected.

This need to validate tests relates not only to those that specifically detect food allergens (for example ELISAs or LFDs), as it is know that different factors (such as the food matrix and the processing the sample as undergone) can affect their efficacy, but also and

perhaps more so, the tests that are indirect measures of cleaning efficacy. In particular, tests for the detection of ATP have variously been found to be comparable, but more frequently, non-interchangeable with specific food allergen tests.

Of most relevance to cleaning validation and verification for allergen removal are tests specific for food allergens, not only because these have been found to be more sensitive than other tests (with plate ELISAs being more sensitive than LFDs, and both generally being more sensitive than total protein tests, for example), but also because they are the most clinically relevant (due to them detecting protein from allergenic foods, which is the constituent to which allergic people react). Such tests, however, are not always available, or they may not be appropriate, for example due to ease of use, cost, possible interference or cross-reactivity due to the matrix being tested or the processing that the samples have undergone. In which case the general advice is to test using the most specific, relevant, sensitive tests for validation and alongside the non-specific tests that will be used for verification, to check for agreement or at least to understand the limits of those methods.

In terms of acceptable levels, consensus is on the whole that for cleaning validation, the lower limit of quantification (LLOQ) should be considered. As stated in this report, much work is being undertaken at the time of writing regarding the use of ‘thresholds’ or ‘action levels’ for PAL and information; however, these should not be regarded as ‘acceptable limits to work to’, but rather as an approach to harmonised data gathering and methodologies for food allergen risk assessment (ILSI Europe, 2022). Mention was made in one guidance document (AFREA, 2014) of HACCP critical limits. Codex Alimentarius (2020b) states that a deviation from the critical limit indicates that it is likely that unsafe food has been produced. In addition, critical limits for control measures should be specified and scientifically validated to obtain evidence that they are capable of controlling hazards to an acceptable level if properly implemented. Critical limits could be based on existing literature, legislation or guidance from competent authorities, or studies carried out by a third party for example studies conducted by an equipment manufacturer. Validation of control measures are further described more fully by Codex Alimentarius (2008).

ATP tests were mentioned throughout the literature in relation to allergen cleaning validation and verification on the whole with a note of caution. As summarised by Courtney (2016) “ATP testing is not ideal for allergen detection as it does not specifically

detect allergen proteins and various factors can influence the [..] readings which complicate the determination of a limit value".

One source not included in the book chapters results section of this report, as it is not focussed on cleaning, validation or verification per se, so was not picked up during the initial searches relates to sampling for food allergens (Brown and Arrowsmith, 2015). It is pointed out that sampling is a critical part of analytical testing for food allergens, and its significance can not be overemphasised. Information is provided on approaches to sampling (representative sampling, selective sampling, random sampling and composite sampling), sample types (food samples, rinse water, wash water and flushing materials, settle plates to sample allergens deposited from the air, environmental swabbing) and ensuring the quality of samples. This information is therefore relevant to cleaning validation and verification where samples are collected and should be considered.

In summary then, there is no one straight answer as to what is the best test to use, as this will depend on factors such as the situation, the question/s being asked, the sample type, the sample matrix, whether tests are to be conducted on-site in the production facility or by an analytical laboratory and any time limitations for example. As the choice of detection methods for food allergens can be complicated, it is best to seek the advice of experts (for example test kit suppliers or an accredited testing laboratory) to determine the most appropriate tests, whilst designing the cleaning validation, i.e. before sampling commences. In addition, understanding the results can be complex, it is recommended (Codex Alimentarius, 2020a) that, if necessary, the FBO should obtain expert advice on interpretation of results (again from the test kit supplier or an accredited testing laboratory).

7.4.1.4 Interference of cleaning chemicals in allergen detection tests

There was limited evidence in the peer-reviewed journal articles of the potential for interference of cleaning chemicals with allergen detection methods. Such chemicals may be present in samples such as rinse waters from cleaning operations or equipment, such as tray washers, or even in swab solutions from surfaces from which disinfectants have not been rinsed.

In a thesis by Courtney (2016) removal of milk soils from various food processing surfaces was investigated by commercial milk-specific LFDs and general protein tests. It

was found that the caustic solutions gave false negative results with LFDs, while the sanitiser caused false positive results with a general protein kit.

In a study by Arrowsmith and Brown (2006, Campden BRI Research Summary Sheet (No. 2006-67) Effect of cleaning fluids on detection of allergens, not published in the public domain), when cleaning fluids alone were tested directly at their recommended working concentration, a number of false positive results were obtained in different brands of allergen ELISA test kits and a general protein test. However, false positive results were found to depend on the particular combination of a specific cleaning fluid with an individual test; no one fluid gave false positive results in all the tests and no one test had false positive results for all concentrations of cleaning fluids. When testing a known concentration of allergen in the presence of cleaning fluids at the working concentration, some false negative results, and interferences in terms of higher and lower than expected results, were observed.

Sanitisers are a detergent plus disinfectant blend and must therefore be rinsed from surfaces due to the detergent component. Disinfectants with a defined maximum residue level (MRL), set under biocides or pesticides legislation, are not required to be rinsed from surfaces if the user can prove that they do not exceed the MRL after the recommended contact time. Those that do not meet the relevant MRL must be rinsed off, as is the case for quaternary ammonium chloride compounds (quats), for example (N Blitz 2023, personal communication, 22 March). Some disinfectants may therefore remain on surfaces following cleaning.

In the study reported above, Arrowsmith and Brown (2006, Campden BRI Research Summary Sheet (No. 2006-67) Effect of cleaning fluids on detection of allergens, not published in the public domain) found that when alcohol was used as part of the terminal clean of filler nozzles after packing pasteurised soya milk, the alcohol showed no effect in a soya residue ELISA, but gave a false positive in a general protein test. In this case the ELISA was suitable for validation work, but the general protein assay was not.

These studies show that when samples that may contain cleaning fluids (for example wash waters, rinse waters, swabs from surfaces with terminal disinfectants) are analysed for the presence of allergens, the cleaning fluid should be tested both alone and in the presence of the allergen to confirm there is no interference with the test being used. This

is important to avoid arriving at the wrong conclusion about the presence or absence of food allergens.

7.5 Evidence gaps in the published literature

This review found that only six allergens (milk, soy, peanut, egg, hazelnut (as just one of the eight nuts), gluten (as a marker for cereals containing gluten)) were included in studies in peer-reviewed journal articles, meaning that for eight of the allergenic foods requiring mandatory labelling declaration in the UK (celery, crustaceans, fish, lupin, molluscs, mustard, sesame, sulphites) plus the remaining nuts (almonds, walnuts, cashews, pecan nuts, Brazil nuts, pistachio nuts, macadamia or Queensland nuts) there was no published literature investigating the efficacy of cleaning found during the review period of ten years (2012-2022). Of the matrices or soils studied few were heat treated, or for those that were the soils were unrepresentative substances like slurries containing peanut flour, skim milk powder, whole egg powder, soy flour, soy milk and soy infant formula powder, rather than foodstuffs typically present in food service kitchens, such as scrambled or fried egg for example.

It was also found that there was more published literature covering wet cleaning methodologies compared to dry, push-through or controlled-wet methods. Only one study was carried out using CIP (albeit in a simulated environment). Where automatic dishwashers were mentioned it was generally as part of much larger studies, so it was not always possible to deduce results specific to this cleaning methodology. Studies on these cleaning methods did not specifically investigate the reuse of cleaning fluids in CIP or recirculation of water in automatic dishwashers for example; one study, however, did implicate partial recirculation of water in a dishwasher for higher levels of allergen contamination of utensils washed using this method (Galan-Malo et al., 2019).

COP was not referred to specifically; although several studies utilised this methodology it was difficult to form conclusions on its efficacy due to the confounding factors between the different studies, or the lack of specific information on the effectiveness of this cleaning methodology. OPC, however, which involves for example conveyor belt removal and cleaning ‘in situ’, was not studied.

Although some journal articles investigated food service scenarios, most literature types focussed on food processing environments suggesting that there is a gap for general principles and guidance for cleaning methodologies suitable for food service and any

additional considerations that need to be taken into account for cleaning validation and verification in that context.

It is also clear, with respect to food service, that further evidence on the efficacy of handwashing, laundry and dishwashing appliances is needed.

In terms of detection of food allergens, it is widely reported that even when surfaces seem to be visually clean, analytical tests may still detect the presence of allergenic food soils. It is unclear how the detection of residues on visibly clean surfaces relates to contamination within foodstuffs. It is pointed out by FDE (2022) that in risk assessment terms, the important consideration is the extent to which any residue transfers to the product.

Further outlined in the report is the lack of information on cost considerations for different cleaning methodologies in the context of cleaning to remove food allergens.

The lack of information about the efficacy of cleaning for allergen removal in the public domain could be improved if more could be done to investigate current industry practices and examine data held by FBOs, cleaning chemical manufacturers, cleaning services providers to the food sector and other organisations to understand the variety of methodologies applied and their efficacy in specific contexts. It remains, however, that it is difficult to directly extrapolate from cleaning practices in food processing to food service, where the time, resources and expertise are generally not available, especially in micro, small and even medium businesses.

7.6 Emerging cleaning methodologies for allergen removal

The literature review detailed throughout this report was primarily focussed on existing cleaning practices for allergen removal, as not only was this area where most information was found, but arguably these methods are most relevant to the intent of this review, i.e. as a starting point in co-developing allergen cleaning guidance with industry. It was found, however, that in various publications mention was made of emerging cleaning methodologies, which are being developed in part to fulfil the need of FBOs looking to improve the efficiency of their processes and reduce energy and water usage. But, as these methods are generally still at the development stage (some of the published studies describe this development) and are not in routine use, they have not been

included in the preceding sections of the report. This section discusses some examples of emerging cleaning techniques and provides illustrations of where their efficacy has been studied in regard to allergen removal.

Ultrasound (sonic waves above human-hearing threshold) has been used for a wide range of food processing operations both in research laboratories and commercially; including for example for cutting, food preservation, defoaming, degassing and sealing packages (McHugh, 2016). Ultrasound can be used for surface cleaning of a wide range of materials (Otto et al, 2011), such as conveyor belt materials, and is generally applied at laboratory scale using sonication baths or ultrasonic probes. Axelsson et al. (2013) used an ultrasonic probe mounted on a rig above petri dishes containing pieces of conveyor belt materials (polyurethane and polyvinyl chloride) that had been soiled with dried suspensions of wheat flour or skimmed milk, to demonstrate that allergen residues were removed more efficiently by ultrasound procedure than by rinsing with water only, as determined by allergen-specific ELISA testing.

Wet steam (water vapour at the boiling point of water, containing water droplets) has long been used for cleaning, and whilst although the use of **dry steam** (water vapour at the boiling point of water but without water droplets) as a cleaning tool has become much more common in recent years, the technology is still very much confined to certain niche segments within the cleaning industry (Stücken, 2017). Yan et al. (2013) investigated the use of a dry steam vacuum-cleaning device to remove peanut butter, soy protein and egg white soils dried onto the surface of two conveyor belts (vinyl fabric-reinforced and polyurethane solid-homogenous-plastic). LFDs were used to test for allergen residues remaining on the conveyor belts following cleaning until the surface was visibly clean. It was found that peanut butter was more difficult to remove than soy and egg white from the vinyl fabric reinforced belt, but all of the three soils were effectively removed from the polyurethane solid-homogenous-plastic belt. The use of **superheated steam** (water vapour at a temperature higher than the boiling point of water that does not contain water droplets) in cleaning is being investigated for the inactivation of microorganisms (for example, Labs, 2023). Rana et al. (2022) applied peanut butter and non-fat dry milk to aluminium foil coupons, which were then treated with superheated steam. It was found that as the duration of superheated steam treatment increased, the ease of visual removal of peanut butter from surfaces increased, however, the ease of non-fat dry milk removal decreased. Allergen residues were though detected on surfaces using allergen-specific LFDs, regardless of the duration of superheated steam treatment. Changes to

the microstructure (by scanning electron microscopy) of the non-fat dried milk soil were attributed to the high lactose content. In addition, severe colour changes of the non-fat dried milk were recorded after superheated steam treatment; such modifications may be due to the soil becoming ‘baked’ onto the surface by the high temperature.

Enzymes are proteins that catalyze chemical reactions (Timmerman, Mogensen and Graßhoff, 2016). Enzyme-based cleaning is not yet commonly used throughout the food industry (Delhalle et al., 2020), however, processes for enzymatic cleaning of equipment and plants in the egg and meat processing industry, ice cream manufacturing and dairies have been established (Timmerman, Mogensen and Graßhoff, 2016). Fuciños et al. (2019) studied the effectiveness of proteolytic enzymes to remove gluten residues and the feasibility of incorporating them into cleaning products for industrial purposes. Preliminary validation of the effectiveness the enzymatic cleaning formulation developed to hydrolyse gluten was performed in a ready-to-eat/frozen food company. It was found that after application of the enzymatic formulation, with a contact time of five or 15 minutes, followed by rinsing with water, the gluten content decreased to values lower than 0.125 µg/100 cm^2 (i.e. lower than the detection limit of the R5 gluten ELISA used).

Other emerging techniques that are being investigated for their potential to be used for cleaning, and that may be of use for allergen removal, are cold plasma and surface texturising (D Bayliss 2023, personal communication, 18 May). **Cold plasma** is otherwise referred to as the 4th state of matter, created when enough energy is applied to a gas to achieve a plasma discharge. **Surface texturising** involves the use of super hydrophobic surfaces to support easy rinse down and reduced bacterial adhesion. The application of these techniques to cleaning is currently in the early phases of development, future research will be required to assess efficacy and applicability to the food industry.

8. Conclusions

This report has reviewed and consolidated findings from literature published post-2012 on cleaning to remove food allergens. The sources include peer-reviewed literature published in scientific journals as well as guidance documents, industry and professional body publications, information on websites, book chapters and webinars, from different geographical regions.

Cleaning to remove food allergens is part of a holistic food safety management system the purpose of which, with specific reference to food allergens, is to prevent or minimise the potential for allergen cross-contact that is of risk to the consumer with food allergy and to ensure that accurate information about food allergens can be provided to consumers on the label of prepacked food or at the point of sale when the food is not prepackaged.

It is widely agreed that cleaning should be applied in any part of the food handling, manufacturing/preparation, storage environment where allergenic protein may have been in contact, and which could result in allergen cross-contact. The importance of hygienic design, effective management (including cleaning and colour coding where possible) of equipment used to conduct cleaning is recognised, as such equipment can itself be a potential source of allergen cross-contact.

The general consensus across the different literature types was that cleaning methodologies should be chosen on a case-by-case basis, as many factors affect cleaning efficacy (including for example food matrix, surface, environment, equipment accessibility, cleaning chemical characteristics, concentration and temperature etc.). Principles of cleaning to remove food allergens are therefore aligned with the general principles of cleaning.

Nonetheless, ‘wet cleaning’ was continuously endorsed as the most effective methodology for the removal of allergenic residues; it is, however, recognised that this method may not be applicable in every situation. In terms of cleaning chemicals, again their selection depends on the situation and the overall matrix of the food, as it is the food soil that needs to be removed, not just the allergenic protein. However, it was often remarked that chlorinated alkaline seems to be more effective than acid detergent for removing allergenic foodstuffs.

Principles of allergen cleaning validation and verification were identified from the literature and are collated in this report as principles; these principles are understood to be important when undertaking validation studies and subsequent verification activities.

There was consensus among the selected literature that ‘visually clean’ should always be the first monitoring control point, for areas across food handling, manufacturing, preparation, packing processes and storage, prior to any further types of cleaning and prior to applying any analytical testing.

In-depth discussion of the inherent limitations of different analytical techniques has not been included, however, the need to use specific, sensitive, relevant, validated testing methods has been discussed. It is also found that many sources state that visual inspection should not be the only method of gauging cleaning efficacy, as visually clean surfaces may still harbour detectable allergen residues.

Ultimately, much of the available information relates to large food processing operations; there are evidence gaps throughout the literature on cleaning to remove food allergens in food service and micro, small and medium food processing businesses. It is recommended that research is therefore needed to acquire knowledge of the efficacy of existing cleaning procedures and to inform best practice guidance for these businesses in future.

9. Recommendations

In view of the remit of this review, to identify gaps in the published literature to inform further research and guidance development, the gaps are summarised in Section 7.5. This section details recommendations relating to areas not covered by, or where there is disparity among, the published literature that need elucidation before the development of future guidance. Points to consider when developing guidance are also included.

9.1 Research needs

Much of the published information on efficacy of cleaning for allergen removal relates to food processing or manufacturing environments. To enable guidance to be widely applicable, research is required into the removal of difficult to clean foodstuffs from relevant surfaces in 'real-world' scenarios, encompassing food service as well as, micro, small and medium food processing or manufacturing businesses. Studies are needed into the capability of existing, widely applicable cleaning practices to demonstrate what is achievable; for example, in food service, by the use of commercial dishwashers. It is not necessary to study all the allergenic foods listed in Annex II to the FIC that require mandatory labelling declaration in the UK, but rather to base the research on worst-case, or most difficult to remove, food soils. It would also be of benefit to investigate current industry practices and examine data held by FBOs, cleaning chemical manufacturers, cleaning services providers to the food sector and other organisations to understand the practical application of different cleaning methodologies and their efficacy in a variety of contexts.

Studies in food service should include a range of foods that are known to be difficult to remove, such as cooked egg or heated milk, from surfaces such as crockery (for example plates and bowls), utensils (for food preparation and cutlery), kitchenware (pots and pans) and bakeware (baking trays and sheets), as well as other equipment that may be washed in a dishwasher or by hand. It should be considered as to whether dishwasher manufacturers may have recommended protocols or businesses themselves know what procedures work for them (for example, prior to dishwashing, first scrape or pre-clean dishes and utensils to remove visible food debris, then soak

in a pre-wash sink, how long for, and at what temperature). It may be that a prewash cycle is recommended and there is advice on draining and cleaning dishwashers regularly; the effect of these factors on cleaning efficacy in the context of allergen removal should be considered in research to enable recommendations to be made. Different types of dishwasher should also be investigated, particularly those involving recirculation, to check for cross-contact potential.

A lack of information on the efficacy of manual cleaning in food service establishments was also evidenced; it may be possible here to provide pragmatic guidance on the use of dedicated cleaning equipment (for example sponges and cloths) and the need for water changes between washing equipment contaminated with different allergens, without the need for research. Guidance on communication of such best practice advice should be provided to aid with staff awareness and understanding by training. It would, however, be beneficial to look at the efficacy of different types of detergents in these scenarios, bearing in mind the range of chemicals that are appropriate for use in food service settings.

Another area where there is potential to provide practical guidance without research is around washing of hands, where literature shows that soap and (warm) water are effective at removing food allergens, but hand sanitisers, sanitising wipes and water alone are not.

For laundering of workwear, for example overalls, mop caps and beard snoods, again the capability of existing practices is not covered in peer-reviewed studies from the last ten years. In addition, the potential for cross-contact either of food within food handling areas or between the clothing in the laundry was not found to be investigated in the selected literature. This may be another area where information is held by individual food processors, those laundering workwear or the washing machine manufacturers.

Another area that has not been investigated in the selected literature is that of ‘burn-on’ of food soils, for example due to high temperatures in grills and ovens, how these should be cleaned and what the potential risk of allergen cross-contact is. As detection of allergens can be affected by processing, it should be considered as to whether allergen tests (although the most sensitive and relevant) are the most applicable in such studies involving heat treated food soils; suitable tests are likely to

be scenario dependent. Nevertheless, any analytical tests used must be validated for the intended purpose.

Many of the research needs described above also extend to micro, small and medium food processing or manufacturing businesses, whether they are certificated to commercial food management standards or not, and the cleaning practices in use in these environments. The challenge as evidenced throughout this report, it is difficult to generalise in terms of the efficacy of cleaning as it is so context dependent. Research could be conducted to benchmark what cleaning methods are used by such businesses as a way of prioritising those that are most used; these can then be studied to determine the efficacy of those methods. Research could also be conducted to propose simple practical ‘Do’s and Don'ts’ for cleaning based upon known good hygiene practices to ensure prevention of allergen cross-contact whilst supporting prevention of microbiological risks for example physical cleaning to remove visible debris prior to any use of cleaning materials.

It was widely reported throughout the literature that visually clean surfaces can still be contaminated with allergenic foodstuffs, however, there is little published evidence on the relationship between visibly clean and cross-contact of products in subsequent contact with those surfaces. This is an area that would benefit from further research, especially as it is the levels of allergen protein carried-over into products are of importance in the context of ‘thresholds or ‘action levels’ for deciding whether PAL is appropriate.

This leads on to the need for a standardised approach to studies of cleaning efficacy, which it is recommended should adhere to the principles of validation. These principles, as derived from the literature, are described in Section 6.2.4 of this report. Attention must be paid to documenting all aspects of the cleaning regime, and studies should be based on worst-case and/or real-world scenarios as appropriate. When deciding on sampling, consideration should be given to the form of the allergen, sampling from hard-to-clean areas and the inclusion of both positive and negative control samples. Multiple separate occasions (at least three) of the cleaning procedure should be incorporated to check for consistency. Studies should include environmental sampling (for example swabs, rinse water, push-through etc) as well as collection of product samples to investigate cross-contact.

Appropriate analytical methods should be chosen for each study scenario, a combination of tests based on different analytes may provide further information. Visual inspection should be included and analytical testing should only be conducted when surfaces are visually clean. When conducting studies into the efficacy of cleaning methodologies ELISAs and LFDs are generally the most appropriate, as they are based on the constituent to which allergic individuals react (i.e. protein). However, their applicability in each specific scenario should be considered along with the inherent limitations of the methods. Quantitative, sensitive, validated ELISA tests are most appropriate for analysing product samples, especially when investigating cross-contact in the context of quantitative risk assessment. LFDs are generally not as sensitive as quantitative ELISAs but can provide quick results; these tests must be validated for in-house use and compared with the more sensitive ELISA tests to ensure that results agree. Good quality control procedures must be in place (including analysis of positive and negative control samples) to provide confidence in the results. Consideration should be given to staff training to conduct testing and to interpret results appropriately.

When researching efficacy of cleaning methodologies it is crucial to consider whether cleaning chemicals may interfere with analytical methods and to test for this if samples may contain such chemicals.

There is work underway to develop new technologies using significantly less water to support environmental sustainability agendas, the impact of these emerging techniques needs to be understood and addressed perhaps in further research once best practices have been identified.

Ultimately, even with additional research, it will not be possible to provide one answer as to the ‘best’ cleaning methodology, as what is practicable will be situationally dependent. What can though be achieved, through elegantly designed experiments based on the principles of cleaning validation, are studies to support future guidance in areas where cleaning capability is not currently understood as described above.

9.2 Guidance development considerations

It is difficult to provide specific guidance on cleaning to remove food allergens for all scenarios, as different types of cleaning methodology are applicable in different

environments and situations. General guidance on cleaning in the food industry is already available and that which refers to removal of food allergens is included in this review. Much of the guidance is around the preferable use of wet cleaning where this is feasible; to first remove physical soil by the most appropriate means (for example, physical abrasion, scraping, rinsing, soaking), then cleaning using appropriate chemicals for the soil type (see Section 7.3.3.4 for a summary), followed by rinsing, sanitising and drying. Special attention should be paid to areas that are difficult to clean, need to be disassembled prior to cleaning or have constrictions or “dead legs”, that could cause product to get stuck.

Consistent guidance is required on the principles of validation and verification. Again, it is not possible to be specific because each situation is different, but the general principles can be explained and examples provided in guidance to aid consistent application.

Guidance could be based on the structure and principles laid down in Codex Alimentarius Guidelines for the Validation of Food Safety Control Measures (2008), in that firstly definitions should be provided so that there is an understanding of the terminology used (particularly the purpose and intention of validation and verification respectively). The guidance could then lay out tasks or considerations to undertake prior to the validation study, for example deciding on a worst-case scenario (for example highest level of allergen, most difficult product to remove by cleaning), determining the allergen/s under investigation, defining the cleaning regime, planning sampling and establishing acceptability criteria for analytical results. Prior to the validation the most appropriate analytical methods will need to be selected and validated. Advice will need to be provided on all these areas.

It would also be beneficial to provide a flow diagram of when to take samples and where from, in general terms. Guidance on sampling again cannot be prescriptive, but case studies with examples of sampling plans could be provided to inform best practice. It would be useful for a stance to be taken and advice provided on visual inspection; as detailed in Section 9.1 further research is required in this area.

A checklist could be provided as part of an example cleaning validation study; this should not be intended to be prescriptive but rather an aide memoir to prompt FBOs to consider the agreed principles of validation and verification. Such a checklist could

also be used to advise what should be documented regarding validation and verification of cleaning.

Of utmost importance is consistency of the advice and alignment with other available guidance on widely accepted principles, in particular from Codex Alimentarius, as this is based on international consensus from the WHO and FAO.

9.3 Recommendations summary

Ultimately, as evidenced from the findings of this review, there exists much general guidance for large food processing or manufacturing businesses on the efficacy of cleaning to remove food allergens; what is lacking is the same information applicable to food service and catering, as well as micro, small and medium food processing businesses. It is difficult to draw parallels between these different business types and sizes, as some cleaning operations are just not feasible in the food service sector or in smaller food processing businesses. Research is therefore needed to acquire knowledge of the efficacy of existing cleaning procedures for specific types of foodstuffs handled and specific types of food handling and processing scenarios, which can then be used to inform guidance on best practice in these businesses.

10. References

Acharya, S. (2021) Food Standards Agency Blog: Our food hypersensitivity strategy and commitment to consumers. available from https://food.blog.gov.uk/2021/03/22/our-food-hypersensitivity-strategy-and-commitment-to-consumers/ [28 March 2023].

AIB International (2022) Cleaning tips to prevent allergen cross-contact issues [online] available from https://blog.aibinternational.com/cleaning-tips-to-prevent-cross-contact-issues [28 March 2023].

Alberta Agriculture and Rural Development (2014) Food Safety Guidebook. Edmonton: Alberta Agriculture and Rural Development.

Aleksić, M., Popov-Raljić, J., Đorđević, V., Rašeta, M., Lukić, M., Spirić, D. and Janković, V. (2020) Control of nutritive allergens in a hospitality kitchen. Meat Technology, 61(1), pp.75-81.

Allergen Bureau (2023) Production: Cleaning [online] available from https://info.allergenbureau.net/infographic/cleaning/ [28 March 2023].

Anaphylaxis Campaign (2020) The role of cleaning in the management of allergens [webinar], 11 November 2020. [online] available from https://www.youtube.com/watch?v=sy1eGnw9UUw [28 March 2023].

ASSIFONTE (2018) European Guide for the Hygienic Manufacture of Processed Cheese. Brussels: ASSIFONTE.

Australian Food and Grocery Council and the Allergen Bureau (2021) Food Industry Guide to Allergen Management and Labelling for Australia and New Zealand. Griffith: Australian Food and Grocery Council/Allergen Bureau.

Axelsson, L., Holck, A., Rud, I., Samah, D., Tierce, P., Favre, M., & Kure, C. F. (2013) Cleaning of conveyor belt materials using ultrasound in a thin layer of water. Journal of Food Protection, *76*(8), pp.1401–1407.

Baumert, J.L. and Taylor, S.L. (2013) Best practices with allergen swabbing. Food Safety Magazine [online] 30 May. available from https://www.food-safety.com/articles/4434-best-practices-with-allergen-swabbing [28 March 2023].

Bedford, B., Liggans, G., Williams, L. and Jackson, L. (2020) Allergen removal and transfer with wiping and cleaning methods used in retail and food service establishments. Journal of Food Protection, 83(7), pp.1248-1260.

Biocel (2022) Allergen eradication cleaning & validation [online] available from https://www.biocel.ie/allergen-eradication-cleaning-validation/ [28 March 2023].

Brazilian Health Regulatory Agency (2018) Guia sobre Programa de Controle de Alergênicos. Brasília: Agência Nacional de Vigilância Sanitária Brasil.

BRCGS (2022) Effective Allergen Management. London: BRCGS.

Brown, H. M. and Arrowsmith, H.E. (2015) Sampling for Food Allergens. in Handbook of Food Allergen Detection and Control. ed by S. Flanagan, Sawston: Woodhead Publishing, 181-197.

Brown, P. (2019) Innovations to combat cross-contact risks in dairy processing. International Food & Meat Topics, 30(4), pp. 7-8. [online] available from http://www.positiveaction.info/pdfs/articles/fm30_4p7.pdf [28 March 2023].

Burrows, V.D. (2010) Allergen Management and Control as Part of Agricultural Practices. in Allergen Management in the Food Industry. ed by Boye, J.I. and Godefroy, S.B. Hoboken: John Wiley & Sons, 131-144.

Campden BRI (2009) Validation of cleaning to remove food allergens Guideline no. 59. Chipping Campden: Campden BRI.

Campden BRI (2013) Food allergens: practical risk analysis, testing and action levels Guideline no. 71. Chipping Campden: Campden BRI.

Campden BRI (2020a) Cleaning and disinfection of food factories – Cleaning for allergen control [online] available from https://www.campdenbri.co.uk/videos/cleaning-allergen-control.php [28 March 2023].

Campden BRI (2020b) Cleaning and disinfection of food factories: a practical guide Guideline no. 55, 2nd edition. Chipping Campden: Campden BRI.

Canadian Celiac Association (2018) Guide to Best Practices for Sampling and Testing and Risk Management for Gluten. Milton: Allergen Control Group Inc.

Canadian Food Inspection Agency (2020) Cleaning and Sanitation Program [online] available from https://inspection.canada.ca/preventive-controls/cleaning-and-sanitation-program/eng/1511374381399/1528206247934 [28 March 2023].

Canadian Food Inspection Agency (2022) Preventive controls for food allergens, gluten and added sulphites [online] available from https://inspection.canada.ca/preventive-controls/food-allergens-gluten-and-added-sulphites/eng/1517924742613/1528203218321 [28 March 2023].

Catalan Food Safety Agency (2009) Guia per a la gestió dels al· lèrgens i el gluten a la indústria alimentària. Barcelona: Agència Catalana de Seguretat Alimentària.

Centers for Disease Control and Prevention (2013) Voluntary Guidelines for Managing Food Allergies in Schools and Early Care and Education Programs. Washington, DC: US Department of Health and Human Services.

Chen, L., Rana, Y.S., Heldman, D.R. and Snyder, A.B. (2022) Environment, food residue, and dry cleaning tool all influence the removal of food powders and allergenic residues from stainless steel surfaces. Innovative Food Science & Emerging Technologies, 75, p.102877.

Christeyns Food Hygiene (2020) White paper on the management of allergens through cleaning. Warrington: Christeyns Food Hygiene Ltd.

Cochrane, S. and Skrypec, D. (2014) Food Allergen Risk Management in the Factory – From Ingredients to Products. in Risk Management for Food Allergy. ed by Madsen, C., Crevel, R., Mills, C. and Taylor, S. Oxford: Academic Press, 155-166.

Codex Alimentarius (2008) Guidelines for the validation of food safety control measures (CXG 69-2008) Rome: FAO/WHO.

Codex Alimentarius (2020a) Code of practice on food allergen management for food business operators (CXC 80-2020). Rome: FAO/WHO.

Codex Alimentarius (2020b) General principles of food hygiene (CXC 1-1969). Rome: FAO/WHO.

Coenye, T. (2013) Brenner's Encyclopedia of Genetics, 2nd edition. ed by Maloy, S. and Hughes, K. Amsterdam: Elsevier Inc.

Commission Regulation (EU) 2021/382 of 3 March 2021 amending the Annexes to Regulation (EC) No 852/2004 of the European Parliament and of the Council on the hygiene of foodstuffs as regards food allergen management, redistribution of food and food safety culture. [online] available from https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32021R0382&qid=1680080936045&from=EN [28 March 2023].

Council Regulation (EC) No. 178/2002 of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, as retained. [online] available from https://www.legislation.gov.uk/eur/2002/178/contents [28 March 2023].

Council Regulation (EC) No. 852/2004 of 29 April 2004 on the hygiene of foodstuffs, as retained. [online] available from https://www.legislation.gov.uk/eur/2004/852/contents [28 March 2023].

Council Regulation (EU) No. 1169/2011 of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004, as retained. [online] available from https://www.legislation.gov.uk/eur/2011/1169/contents [28 March 2023].

Courtney, R.C. (2016) Evaluation of qualitative food allergen detection methods and cleaning validation approaches. Masters of Science dissertation. University of Nebraska.

Crevel, R.W.R. (2016) Managing risks from allergenic residues. in Handbook of Hygiene Control in the Food Industry, 2nd edition. ed by Lelieveld, H., Holah, J. and Gabrić, D. Sawston: Woodhead Publishing, 135-145.

Dairy Food Safety Victoria (2018) A Guide to Managing Allergens in the Dairy Industry. Camberwell: Dairy Food Safety Victoria.

Dasgupta and Wahed (2014) Immunoassay platforms and designs. In Clinical Chemistry, Immunology and Laboratory Quality Control: A Comprehensive Review for Board Preparation, Certification and Clinical Practice. Amsterdam: Elsevier Inc.

Delhalle, L., Taminiau, B., Fastrez, S., Fall, A., Ballesteros, M., Burteau, S. and Daube, G. (2020) Evaluation of Enzymatic Cleaning on Food Processing Installations and Food Products Bacterial Microflora. Frontiers in Microbiology, 11, p.1827.

Demetrakakes, P. (2022) How food processors are cleaning up allergens in their facilities. Food Processing [online] 30 November. available from https://www.foodprocessing.com/food-safety/cleaning-sanitation-hygiene/article/21438416/how-food-processors-are-cleaning-up-allergens-in-their-facilities [28 March 2023].

Diversey (2021) Best practice standard sanitation operating procedures for allergen control in food processing [online] available from https://diversey.com/en/blog/best-practice-standard-sanitation-operating-procedures-allergen-control-food-processing [28 March 2023].

Dominguez, S., Théolier, J., Povolo, B., Gerdts, J., Godefroy, S.B. (2022) Allergen management under a voluntary PAL regulatory framework - A survey of Canadian food processors. Heliyon, 8(11), p.e11302

Easter, M. (2015) Comparative study looks at cleaning procedures for effective allergen control. International Food Hygiene, 26(3), pp. 7-9. [online] available from https://cdn.brandfolder.io/VZSMQ4LE/at/wjbn24vpzqzk4txtmj7xjk/Comparative-Study-Looks-at-Cleaning-Procedures-for-Effective-Allergen-Control.pdf [28 March 2023].

Ebisawa, M., Ito, K., Fujisawa, T., Aihara, Y., Ito, S., Imai, T., Ohshima, Y., Ohya, Y., Kaneko, H., Kondo, Y., Shimojo, N., Nagao, M., Ito, Y., Inoue, Y., Okafuji, I., Sato, S., Nakajima, Y., Nishimoto, H., Fukuie, T., Futamura, M., Manabe, T., Yanagida, N., Yamada, Y. and Urisu, A. (2020) Japanese guidelines for food allergy. Allergology International, 69(3), pp.370-386.

Eisenberg, M. and Delaney, N. (2018) Allergen management in food service. in Food Allergens: Best Practices for Assessing, Managing and Communicating the Risks. ed by Fu, TJ., Jackson, L., Krishnamurthy, K. and Bedale, W. Berlin: Springer, 167-180.

Emport LLC (2015) Cleaning procedures for effective allergen control [online] available from https://emportllc.com/2015/09/17/cleaning-procedures-effective-allergen-control/ [28 March 2023].

European Commission (2022) Commission Notice on the implementation of food safety management systems covering Good Hygiene Practices and procedures based on the HACCP principles, including the facilitation/flexibility of the implementation in certain food businesses. Official Journal, C355/1.

European Hygienic Engineering & Design Group (2018) Doc. 8 Hygienic Design Principles. Amsterdam: EHEDG.

European Hygienic Engineering & Design Group (2021a) Doc. 52 Basic Principles of Cleaning and Disinfection in Food Manufacturing. Amsterdam: EHEDG.

European Hygienic Engineering & Design Group (2021b) Doc. 45 Cleaning Validation, Monitoring and Verification. Amsterdam: EHEDG.

Farmhouse and Artisan Cheese & Dairy Producers European Network (2018) European Guide for Good Hygiene Practices in the Production of Artisanal Cheese and Dairy Products. Paris :Farmhouse and Artisan Cheese & Dairy Producers European Network.

Flanagan, S. (2015) The importance of cleaning validation in allergen management. Uxbridge: Reading Scientific Services Ltd. [online] available from https://www.foodnavigator.com/Product-innovations/The-Importance-of-Cleaning-Validation-in-Allergen-Management [28 March 2023].

Food & Allergy Consulting & Testing Services (2021) Validation vs verification in a food factory [webinar], 23 June 2021. [online] available from https://www.hygiena.com/validation-vs-verification-webinar/ [28 March 2023].

Food & Allergy Consulting & Testing Services (2022) Rapid on-site testing kits, an allergen management tool [online] available from https://www.factssa.com/news/rapid-on-site-testing-kits-an-allergen-management-tool/ [28 March 2023].

Food Allergy & Anaphylaxis Connection Team (FAACT) (2023) How to prevent cross-contact and accidental environmental exposure [online] available from https://www.foodallergyawareness.org/food-allergy-and-anaphylaxis/cross-contact/cross-contact/ [28 March 2023].

Food Allergy Canada (2022) Allergen Management Guidelines for Food Manufacturers. Toronto: Food Allergy Canada.

Food Allergy Research & Education (2017) Cleaning methods [online] available from https://www.foodallergy.org/resources/cleaning-methods [28 March 2023].

Food Allergy Research and Resource Program (FARRP) (no date) Components of an Effective Allergen Control Plan A Framework For Food Processors. Lincoln: FARRP.

Food Safety Authority of Ireland (2012) Audit of Irish food manufacturer allergen controls and labelling [online] available from https://www.fsai.ie/uploadedFiles/Enforcement_and_Audit/Audit/Reports/Control_and_Labelling_Allergens_Manufacturers.pdf [30 March 2023].

Food Safety Authority of Ireland (2020) Safe catering: allergens [online] available from https://www.fsai.ie/uploadedFiles/Food_Business/Allergens_FA2-accessible%202.pdf [28 March 2023].

Food Safety Experts (2017) 6 Areas for successful allergen management [online] available from https://www.foodsafety-experts.com/food-safety/allergen-management-2/ [28 March 2023].

Food Safety Magazine (no date) CIP/COP [online] available from https://www.food-safety.com/topics/321-cip-cop [31 March 2023].

Food Safety Standard (2023) Validation of cleaning and sanitation programs [linkedin] available from https://www.linkedin.com/pulse/validation-cleaning-sanitation-programs-foodsafety-standard/ [28 March 2023].

Food Standards Agency (2006) Guidance on allergen management and consumer information. London: Food Standards Agency.

Food Standards Agency (2021) Guidance for small food businesses on using precautionary allergen labelling such as ‘may contain’ [online] available from https://www.food.gov.uk/business-guidance/precautionary-allergen-labelling [28 March 2023].

Food Standards Agency (2022) Risk analysis and precautionary allergen labelling research report [online] available from https://www.food.gov.uk/research/food-allergy-and-intolerance-research/risk-analysis-and-precautionary-allergen-labelling-research-report [30 March 2023].

Food Standards Agency (2022) Safe catering [online] available from https://www.food.gov.uk/business-guidance/safe-catering [28 March 2023].

FoodDrinkEurope (2022) Guidance on food allergen management for food manufacturers. Brussels: FoodDrinkEurope.

Foreign, Commonwealth and Development Office (2023) Small to medium sized enterprise (SME) action plan [online] available from https://www.gov.uk/government/publications/fcdo-small-to-medium-sized-enterprise-sme-action-plan [18 May 2023].

Franzmeier, K.D. (2019) Best practices for allergen changeovers and sanitizing of confectionery equipment. The Manufacturing Confectioner [online] 1 February. available from https://www.gomc.com/firstpage/201902037.pdf [28 March 2023].

Fryer, P.J. and Asteriadou, K. (2009) A prototype cleaning map: a classification of industrial cleaning processes. Trends in Food Science & Technology, 20(6-7), pp.255-262.

Fuciños, C., Estévez, N., Míguez, M., Fajardo, P., Chapela, M. J., Gondar, D., & Rúa, M. L. (2019) Effectiveness of proteolytic enzymes to remove gluten residues and feasibility of incorporating them into cleaning products for industrial *purposes.* Food research international, 120*,* pp.167–177.

Galan-Malo, P., Ortiz, J.C., Carrascon, V., Razquin, P. and Mata, L. (2019) A study to reduce the allergen contamination in food-contact surfaces at canteen kitchens. International Journal of Gastronomy and Food Science, 17, p.100165.

Gill, S. (2020) Dry steam changes cleaning regime for the better. Food Processing [online] 13 April. available from https://www.fponthenet.net/article/177831/Dry-steam-changes-cleaning-regime-for-the-better.aspx [28 March 2023].

Gloves by web (2016) The importance of allergen cleaning [online] available from https://glovesbyweb.com/blogs/news/the-importance-of-allergen-cleaning [28 March 2023].

Government of Canada (2019) Food allergen cross contamination (or precautionary) statements [online] available from https://inspection.canada.ca/food-labels/labelling/industry/allergens-and-gluten/eng/1388152325341/1388152326591?chap=4 [17 May 2023].

Gowland, M.H. (2010) Allergen Management and Control in the Foodservice Industry. in Allergen Management in the Food Industry. ed by Boye, J.I. and Godefroy, S.B. Hoboken: John Wiley & Sons, 167-204.

Gupta, R.S., Taylor, S.L., Baumert, J.L., Kao, L.M., Schuster, E. and Smith, B.M. (2017) Economic factors impacting food allergen management: perspectives from the food industry. Journal of Food Protection, 80(10), pp.1719-1725

Haley, T. and Brouillette, R. (2018) The evolution of sanitation and hygienic design in bakeries. Food Safety Magazine [online] 14 December. available from https://www.food-safety.com/articles/6054-the-evolution-of-sanitation-and-hygienic-design-in-bakeries [28 March 2023].

Hashimoto, H., Yoshimitsu, M. and Kiyota, K. (2014) Comparison of egg allergens retained on food service tableware made from different materials. Nihon Kasei Gakkaishi (Journal of Home Economics of Japan), 65, pp.681-687.

Holah, J., West, S. and McHardy, M. (2016) Hygiene requirements in food service. in Handbook of Hygiene Control in the Food Industry, 2nd edition. ed by Lelieveld, H., Holah, J. and Gabrić, D. Sawston: Woodhead Publishing, 205-219.

Holah, J.T. (2014). Cleaning and disinfection practices in food processing. In Hygiene in Food Processing, 2nd edition, ed by Lelieveld, H.L.M., Holah, J.T. and Napper, D. Sawston: Woodhead Publishing, 259-304

Howlett, G. (2016) Validation of cleaning programs with a focus on allergens. Safefood 360° User Conference. [online] available from https://safefood360.com/wp-content/uploads/2016/01/ValidationCleaningProgramsAllergens.pdf [28 March 2023].

Hygiena (2021) Allergen cleaning as a control [online] available from https://www.hygiena.com/allergen-cleaning-as-a-control/ [28 March 2023].

Hygiena (2022) Allergen cleaning validation and verification [online] available from https://www.hygiena.com/allergen-cleaning-validation-and-verification/ [28 March 2023].

International Food Safety and Quality Network (2017) Validation of cleaning programs [webinar], 5 May 2017. [online] available from https://www.youtube.com/watch?v=ciPGHZRN8l4 [28 March 2023].

International Life Sciences Institute (2022) Practical guidance on the application of food allergen quantitative risk assessment within food operations. Brussels: ILSI Europe.

Jackson, L.S. (2017) Cleaning strategies to remove food allergens and tools for determining efficacy. [online] available from https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-712-49%252FPresentations%252FCleaning_for_Controlling_Allergens_CCFH.pdf [28 March 2023].

Jackson, L.S. (2018) Allergen cleaning: best practices. in Food Allergens: Best Practices for Assessing, Managing and Communicating the Risks. ed by Fu, TJ., Jackson, L., Krishnamurthy, K. and Bedale, W. Berlin: Springer, 131–154.

Jackson, L.S. and Al-Taher, F. (2010) Efficacy of different dry cleaning methods for removing allergenic foods from food-contact surfaces. In: Poster presentation, International Association of Food Protection Annual Meeting, 1/4 August 2010, Anaheim. Des Moines: International Association for Food Protection Annual Meeting Abstracts, pp. 70.

Jackson, L.S., Al-Taher, F.M., Moorman, M., DeVRIES, J.W., Tippett, R., Swanson, K.M., Fu, T.J., Salter, R., Dunaif, G., Estes, S. and Albillos, S. (2008) Cleaning and other control and validation strategies to prevent allergen cross-contact in food-processing operations. Journal of Food Protection, 71(2), pp.445-458.

Japan Food Safety Management Association (2022) Manufacture of food products and manufacture of chemicals. Tokyo: Japan Food Safety Management Association.

Kiyota, K., Sakata, J., Satsuki-Murakami, T., Yoshimitsu, M., Akutsu, K., Ki, M., Hashimoto, H., Kajimura, K. and Yamano, T. (2018) Evaluation of cleaning methods for residual orange extract on different cookware materials using ELISA with profilin allergen indicator. Journal of Food Process Engineering, 41(2), p.e12652.

Kochak, J.W. (2016) Getting ready for FSMA's allergen guidelines. Food Safety Magazine [online] 14 December. available from https://www.food-safety.com/articles/5114-getting-ready-for-fsmae28099s-allergen-guidelines [28 March 2023].

Labs, W. (2023) New Ideas for Steam: Superheat it to Kill Pathogens on Contact. Food Engineering Magazine [online] 1 February. available from: https://www.foodengineeringmag.com/articles/100834-new-ideas-for-steam-superheat-it-to-kill-pathogens-on-contact [15 May 2023].

Littleton, P., Walker, M. and Ward, R. (2021) Controlling cross-contact by food allergens. Food Science and Technology, 35(2), pp. 47-51. [online] 15 June. available from https://ifst.onlinelibrary.wiley.com/doi/10.1002/fsat.3502_14.x [28 March 2023].

Lopez, S. and Morales, M. (2015) Implementing an allergen cleaning validation program: practical tips. International Food Hygiene, 26(3), pp. 18-19. [online] available from http://www.positiveaction.info/pdfs/articles/fh26_3p18.pdf [28 March 2023].

Marriott, N.G., Schilling, M.W., Gravani, R.B. (2018) The relationship of allergens to sanitation. in Principles of Food Sanitation, 6th edition. ed by Marriott, N.G., Schilling, M.W., Gravani, R.B. Berlin: Springer, 73–81

McHugh, T. (2016) Putting Ultrasound to Use in Food Processing. Food Technology Magazine [online] 1 December. available from https://www.ift.org/news-and-publications/food-technology-magazine/issues/2016/december/columns/processing-ultrasound-use-in-food-processing [15 May 2023].

Moerman, F. and Mager, K. (2016) Cleaning and disinfection in dry food processing facilities. in Handbook of Hygiene Control in the Food Industry, 2nd edition. ed by Lelieveld, H., Holah, J. and Gabrić, D. Sawston: Woodhead Publishing, 521-554.

Neogen (2016) Best practices for food allergen validation & verification. Lansing: Neogen.

Neogen (2021) Food allergen handbook. Lansing: Neogen.

Nikoleiski, D. (2015) Hygienic design and cleaning as an allergen control measure. in Handbook of Food Allergen Detection and Control. ed by Flanagan, S. Sawston: Woodhead Publishing, 89-102.

Ortiz, J.C., Galan-Malo, P., Garcia-Galvez, M., Mateos, A., Ortiz-Ramos, M., Razquin, P. and Mata, L. (2018) Survey on the occurrence of allergens on food-contact surfaces from school canteen kitchens. Food Control, 84, pp.449-454.

Ortiz-Menéndez, J.C., Cabrera, M., Mateos Alonso A., García Álvarez M., Ortiz Ramos, M., Garzón, B., Galán-Malo, P. and Mata, L. (2019) Detection of egg and milk residues on work surfaces in school canteens in the Hortaleza District, Madrid and their relevance to children with allergy to these food groups. Journal of Investigational Allergology and Clinical Immunology, 29(1), pp.46-83.

Otto, C., Zahn, S., Rost, F., Zahn, P., Jaros, D. and Rohm, H. (2011) Physical Methods for Cleaning and Disinfection of Surfaces. Food Engineering Reviews, 3, pp.171-188.

Peanut and Tree Nut Processors Association (PTNPA) and the Consumer Brands Association (Consumer Brands) (2020) Industry Handbook for Safe Processing of Nuts. Alexandria: PTNPA.

Perry, T.T., Conover-Walker, M.K., Pomés, A., Chapman, M.D. and Wood, R.A. (2004) Distribution of peanut allergen in the environment. Journal of Allergy and Clinical Immunology, 113(5), pp.973-976.

Rana, Y.S., Chen, L., Balasubramaniam, V.M., Snyder, A.B. (2022) Superheated steam effectively inactivates diverse microbial targets despite mediating effects from food matrices in bench-scale assessments. International Journal of Food Microbiology, 378, p.109838.

Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC, as retained. [online] available from https://www.legislation.gov.uk/eur/2005/396/contents [18 May 2023].

Remington, B.C., Blom, W.M., Bassa, B. and Koppelman, S.J. (2020) Risk of shared equipment in restaurants for consumers with peanut allergy: a simulation for preparing Asian foods. Annals of Allergy, Asthma & Immunology, 125(5), pp.543-551.

Ridler, G. (2022) Cleaning to prevent allergen cross contamination [online] 19 May. Available from: https://www.foodmanufacture.co.uk/Article/2022/05/19/cleaning-to-prevent-allergen-cross-contact [30 March 2023]

Rochester Midland Corporation (2021) CHECKLIST: 9 Considerations for allergen control in the food industry [online] available from https://www.rochestermidland.com/foodsafetyblog/allergen-control-top-10-considerations [28 March 2023].

Röder, M., Ibach, A., Baltruweit, I., Gruyters, H., Janise, A., Suwelack, C., Matissek, R., Vieths, S. and Holzhauser, T. (2008) Pilot plant investigations on cleaning efficiencies to reduce hazelnut cross-contact in industrial manufacture of cookies. Journal of food protection, 71(11), pp.2263-2271.

Romer Labs (2019a) Beyond due diligence: 10 “musts” of allergen management [online] available from https://www.romerlabs.com/en/knowledge-center/knowledge-library/articles/news/beyond-due-diligence-10-musts-of-allergen-management/ [28 March 2023].

Romer Labs (2019b) 5 Fundamentals of allergen analysis #1: Allergen sources and allergen load [online] available from https://www.romerlabs.com/en/knowledge-center/knowledge-library/articles/news/5-fundamentals-of-allergen-analysis-1-allergen-sources-and-allergen-load/ [28 March 2023].

Romer Labs (2020a) 5 Fundamentals of allergen analysis #5: Make it easier to keep your plant clean [online] available from https://www.romerlabs.com/en/knowledge-center/knowledge-library/articles/news/5-fundamentals-of-allergen-analysis-5-make-it-easier-to-keep-your-plant-clean/ [28 March 2023].

Romer Labs (2020b) Identify. Control. Eliminate. New developments in allergen management and cleaning [webinar], 28 May 2020. [online] available from https://www.romerlabs.com/en/knowledge-center/knowledge-library/events/news/webinar-identify-control-eliminate-new-developments-in-allergen-management-and-cleaning/ [28 March 2023].

Romer Labs (2021a) Effective food allergen management for businesses and consumers [webinar], 3 September 2021. [online] available from https://www.youtube.com/watch?v=SnOztNFndK0 [28 March 2023].

Romer Labs (2021b) How do you manage allergens in gluten-free production? [webinar], 4 May 2021. [online] available from https://www.romerlabs.com/knowledge-center/knowledge-library/videos/news/webinar-how-do-you-manage-allergens-in-gluten-free-production/ [28 March 2023].

Safe Quality Food Institute (2012) Allergen Cleaning and Sanitation Practices. Arlington: Safe Quality Food Institute.

Schaffner, D.F. (2020) Removing allergens means rethinking what “clean” means. Food Safety Magazine [online] 20 February. available from https://www.food-safety.com/articles/6467-removing-allergens-means-rethinking-what-e2809ccleane2809d-means [28 March 2023].

Schembri, P. (2017) Improving food allergen management in small food service businesses serving loose food. Doctoral thesis. University of Central Lancashire.

Schmidt (2018) Basic elements of equipment cleaning and sanitizing in food processing and handling operations. University of Florida Cooperative Extension Service, Institute of Food and Agricultural Sciences. [online] available from https://edis.ifas.ufl.edu/publication/FS077?downloadOpen=true [30 March 2023].

Schmidt, R.H. (1997) Basic elements of equipment cleaning and sanitizing in food processing and handling operations. Gainesville: University of Florida. [online] available from https://ucfoodsafety.ucdavis.edu/sites/g/files/dgvnsk7366/files/inline-files/26501.pdf. [28 March 2023].

Schmitt, R. and Moerman, F. (2016) Validating cleaning systems. in Handbook of Hygiene Control in the Food Industry, 2nd edition, ed by Lelieveld, H., Holah, J. and Gabric, D. Sawston: Woodhead Publishing, 587-601

Schreder, C., Wild, B., Jäger, M., Reiselhuber-Schmölzer, S. and Prüller-Strasser, B. (2013) Management of allergens in the gastronomy. Difficulty of cross-contact referred to the context of food regulatory. Ernaehrungs Umschau international 60 (7): 104–109

Singapore Food Agency (2021) Protecting Consumers from Food Allergens [online] available from https://www.sfa.gov.sg/food-information/food-allergens/protecting-consumers-from-food-allergens [28 March 2023].

Sinner, H. (1960) Über das Waschen mit Haushaltwaschmachinen: in welchem Umfang erleichtern Haushaltwaschmaschinen und -geräte das Wäschehaben im Haushalt? Haus & Heim Verlag, (8).

Smith, D. (2015) The hygienic design of food industry brushware – the good, the bad and the ugly. Journal of Hygienic Engineering and Design, 12, [online] available from https://keypublishing.org/jhed/jhed-volumes/jhed-volume-12-hed-2-debra-smith-2015-the-

hygienic-design-of-food-industry-brush-ware-the-good-the-bad-and-the-ugly/ [28 March 2023].

Smith, D. (2016) The hygienic design of manual cleaning equipment. IFST Hygienic Design Conference. [online] available from https://www.ifst.org/sites/default/files/D%20Smith%20-%20IFST%20Hygiene%2025th%20February.pdf [28 March 2023].

Smith, D. (2019) Optimise your allergen control with colour coding. New Food [online] 18 June. available from https://www.newfoodmagazine.com/article/93879/optimise-your-allergen-control-with-colour-coding/ [28 March 2023].

Spektor, Y. (2009) Effect of cleaning protocols on the removal of milk, egg, and peanut allergens from abraded and unabraded stainless steel surfaces. Doctoral dissertation. University of Florida.

Stone, W.E. and Yeung, J.M. (2010) Principles and Practices for Allergen Management and Control in Processing. in Allergen Management in the Food Industry. ed by Boye, J.I. and Godefroy, S.B. Hoboken: John Wiley & Sons, 145-165.

Stone, W.E., Jantschke, M. and Stevenson, K.E. (2009) Key components of a food allergen management program. in Managing Allergens in Food Processing Establishments, 4th edition. ed by Stone, W.E. and Stevenson, K.E. Washington, D.C.: Grocery Manufacturers Association (GMA), 25-40.

Stücken, T. (2017) The truth about steam cleaning [online] 22 December. Available from: http://www.europeancleaningjournal.com/magazine/articles/special-features/the-truth-about-steam-cleaning [16 May 2023].

Tamime, A (2008) Cleaning-in-Place: Dairy, Food and Beverage Operations, 3rd edition. ed by Tamime, A. Oxford: Blackwell Publishing Ltd.

Taylor, S.L., Hefle, S.L., Bindslev-Jensen, C., Bock, S.A., Burks Jr, A.W., Christie, L., Hill, D.J., Host, A., Hourihane, J.O.B., Lack, G. and Metcalfe, D.D. (2002) Factors affecting the determination of threshold doses for allergenic foods: how much is too much?. Journal of Allergy and Clinical Immunology, 109(1), pp.24-30.

Taylor, S.L., Hefle, S.L., Farnum, K., Rizk, S.W. Yeung, J., Barnett, M.E., Busta, F., Shank F.R., Newsome, R., Davis, S. and Bryant, C.M (2006) Analysis and evaluation of

food manufacturing practices used to address allergen concerns. Comprehensive Reviews in Food Science and Food Safety, 5(4), pp.138-157.

Teng, A. (2013) Food manufacturers implement a rainbow of hues in their color-coding programs. Food Quality & Safety [online] 15 February. available from https://www.foodqualityandsafety.com/article/food-manufacturers-implement-a-rainbow-of-hues-in-their-color-coding-programs/ [28 March 2023].

The Acheson Group (2016) Using diagnostic tools for validation and verification of an allergen control program. [online] available from https://www.neogen.com/en-gb/neocenter/resources/tag-allergen-control-program/ [28 March 2023].

The Food Information Regulations (2014) SI 2014 No. 1855. London: HMSO. [online] available from https://www.legislation.gov.uk/uksi/2014/1855/contents [28 March 2023].

Timmerman, H., Mogensen, P.K., Graßhoff, A. (2016) Enzymatic Cleaning in Food Processing. in Handbook of Hygiene Control in the Food Indsutry, 2nd edition. ed by Lelieveld, H., Holah, J. and Gabrić, D. Sawston: Woodhead Publishing, 555-568.

Uğurcan, K. (2022) Cleaning and Disinfection Applications in Food and Beverage Processing Plants [linkedin] available from https://www.linkedin.com/pulse/cleaning-disinfection-applications-food-beverage-plants-kartal-1e [28 March 2023].

US Department of Agriculture Food Safety and Inspection Service (2022) Fish and Fishery Products Hazards and Controls Guidance. Washington, DC: USDA Food Safety and Inspection Service.

US Food and Drug Administration (2006) Food Allergen Labeling and Consumer Protection Act of 2004 Public Law 108-282 [online] available from http://wayback.archive-it.org/7993/20180125103035/https:/www.fda.gov/downloads/Food/GuidanceRegulation/UCM179390.pdf [31 March 2023].

US Food and Drug Administration (2022) Food code. 2022 Recommendations of the United States Public Health Service and Food and Drug Administration. Washington, DC: US Food and Drug Administration.

Walker, M.J., Burns, D.T., Elliott, C.T., Gowland, M.H., Mills, E.N.C. (2016) Is food allergen analysis flawed? Health and supply chain risks and a proposed framework to address urgent analytical needs. Analyst, 141(1), pp.24-35.

Wang, X., Young, O.A. and Karl, D.P. (2010) Evaluation of cleaning procedures for allergen control in a food industry environment. Journal of Food Science, 75(9), pp.T149-T155.

Watson, W.T., Woodrow, A. and Stadnyk, A.W. (2013) Persistence of peanut allergen on a table surface. Allergy, Asthma & Clinical Immunology, 9(1), pp.1-3.

Watson, W.T., Woodrow, A. and Stadnyk, A.W. (2015) Removal of peanut allergen Ara h 1 from common hospital surfaces, toys and books using standard cleaning methods. Allergy, Asthma & Clinical Immunology, 11(1), pp.1-4.

Wells, C. and Jeong, S. (2017) Evaluating current industry dry cleaning practice using vacuum with regard to food allergens on processing surfaces. In: International Association for Food Protection Annual Meeting, 9/12 July 2017, Tampa. Des Moines: International Association for Food Protection Annual Meeting Abstracts, pp. 140.

World Health Organisation (2006) Five keys to safer food manual. Rome: FAO/WHO.

Yan, Z., Larsen, G., Scheffler, R. and Blacow, K. (2013) Examination of food allergen removal from two flat conveyor belts. EHEDG Yearbook 2013/2014 [online] available from: https://www.ehedg.org/ [16 May 2023].

Zerva, K. (2015) Changeover allergen cleaning challenges and options. Quality Assurance & Food Safety [online] 1 October. available from https://www.qualityassurancemag.com/article/aib1015-managing-allergen-changeover-cleaning/ [28 March 2023].

Zhang, L., Bedford, B., Sharma, G., Brown, A., Hopfer, H., Ziegler, G. and Jackson, L. (2019) Effectiveness of cleaning strategies for removing milk chocolate from pilot-scale Chocolate Processing Equipment. In IAFP 2019 Annual Meeting. IAFP.

Zhang, L., Warren, J., Suehr, Q., Anderson, N., Bedford, B. and Jackson, L. (2018) Effectiveness of push-through cleaning methods for removing milk chocolate from a stainless steel pipe and butterfly valve. In IAFP 2018 Annual Meeting. IAFP.

Zhang, X. (2014) Effectiveness of cleaning regimens for removing peanut, milk and egg residue from pilot-scale cereal bar and muffin processing lines. Doctoral dissertation. Illinois Institute of Technology.

11. Appendix

11.1 Lists of websites searched

List of organisation websites searched

Allergen Bureau	Food and Drink Europe (FDE)	National Food Processors Association
Allergy & Anaphylaxis Australia	German Institute of Food Technologies	Research Association of the German Food Industry
American Academy of Allergy, Asthma & Immunology	Institute of Food Technologists (IFT)	Society of Food Hygiene and Training
Anaphylaxis UK (previously Anaphylaxis Campaign)	Institute of Food Science and Technology (IFST)	Swiss Allergy
Codex Alimentarius	International Life Sciences Institute (ILSI)	TNO
European Hygienic Equipment and Design Group	Japan Food Safety Management Association	3-A sanitary
Food Allergy Research and Education (FARE)	Japanese Society of Allergology	
Food Allergy Research and Resource Program (FARRP)	Lucideon	

List of trade association websites searched

Association of Bakery Ingredient Manufacturers	Dairy UK	Seafish
British Egg Industry Council	International Dairy Federation	UK Flour Millers
British Egg Products Association	Peanut and Tree Nut Processors Association	

List of analytical test kit and cleaning chemical suppliers and analytical laboratory websites searched

Bio-Check (UK) Ltd	Holchem Laboratories Ltd	SGS
Christeyns Food Hygiene Limited	Hygiena	R-Biopharm AG
Ecolab	LGC Group Limited	Romer Labs
ELISA systems	Morinaga Institute of Biological Science, Inc	Reading Scientific Services Ltd (RSSL)
Eurofins	Neogen	Vikan UK Ltd
3M		

Authority and agency websites searched

Agriculture and Agri-Food Canada	European Food Safety Authority (EFSA)	Food Standards Scotland
Canadian Food Inspection Agency (CFIA)	Food Safety Authority of Ireland (FSAI)	Food Standards Australia and New Zealand
European Commission	Food Standards Agency	USDA (US Department of Agriculture)

Governmental websites searched

Argentina (Ministry of Agriculture and Food,Ministry of Health)	GSO (**Gulf States**)(GCC Standardization Organization)	**Philippines** (Government, Department of Health, Department of Science and Technology)
Brazil (Government)	**Hong Kong** (Government, Food and Environmental Hygiene , Center for Food Safety)	**Singapore** (Ministry of Health, Singapore Food Agency)
Caricom std (**Caribbean countries**)	**India** (Ministry of Food Processing Industries , Food Safety and Standards Authority of India , Central Technological Research Institute , Department of	**South Africa** (Department of Health, Department of Science and Innovation, Agriculture, Land Reform & Rural Development)

	Food and Public Distribution , Department of Health Research , Food Corporation of India); Israel (Government, Ministry of Health)	
Central Amercia (Central American Parliament)	**Japan** (Food Safety Commission , Ministry of Agriculture, Forestry and Fisheries , National Agriculture and Food Research Organisation)	**South Korea** (Ministry of Health and Welfare)
Chile (National Research and Development Agency, Ministry of Health)	**Kazakhstan** (Government)	**Taiwan** (Government, Ministry of Agriculture - Agriculture and Food Agency, Ministry of Health - food and drug administration)
China (National Health Commission ; Ministry of Agriculture and Rural Affairs)	**Malawi** (Government, Ministry of Health, Ministry of Agriculture)	**Thailand** (Government, Ministry of Agriculture and Cooperatives, Ministry of Public Health)
Colombia (Government)	**Malaysia** (Government, Ministry of Agriculture and Food Security, Ministry of Health Food Safety and Quality division, Institute of Public Health, Ministry of Science and Technology)	**Turkey** (Ministry of Agriculture and Forestry)
Cuba (Ministry of Public Health)	**Mexico** (Government)	**Venezuela** (Ministry of Health, Ministry of Food)
Fiji (Government, Food Processors agency ,	**Morocco** (Government, Department of Agriculture)	**Vietnam** (Government, Ministry of Health)

Ministry of Health and Medical Services)		

The websites of Belarus, Russia and Ukraine Governments were not searched.

The websites of Bolivia, Cuba, Egypt and South Korea did not upload after several attempts.

11.2 Journal articles and theses summaries

- **Perry et al. (2004)** Distribution of peanut allergen in the environment. Journal of Allergy and Clinical Immunology.
  Study design summary: Peanut butter applied to a clean table and hands of volunteers before samples taken after cleaning with cleaning agents or plain water and using a regular hand-washing method respectively.

Allergen	Surfaces	Detection method	Cleaning methodologies	Efficacy of cleaning summary
Peanut	Tables; Hands	Ara h 1 ELISA (INDOOR Biotechnologies)	TABLE: Plain water; Dishwashing liquid; Formula 409 cleaner; Lysol sanitising wipes; Target cleaner with bleach HANDS: Antibacterial hand sanitiser; Tidy Tykes wipes; Wet Ones antibacterial wipes; Liquid soap; Bar soap	After hand washing with liquid soap, bar soap, or commercial wipes, Ara h 1 was undetectable. Plain water and antibacterial hand sanitiser left detectable Ara h 1 on 3 of 12 and 6 of 12 hands, respectively. Common household cleaning agents removed peanut allergen from tabletops, except dishwashing liquid, which left Ara h 1 on 4 of 12 tables. Of the 6 area preschools and schools evaluated, Ara h 1 was found on 1 of 13 water fountains, 0 of 22 desks, and 0 of 36 cafeteria tables. **Conclusion: The major peanut allergen, Ara h 1, is relatively easily cleaned from hands and tabletops with common cleaning agents and does not appear to be widely distributed in preschools and schools.**

- **Jackson et al. (2008)** Cleaning and other control and validation strategies to prevent allergen cross-contact in food-processing operations. Journal of Food Protection.

  Study design summary: This is a review, which includes reference to the following studies conducted by the same author: The efficacy of different cleaning protocols for removing hot milk soils, cold milk soils, and peanut butter soils from plates made of different food contact materials.

Allergens	Surfaces	Detection methods	Cleaning methodologies	Efficacy of cleaning summary
Milk; Peanut	Stainless steel; Teflon; polyethylene; urethane; polycarbonate	No details provided	Washed with various types of cleaning agents or solutions (water; chlorinated alkali cleaner; acid detergent cleaner) at different temperatures (ambient temperature; 62.8ºC; 73.8ºC) for 30 minutes	The efficacy of the cleaning protocols differed depending on the type of soil, the food contact surface, the temperature of the cleaning solution, and the concentration of the detergent in the cleaning solution. For example, water without chlorinated alkali cleaner was not effective at removing hot milk soil from stainless steel plates. Chlorinated alkali cleaner was able to remove all hot milk residues even when the detergent solution was at ambient temperature. In contrast, water alone at 62.8ºC and 73.8ºC was effective at removing cold milk soils. Water alone at 62.8ºC, but not at ambient temperature, was effective at removing peanut butter soils from most of the food contact surfaces studied. Both chlorinated alkali cleaner and acid detergent cleaner at 62.8ºC, but neither at ambient temperature, were able to effectively remove all peanut butter residues from the food contact surfaces.

- **Röder et al. (2008)** Pilot plant investigations on cleaning efficiencies to reduce hazelnut cross-contact in industrial manufacture of cookies. Journal of Food Protection.

  Study design summary: Product change after cleaning, from cookie dough with 10% hazelnut to cookies without hazelnuts simulated in a pilot plant. The experiments were performed repeatedly with finely ground hazelnuts and with roughly chopped hazelnut kernels.

Allergen	Surfaces	Detection method	Cleaning methodologies	Efficacy of cleaning summary
Hazelnut	Kneaders; rotary molder; wire cutting machine; steel band oven	Hazelnut protein specific ELISA	No cleaning – push-through with cookies without hazelnut; Manual scraping; Manual scraping plus cleaning with 52ºC hot water; Manual scraping plus cleaning with 52ºC hot water containing 0.2% dish detergent and final rinse with hot water.	Cross-contact from chopped kernels was distributed heterogeneously; sampling and analysis with the ELISA was therefore not reproducible. For the homogeneously distributed, finely ground hazelnut, apart from product changes without intermediate cleaning, the highest cross-contact was found after mechanical scraping: up to 100 mg/kg hazelnut protein was found in the follow-up product. After additional cleaning with hot water, the cross-contact decreased to levels at or below 1 mg/kg hazelnut protein. In the pilot plant study, an appropriate wet cleaning procedure in combination with quantitative monitoring of the cleaning efficiency reduced the hazelnut protein cross-contact to a level at which severe hazelnut-related allergic reactions are unlikely to occur.

- **Spektor (2009)** Effect of cleaning protocols on the removal of milk, egg and peanut allergens from abraded and unabraded stainless steel surfaces (Thesis).

  Study design summary: Peanut butter, pasteurised liquid egg and milk were applied to coupons, which were subjected to four cleaning protocols.

Allergens	Surfaces	Detection methods	Cleaning methodologies	Efficacy of cleaning summary
Egg; Peanut; Milk	Abraded and unabraded stainless steel surfaces	Visual inspection; Veratox Allergen Test Kits, Neogen Corporation, Lansing, MI.	Juice Products Association (JPA) Type 4 wash and food degreaser wash; Chlorinated alkaline detergent (CAD) and food degreaser wash; Acid detergent (AD) and food degreaser wash; Water only treatment. All applied at 63°C	For all three allergens, JPA and CAD resulted in the highest percentage reductions (99.6% on average for all surfaces), while AD resulted in the least allergen percentage reduction (91.6% on average for all surfaces). The average reduction for water was 96.5% for all allergens and surfaces.

- **Wang, Young and Karl (2010)** Evaluation of cleaning procedures for allergen control in a food industry environment. Journal of Food Science.

  Study design summary: Eleven products (chicken products with wheat derivates as a batter) prepared on three processing lines and 15 production runs sampled at random over six months. Cleaning protocols carried out over 5 hours and the still-wet rinsed surfaces swabbed 20 minutes after each step.

Allergen	Surface	Detection methods	Cleaning methodologies	Efficacy of cleaning summary
Gluten	Stainless steel wire mesh conveyors	ATP surface swabs (Biotrace Intl.); Protein (Coomassie dye method, Pierce); ELISA (gliadin) immunoassay (RIDASCREEN	RINSING: remove solid material and wash with water 40-50ºC; FOAM and RINSE: 1% enforce foam comprising NaOH, NaOCl and surfactant, scrub, wait 20 minutes, water rinse; SANITISE and RINSE: broad spectrum sanitiser, comprising of range of antimicrobials, wait 20 minutes, water rinse.	The ELISA assay results for gliadin show that the cleaning procedures at the facility were extremely effective at gliadin removal. The comment is made that even modest cleaning would be sufficient for gliadin removal in this facility. A comparison of ATP results with the gliadin ELISA showed that the results of the 2 tests agree. It was, however, emphasised that these outcomes apply only to the chicken product range processed in the facility and are not necessarily able to be extrapolated to other foods and processing protocols.

- **Jackson and Al-Taher (2010)** Efficacy of different dry cleaning methods for removing allergenic foods from food-contact surfaces (Poster).

  Study design summary: The aim was to evaluate the efficacy of two dry cleaning methods for removing allergenic residues from a variety of food-contact surfaces. For experiments evaluating the effectiveness of wipes, slurries containing peanut flour, skim milk powder, whole egg powder, soy flour, soy milk and soy infant formula powder were deposited on the surface of stainless steel, Teflon and urethane plates. The plates were heated at 80°C for 1 hour to form a cooked food residue. For experiments evaluating the use of vacuum, plates were prepared as described above. In addition, peanut flour, milk powder, whole egg powder, soy flour and soy infant formula powder were applied to the surface of the plates without heat.

Allergens	Surfaces	Detection methods	Cleaning methodologies	Efficacy of cleaning summary
Milk; Egg; Peanut; Soy	Stainless steel; Teflon; Urethane faced belting	Visual inspection; Neogen Alert qualitative ELISA kits for peanut, total milk, egg and soy; conventional ATP swabs (Pocketswab, Charm Sciences); sensitive ATP swabs (Allergiene, Charm Sciences); protein swabs (Aller-tect, 3-M)	Alcohol-moistened wipes; High efficiency vacuum	Wipes removed all cooked food residues from all surfaces, as determined using all the detection methods. However, conventional and sensitive ATP swabs detected the presence of residue when the surfaces were clean according to all tests. For all trials, the vacuum was unable to remove cooked food residues using all detection methods. For uncooked foods, the vacuum was able to remove all visible traces of the foods, with the exception of milk powder on the urethane surface. However, in some cases, ELISA, the protein swab and both ATP swabs detected the presence of food residues.

- **Schreder et al. (2013)** Management of allergens in the gastronomy: difficulty of cross-contact referred to the context of food regulatory. Ernaehrungs-Umschau.

  Study design summary: Investigating cross-contact in restaurants/catering businesses: food preparation stages were filmed at different times (breakfast, midday, evening) and prime activity areas were tested for allergens.

Allergens	Surfaces	Detection method	Cleaning methodologies	Efficacy of cleaning summary
Milk (casein); Gluten (G12); Egg	Work surfaces (for example cutting board), utensils (for example knife) and hands/gloves	Allergen test strips by Romer Labs	Water; Water and detergent/soap	Cleaning work surfaces, utensils or hands and gloves with water only (without detergent and soap) is not sufficient to prevent cross-contact. Cleaning work surfaces, tools or hands and gloves with detergent or soap is mostly sufficient to prevent cross-contact.

- **Watson, Woodrow and Stadnyk (2013)** Persistence of peanut allergen on a table surface. Allergy, Asthma and Clinical Immunology.

  Study design summary: Peanut butter applied to a laminated plastic surface kept in a hospital office at room temperature and ambient light conditions and tested for Ara h 1 at regular intervals. On day 110, a commercial cleaning wipe was used to clean the surface.

Allergen	Surface	Detection method	Cleaning methodologies	Efficacy of cleaning summary
Peanut	Laminated plastic surface	Ara h 1 ELISA (INDOOR Biotechnologies)	Clorox® Disinfecting Wipes	Detectable Ara h 1 on every sample collected for 110 days. Immediately after cleaning the surface, Ara h 1 was not detected.

- **Hashimoto, Yoshimitsu and Kiyota (2014)** Comparison of egg allergens retained on food service tableware made from different materials (Abstract only). Journal of Home Economics of Japan.

  Study design summary: Egg allergens remaining on food service tableware made of different materials were analysed after washing with water or with water and detergent.

Allergen	Surfaces	Detection methods	Cleaning methodologies	Efficacy of cleaning summary
Egg	Food service tableware made from four different materials (polypropylene, strengthened porcelain, polyethylene naphthalate, and melamine)	LFDs and ELISA	Wash with water only; Wash with water and/or detergent	The tableware tested positive or weakly positive after washing with only water, and negative or weakly positive after washing with detergent, there being no differences among the tableware materials. The tableware was then rinsed twice or four times and tested again as positive or weakly positive. The quantitative ELISA results showed the allergen levels to be slightly higher than or close to 50 ng/mL after washing with only water, and below the lower limit of quantification (＜0.78 ng/mL) after washing with detergent for many of the tested allergens. There were no significant differences among the four kinds of tableware material for the residual characteristics of the egg allergens.

- **Zhang (2014)** Effectiveness of cleaning regimens for removing peanut, milk and egg residue from pilot-scale cereal bar and muffin processing lines (Abstract only, Thesis).

  Study design summary: The objectives of this project were to evaluate the effectiveness of cleaning regimens on removing allergenic food residue (peanut flour, non-fat dry milk, egg powder) from pilot-scale cereal bar and muffin processing lines and measure the levels of allergens transferred into allergen-free (control) cereal bars and muffins processed on an inadequately cleaned processing line. Another objective was to investigate the analytical methods used (conventional ATP, sensitive ATP, total protein and lateral flow) to evaluate the effectiveness of allergen cleaning procedures.

Allergens	Surfaces	Detection methods	Cleaning methodologies	Efficacy of cleaning summary
Peanut; Milk; Egg	Mixer; Depositor; Nozzle; Conveyor belt	LFDs for surfaces Quantitative; ELISAs for samples	1) push-through with control cereal bar dough or muffin batter; 2) scraping the equipment surfaces with rubber scrapers; 3) a rinse with hot (54-60°C) water until “visibly clean”; 4) a full cleaning cycle with alkaline detergent followed by use of a sanitiser	Results of LFD tests indicated that hot water rinse was effective for the cereal bar processing line but not for the muffin line. Only the full cleaning cycle was effective at removing allergenic food residues for both processing lines. During the cross-contact study, substantial levels of peanut, milk and egg were detected in samples obtained both before and after baking. Overall, these results illustrate the importance of validated cleaning protocols for preventing allergen cross-contact on shared processing lines.

- **Watson, Woodrow and Stadnyk (2015)** Removal of peanut allergen Ara h 1 from common hospital surfaces, toys and books using standard cleaning methods. Allergy, Asthma and Clinical Immunology.

  Study design summary: Peanut butter smeared on hospital surfaces before cleaning with a common household wipe and two commercial hospital wipes.

Allergen	Surfaces	Detection method	Cleaning methodologies	Efficacy of cleaning summary
Peanut	Laminated plastic surface; plastic doll; textured plastic ball; smooth and textured book covers	Ara h 1 ELISA (INDOOR Biotechnologies)	Clorox® Disinfecting Wipes Ultrawipes™ hospital wipes Butcher's PerCept RTU Wipes™ hospital wipes	After cleaning with any product, no Ara h 1 was detected on any item. Table surfaces, book covers and plastic toys can be cleaned to remove peanut allergen Ara h 1 using common household and hospital cleaning wipes. Regular cleaning of these products or cleaning prior to their use should be promoted to reduce the risk of accidental peanut exposure, especially in areas where they have been used by many children.

- **Courtney (2016)** Evaluation of qualitative food allergen detection methods and cleaning validation approaches (Thesis).
  Study design summary: Chapter 3 of this thesis details a study of the effects of cleaning on removal of milk soils from various food processing syrfaces as detected by commercial milk-specific lateral flow devices and general protein tests. Four food-processing surfaces were soiled with non-fat dried milk and cleaned with each cleaning solution of a typical CIP system separately and then sequentially.

Allergen	Surfaces	Detection methods	Cleaning methodologies	Efficacy of cleaning summary
Milk	316 grade stainless steel; high density polyethylene (HDPE); Nylon 6/6; Delrin	Romer AgraStrip Casein (Romer Labs, Runcorn, Cheshire, UK); Neogen Reveal 3-D Total Milk (Neogen Corporation, Lansing, MI, US); 3M Clean-Trace Surface Protein Allergen (3M Health Care , St. Paul, MN, US)	Commercial caustic; Commodity caustic; Acid cleaner; Oxidizing sanitiser	The caustic solutions easily removed the milk soil while the acid and sanitising solutions left a soiled surface. When used separately, a commercial caustic solution was observed to outperform a commodity caustic solution. Stainless steel was most easily cleaned, followed by HDPE and Nylon 6/6.

- **Wells and Jeong (2017)** Evaluating current industry dry cleaning practice using vacuum with regard to food allergens on processing surfaces (Abstract only). Journal of Food Protection.

  Study design summary: Stainless steel coupons were electrostatically coated with soy protein isolate powder as an allergenic material.

Allergen	Surface	Detection method	Cleaning methodologies	Efficacy of cleaning summary
Soy	Stainless steel coupons	Neogen 3D Reveal test kits	Vacuum cleaning at about 3mm above the surface. After 10 seconds of vacuuming followed by a brushing, second vacuuming was applied for 10 seconds	Allergen tests showed 50% negative and 50% positive for soy (n=6), which indicates the uncertainty of the vacuum cleaning practice for allergen removal. The results of the vacuum cleaning test provided further evidence that visual cleanness poses the risk of allergen cross-contact.

- **Kiyota et al. (2017)** Evaluation of cleaning methods for residual orange extract on different cookware materials using ELISA with profilin allergen indicator. Journal of Food Process Engineering

  Study design summary: Development and production of an antibody detection method (plate ELISA), before spreading orange extract over an area of 5cm x 5cm on 4 types of surface material, then cleaning and analysis for residual orange extract.

Allergen	Surfaces	Detection method	Cleaning methodologies	Efficacy of cleaning summary
Orange	Propylene (PP) chopping board; Wood chopping board; Stainless steel tray; Glass dishes	Study involved development of an ELISA based on recombinant protein to produce polyclonal anti-rCit s 2-SUMO antibody	Rinsed with 1 L running water for 5–10 seconds at 28ºC; Scrubbed 10 times with a urethane sponge scourer containing a household detergent, followed by rinsing with 1 L running water for 5–10 seconds at 28ºC	Rinsing with 1 L of water showed a >95% removal efficiency for stainless steel and glass cookware, whereas half the PP and wood cookware required scrubbing with a detergent-containing sponge for complete cleanliness. When the surfaces were cleaned with foam and rinsed, the orange extract was removed from all cookware; however, in the case of wood, levels below the LOQ were detected in two of the five experiments.

- **Schembri (2017)** Improving food allergen management in small food service businesses serving loose food (Thesis).
  Study design summary: Pans spiked with the target allergens, then washed using different methods, were tested for allergen residue.

Allergens	Surface	Detection method	Cleaning methodologies	Efficacy of cleaning summary
Egg; Gluten	Pan	LFDs: Reveal RAPID 3-D (Neogen)	Washing by hand; Washing by dishwasher; Brisk hand washing with dedicated brush	Egg was not detected following hand washing or dish washing (egg was not tested for following brisk hand washing). Gluten was detected after hand and dish washing, but not after brisk hand washing, even though the pan was visually clean.

- **Zhang et al. (2018)** Effectiveness of push-through cleaning methods for removing milk chocolate from a stainless-steel pipe and butterfly valve (Abstract only). Journal of Food Protection.

  Study design summary: Melted milk chocolate used to coat inner surfaces of a heated stainless-steel pipe and attached butterfly valve. Evaluated effectiveness of using a silicone pig and push-through with cocoa butter, as a cleaning method to remove milk chocolate.

Allergen	Surfaces	Detection method	Cleaning methodologies	Efficacy of cleaning summary
Milk	Stainless steel pipe and butterfly valve	ELISA (Neogen Veratox for Total Milk)	PUSH-THROUGH (use of a silicone pig (7.6cm in length)), followed by dark chocolate; PUSH-THROUGH (recirculating cocoa butter (~27kg, 40°C, 1 hour)	PUSH-THROUGH (silicone pig) – Following the pig, after 13 to 15 kg of milk-free dark chocolate was pumped through the pipe and valve, milk levels were below the ELISA limit of quantitation (LOQ=2.5 ppm). Use of the pig dramatically reduced levels of milk in initial dark chocolate samples. PUSH-THROUGH (recirculating cocoa butter) - Recirculating cocoa butter decreased initial milk levels, but 11 (3% CV) ppm milk was detected after ~13 kg dark chocolate purge.

- **Ortiz et al. (2018)** Survey on the occurrence of allergens on food-contact surfaces from school canteen kitchens. Food Control. **Study design summary:** Fifty school canteens were visited during 2 school years. The study included not only food-contact surfaces of general use but also surfaces for exclusive use in meals free of specific allergens. The total number of samples was 621 (213 were analysed for milk and egg, and 195 for gluten).

Allergens	Surfaces	Detection methods	Cleaning methodologies	Efficacy of cleaning summary
Egg; Milk; Gluten	Kitchen surfaces (glasses, pots, pans, plates, trays and food boxes) and utensils (blenders, knifes, ladles, slotted spoons, spatulas, spoons, strainers, tongs, forks, pastry brushes, scissors and spaghetti spoons)	On-site LFDs: Milk (beta-lactoglobulin), egg (ovalbumin) and gluten (Proteon Express, ZEULAB, Spain). Followed by ELISAs for laboratory confirmation: Proteon Milk and Egg (ZEULAB, Spain) and GlutenTox ELISA (Biomedal, Spain).	Most of the kitchens used automatic washer systems for small tools and containers of general use. Some kitchens washed by hand the biggest food-contact surfaces of general use and the tools and containers of exclusive use to prepare allergen-free menus. In all cases, cleaning was performed with conventional detergents and disinfectants to control microbial contamination.	The current cleaning procedures in kitchens of school canteens are not effective to remove allergens from food-contact surfaces and surfaces. Therefore, processes should be improved in order to reduce the risk of allergen cross-contact. Validation of cleaning processes and verification of its effectiveness after each cleaning should be demonstrated by using the suitable tools of analysis. The use of exclusive food-contact surfaces to avoid allergen cross-contact during the preparation or serving meals is not a guarantee of the absence of allergens.

- **Zhang et al. (2019)** Effectiveness of cleaning strategies for removing milk chocolate from pilot-scale chocolate processing equipment (Abstract only). Journal of Food Protection.

  Study design summary: Piot scale investigations involving milk chocolate processed in a ball mill and horizontal-shaft conch, followed by draining the majority of the chocolate, then carrying out cleaning or push-through with cocoa butter. After cleaning, three batches of milk-free dark chocolate were processed and each batch was collected for analysis. Milk chocolate processed on a three-roller refiner, followed by push-through with dark chocolate, after which samples were collected for analysis.

Allergen	Surfaces	Detection method	Cleaning methodologies	Efficacy of cleaning summary
Milk	Ball mill; horizontal shaft conch; three-roller refiner	ELISA (Neogen Veratox® for Total Milk)	PUSH-THROUGH (cocoa butter (40ºC, 5 min rinse); WET CLEANING (detergent-rinse-air dry); PUSH-THROUGH (dark chocolate)	PUSH-THROUGH (cocoa butter) - Levels of milk reduced from up to 40,300ppm milk (ball mill) and 18,100ppm milk (conch) detected in dark chocolate that had been passed through uncleaned equipment, to 1,960ppm milk (ball mill) and 2,440ppm milk (conch) in the first batch of dark chocolate following the cocoa butter push-through. Milk levels decreased in subsequent batches of dark chocolate processed on both pieces of equipment. WET CLEANING - Milk levels were below the ELISA limit of quantitation (LOQ; 2.5 ppm) for all three dark chocolate batches produced. PUSH-THROUGH (dark chocolate) - Initial dark chocolate samples contained up to 2,140ppm milk. After approximately 3kg of dark chocolate was processed on the refiner, measured milk levels were below the ELISA LOQ.

- **Galan-Malo et al. (2019)** A study to reduce the allergen contamination in food-contact surfaces at canteen kitchens. International Journal of Gastronomy and Food Science.

  Study design summary: Ten school canteens were visited during a school year. Between 26 and 34 cleaned utensils were selected from each school (resulting in a total of 308 samples for analysis; 99 for gluten, 100 for egg and 109 for milk).

Allergens	Surfaces	Detection methods	Cleaning methodologies	Efficacy of cleaning summary
Egg; Milk; Gluten	Kitchen surfaces and utensils, made from Teflon, Stainless steel, Plastic	On-site LFDs: Proteon Milk Express, Proteon Casein Express, Proteon Egg Express, Proteon Gluten Express (ZEULAB, Spain) Followed by ELISAs for laboratory confirmation: Proteon Milk, Proteon Egg (ZEULAB, Spain), GlutenTox ELISA, Biomedal, Spain)	The usual cleaning was with conventional detergents in 5 out of the 10 schools - either by hand or in an automatic dishwasher. In the other 5 schools, an additional cleaning step was implemented using a detergent with proteases (DetzymSurfaces, Hypred) after the ordinary cleaning	Detergent with proteases, rinsing the utensils before use and wash by hand, reduced significantly the occurrence of allergens on kitchen surfaces or utensils. Some storage conditions such as keeping utensils in a cupboard or covered somehow, also protect the utensils from allergen post-contamination, this was particularly true for egg and gluten (both of which are used in powdered from). The higher level of contamination when using an automatic dishwasher could be explained by the partial recirculation of water. None of the materials showed a significant impact on the number of utensils contaminated with allergen residues. Only the utensils made of Teflon shown a clear trend to be contaminated with gluten, but this requires confirmation. When comparing LFD and ELISA results, more positive results were found by ELISA test, as the limits of detection of this method are lower.

- **Bedford et al. (2020)** Allergen removal and transfer with wiping and cleaning methods used in retail and food service establishments. Journal of Food Protection.

  Study design summary: Dry or powdered, wet, or sticky and paste forms of foods containing non-fat dry milk powder, cream cheese, fluid whole milk, whole egg powder, mayonnaise, peanut powder and peanut butter were applied individually to surface material coupons (stainless steel, textured plastic and maple wood). Different cleaning regimes were conducted, and surfaces were checked by LFDs.

Allergens	Surfaces	Detection methods	Cleaning methodologies	Efficacy of cleaning summary
Peanut; Milk; Egg	Stainless steel; Textured plastic; Maple wood	Allergen-specific Reveal 3-D (Neogen) LFD tests for total milk, egg and peanut	Dry paper wipes; Dry terry dish cloths; Wet terry cloth (soaked in tap water); Wet terry cloth (soaked in 50ppm of total chlorine sanitiser solution); Alcohol quaternary ammonium chloride wipes; Wash-rinse-sanitise-dry rinse procedure.	Although dry wipes and cloths were not effective for removing allergenic foods, terry cloth pre-soaked in water or sanitiser solution, use of multiple quat wipes, and the wash–rinse–sanitise–air dry procedure were effective in allergen removal from surfaces. Allergens present on dry wipes were transferred to wiped surfaces. In contrast, minimal or no allergen transfer to surfaces was found when allergen-contaminated terry cloth was submerged in sanitiser solution prior to wiping surfaces. The full cleaning method (wash–rinse–sanitise–air dry) and soaking the terry cloth in sanitiser solution prior to wiping were effective at allergen removal and minimizing allergen transfer.

- **Aleksić et al. (2020)** Controls of nutritive allergens in a hospitality kitchen. Meat Technology.

  Study design summary: Hospitality kitchen conducted everyday business operations; allergen status of surfaces was determined after specific cleaning methodology carried out using microfibre cloths and combinations of cold or warm water, with or without detergent, changing the cloth between wipes and changing the work uniform between food preparation and cleaning activities. Foods containing allergens in the kitchen were identified as savoury cornbread (gluten), pizza pastry (gluten), sweet muffin (gluten) and pork neck (soya).

Allergens	Surfaces	Detection method	Cleaning methodologies	Efficacy of cleaning summary
Gluten; Soya	Worktops; knives; meat slicers; convection ovens; worker aprons and worker hands	FLASH® Allergen-Indicator Protein Test swabs (Millipore)	A - Wipe with cold, then warm water, using the same wiping cloth (microfiber); B - Wipe with warm water, then warm water with detergent, using the same wiping cloth (microfiber): C - Wipe with warm water, then warm water with detergent, the cloth (microfiber) was changed to a fresh cloth after the first wipe with warm water;	A - Contamination was detected on all surfaces. There was little difference in results after wiping with cold or warm water. B - Results showed possible contamination or some contamination on all surfaces. C - Results showed possible contamination or some contamination on all surfaces except for the worktop following the wipe with warm water and detergent.

Allergens	Surfaces	Detection method	Cleaning methodologies	Efficacy of cleaning summary
			D - Wipe with warm water, then warm water with detergent, the cloth (microfiber) was changed to a fresh cloth after the first wipe with warm water, the work uniform was changed after food preparation, before the cleaning activity E - Wipe with warm water, then warm water with detergent, the cloth (microfiber) was changed to a fresh cloth after the first wipe with warm water, the work uniform was changed after food preparation, and hands were washed after food preparation	D - Results showed possible contamination or some contamination on all surfaces following the initial wipe with warm water. After the wipe with warm water and detergent only the employee apron showed possible contamination, for all other surfaces contamination was not determined. E - Results showed possible contamination or some contamination on all surfaces following the initial wipe with warm water. After the wipe with warm water and detergent no contamination was determined on any surface.

- **Remington et al. (2020)** Risk of equipment in restaurants for consumers with peanut allergy: a simulation for preparing Asian foods. Annals of Allergy, Asthma, & Immunology.

  Study design summary: Three peanut-containing sauces, representing different textures (stickiness), were prepared using a range of kitchen equipment and utensils, which were washed using common procedures to represent normal daily practice. Although not a study to determine effective cleaning methodology, this study provides important information about the efficacy of cleaning using 'normal' practices with a food service kitchen.

Allergen	Surfaces	Detection method	Cleaning methodologies	Efficacy of cleaning summary
Peanut	EQUIPMENT Wok, Saucepan; UTENSILS: Whisks, Tongs, Spatulas, Ladles, Spoons	Weighing of the equipment/utensils before and after cleaning, followed by calculations of level of peanut protein in the residue	EQUIPMENT: Brief scrub with a brush and warm water (no soap or detergent used); UTENSILS: Brief rinse in a shared pot of warm water for a couple of seconds	EQUIPMENT: There was no measurable sauce residue found in most cases (32 of 35) after common cleaning practice (brief scrub with a brush and warm water). UTENSILS: Rinsing with warm water significantly decreased the amount of peanut residue, but it did not completely remove all peanut protein. Sauce residue, containing calculated levels of peanut protein, remained on all the utensils following cleaning

- **Chen et al. (2022)** Environment, food residue, and dry cleaning tool all influence the removal of food powders and allergenic residues from stainless steel surfaces. Innovative Food Science and Emerging Technologies.
  Study design summary: Powders (wheat flour and non-fat dried milk) deposited on stainless steel coupons. A custom experimental rig was developed to standardise brushing and scraping treatments.

Allergens	Surface	Detection methods	Cleaning methodologies	Efficacy of cleaning summary
Gluten; Milk	Stainless steel	ATP Test swabs (UltraSnap™, Hygiena, Camarillo, CA) General surface protein test swab (Clean-Trace™, 3M, St. Paul, MN) (quantitative) Specific allergen lateral flow devices (LFD) (3M, St. Paul, MN) tests for gluten and milk proteins.	Brushing; Scraping	Number of brush passes needed to reach the “clean state” were numerically but not statistically less than the number of scraper passes needed in the removal of wheat flour under all water activity (aw) conditions. Scraping was significantly less effective than brushing in the removal of powder under all conditions. Two to four passes of scraper required to achieve the “clean state” under all conditions. Wheat flour residues were consistently detected with all biochemical swab tests under all conditions following scraping. Allergenic residues were consistently detected following scraping or brushing under most conditions, even as the surfaces appeared visibly clean and passed ATP testing. Overall, the findings highlight the potential for allergenic residue retention after conventional dry cleaning using hand tools.

11.3 Journal articles and theses publication type, country and citations summary

Publication reference	Country	Journal article	Poster	Thesis	Full text	Abstract only	WoS Citations*	GS Citations*
Perry et al. (2004)	US	Y	-	-	Y	-	123	184
Jackson et al. (2008)	US	Y	-	-	Y	-	62	116
Röder et al. (2008)	Germany	Y	-	-	Y	-	22	34
Spektor (2009)	US	-	-	Y	Y	-	0	1
Wang, Young and Karl (2010)	New Zealand	Y	-	-	Y	-	17	29
Jackson and Al-Taher (2010)	US	-	Y	-	-	-	0	0
Schreder et al. (2013)	Austria	Y	-	-	Y	-	0	0
Watson, Woodrow and Stadnyk (2013)	Canada	Y	-	-	Y	-	7	12
Hashimoto, Yoshimitsu and Kiyota (2014)	Japan	Y	-	-	-	Y	0	3
Zhang (2014)	US	-	-	Y	-	Y	0	0
Watson, Woodrow and Stadnyk (2015)	Canada	Y	-	-	Y	-	3	9
Courtney (2016)	US	-	-	Y	-	-	0	4
Wells and Jeong (2017)	US	Y	-	-	-	Y	0	0
Kiyota et al. (2017)	Japan	Y	-	-	Y	-	1	1
Schembri (2017)	UK	-	-	Y	Y	-	0	0
Zhang et al. (2018)	US	Y	-	-	-	Y	0	0
Ortiz et al. (2018)	Spain	Y	-	-	Y	-	11	26
Zhang et al. (2019)	US	Y	-	-	-	Y	1	0
Galan-Malo et al. (2019)	Spain	Y	-	-	Y	-	7	8
Bedford et al. (2020)	US	Y	-	-	Y	-	4	7
Aleksić et al. (2020)	Croatia	Y	-	-	Y	-	0	3
Remington et al. (2020)	US	Y	-	-	Y	-	4	4
Chen et al. (2022)	US	Y	-	-	Y	-	3	4
TOTAL NUMBER PER PUBLICATION TYPE	N/A	18	1	4	16	5	N/A	N/A

Y = study matches stated category; - = study does not match stated category

*WoS citations = number of citations recorded on Web of Science; GS citations = number of citations recorded on Google Scholar

11.4 Journal articles and theses scenario summary

Publication reference	Food processing	Food service
Perry et al. (2004)	-	Y
Jackson et al. (2008)	Y	-
Röder et al. (2008)	Y	-
Spektor (2009)	Y	-
Wang, Young and Karl (2010)	Y	-
Jackson and Al-Taher (2010)	Y	-
Schreder et al. (2013)	-	Y
Watson, Woodrow and Stadnyk (2013)	-	Y
Hashimoto, Yoshimitsu and Kiyota (2014)	-	Y
Zhang (2014)	Y	-
Watson, Woodrow and Stadnyk (2015)	-	Y
Courtney (2016)	Y	-
Wells and Jeong (2017)	Y	-
Kiyota et al. (2017)	-	Y
Schembri (2017)	-	Y
Zhang et al. (2018)	Y	-
Ortiz et al. (2018)	-	Y
Zhang et al. (2019)	Y	-
Galan-Malo et al. (2019)	-	Y
Bedford et al. (2020)	-	Y
Aleksić et al. (2020)	-	Y
Remington et al. (2020)	-	Y
Chen et al. (2022)	Y	-
TOTAL NUMBER PER SCENARIO	11	12

Y = study matches stated scenario category; - = study does not match stated scenario category

11.5 Journal articles and theses allergens studied summary

Publication reference	Milk	Gluten	Soy	Peanut	Egg	Other
Perry et al. (2004)	-	-	-	Y	-	-
Jackson et al. (2008)	Y	-	-	Y	-	-
Röder et al. (2008)	-	-	-	-	-	H
Spektor (2009)	Y	-	-	Y	Y	-
Wang, Young and Karl (2010)	-	Y	-	-	-	-
Jackson and Al-Taher (2010)	Y	-	Y	Y	Y	-
Schreder et al. (2013)	Y	Y	-	-	Y	-
Watson, Woodrow and Stadnyk (2013)	-	-	-	Y	-	-
Hashimoto, Yoshimitsu and Kiyota (2014)	-	-	-	-	Y	-
Zhang (2014)	Y	-	-	Y	Y	-
Watson, Woodrow and Stadnyk (2015)	-	-	-	Y	-	-
Courtney (2016)	Y	-	-	-	-	-
Wells and Jeong (2017)	-	-	Y	-	-	-
Kiyota et al. (2017)	-	-	-	-	-	O
Schembri (2017)	-	Y	-	-	Y	-
Zhang et al. (2018)	Y	-	-	-	-	-
Ortiz et al. (2018)	Y	Y	-	-	Y	-
Zhang et al. (2019)	Y	-	-	-	-	-
Galan-Malo et al. (2019)	Y	Y	-	-	Y	-
Bedford et al. (2020)	Y	-	-	Y	Y	-
Aleksić et al. (2020)	-	Y	Y	-	-	-
Remington et al. (2020)	-	-	-	Y	-	-
Chen et al. (2022)	Y	Y	-	-	-	-
TOTAL NUMBER PER ALLERGEN	12	7	3	9	9	2

Y = allergen included in the study; - = allergen not included in the study

O = Orange; H = Hazelnut

11.6 Journal articles and theses matrices studied summary

Publication reference	Peanut butter	Peanut flour	Milk liquid	Milk dry	Egg liquid	Egg dry	Soy 'milk'	Soy flour	Wheat flour	Other
Perry et al. (2004)	Y	-	-	-	-	-	-	-	-	
Jackson et al. (2008)	Y	-	Y	-	-	-	-	-	-	Hot milk
Röder et al. (2008)	-	-	-	-	-	-	-	-	-	Cookie dough
Spektor (2009)	Y	-	Y	-	Y	-	-	-	-	
Wang, Young and Karl (2010)	-	-	-	-	-	-	-	-	-	Battered chicken
Jackson and Al-Taher (2010)	-	Y	-	Y	-	Y	Y	Y	-	Soy infant formula
Schreder et al. (2013)	-	-	Y	-	Y	-	-	-	-	See Note (1)
Watson, Woodrow and Stadnyk (2013)	Y	-	-	-	-	-	-	-	-	
Hashimoto, Yoshimitsu and Kiyota (2014)	-	-	-	-	-	-	-	-	-	See Note (2)
Zhang (2014)	-	Y	-	Y	-	Y	-	-	-	Cereal bars, muffins
Watson, Woodrow and Stadnyk (2015)	Y	-	-	-	-	-	-	-	-	
Courtney (2016)	-	-	Y	-	-	-	-	-	-	
Wells and Jeong (2017)	-	-	-	-	-	-	-	-	-	Soy protein isolate
Kiyota et al. (2017)	-	-	-	-	-	-	-	-	-	Orange extract
Schembri (2017)	-	-	-	-	-	-	-	-	-	See Note (2)
Zhang et al. (2018)	-	-	-	-	-	-	-	-	-	Milk chocolate
Ortiz et al. (2018)	-	-	-	-	-	-	-	-	-	See Note (2)
Zhang et al. (2019)	-	-	-	-	-	-	-	-	-	Milk chocolate
Galan-Malo et al. (2019)	-	-	-	-	-	-	-	-	-	See Note (2)
Bedford et al. (2020)	Y	Y	Y	Y	-	Y	-	-	-	See Note (3)
Aleksić et al. (2020)	-	-	-	-	-	-	-	-	-	See Note (4)
Remington et al. (2020)	-	-	-	-	-	-	-	-	-	Asian sauces
Chen et al. (2022)	-	-	-	Y	-	-	-	-	Y	

Publication reference	Peanut butter	Peanut flour	Milk liquid	Milk dry	Egg liquid	Egg dry	Soy 'milk'	Soy flour	Wheat flour	Other
TOTAL NUMBER PER MATRIX	6	3	5	4	2	3	1	1		N/A

Y = matrix included in the study; - = matrix not included in the study
Note (1) – Matrices also included toast, salad, bread, cheese, sausage.
Note (2) – No specific information on the matrix or matrices provided.
Note (3) – Matrices also included cream cheese and mayonnaise.
Note (4) – Matrices were savoury cornbread, pizza pastry, sweet muffin and pork neck.

11.7 Journal articles and theses cleaning methodology summary

Publication reference	Dry	Wet	Controled wet	Push-through	CIP
Perry et al. (2004)	-	-	Y	-	-
Jackson et al. (2008)	-	Y	-	-	-
Röder et al. (2008)	Y	Y	-	Y	-
Spektor (2009)	-	Y	-	-	-
Wang, Young and Karl (2010)	-	Y	-	-	-
Jackson and Al-Taher (2010)	Y	-	Y	-	-
Schreder et al. (2013)	-	Y	-	-	-
Watson, Woodrow and Stadnyk (2013)	-	-	Y	-	-
Hashimoto, Yoshimitsu and Kiyota (2014)	-	Y	-	-	-
Zhang (2014)	Y	Y	-	Y	-
Watson, Woodrow and Stadnyk (2015)	-	-	Y	-	-
Courtney (2016)	-	-	-	-	Y
Wells and Jeong (2017)	Y	-	-	-	-
Kiyota et al. (2017)	-	Y	-	-	-
Schembri (2017)	-	Y	-	-	-
Zhang et al. (2018)	-	-	-	Y	-
Ortiz et al. (2018)	-	Y	-	-	-
Zhang et al. (2019)	-	Y	-	Y	-
Galan-Malo et al. (2019)	-	Y	-	-	-
Bedford et al. (2020)	Y	Y	Y	-	-
Aleksić et al. (2020)	-	-	Y	-	-
Remington et al. (2020)	-	Y	-	-	-
Chen et al. (2022)	Y	-	-	-	-
TOTAL NUMBER PER CLEANING METHODOLOGY	6	14	6	4	1

Y = cleaning methodology included in the study; - = cleaning methodology not included in the study

11.8 Journal articles and theses surface type summary

Publication reference	Steel	Plastic	Wood	Glass	Utensils	Teflon
Perry et al. (2004)	-	Y	-	-	Y	-
Jackson et al. (2008)	Y	Y	-	-	-	Y
Röder et al. (2008)	Y	-	-	-	-	-
Spektor (2009)	Y	-	-	-	-	-
Wang, Young and Karl (2010)	Y	-	-	-	-	-
Jackson and Al-Taher (2010)	Y	Y	-	-	-	Y
Schreder et al. (2013)	-	-	-	-	Y	-
Watson, Woodrow and Stadnyk (2013)	-	Y	-	-	-	-
Hashimoto, Yoshimitsu and Kiyota (2014)	-	-	-	-	Y	-
Zhang (2014)	Y	-	-	-	-	-
Watson, Woodrow and Stadnyk (2015)	-	Y	-	-	-	-
Courtney (2016)	Y	Y	-	-	-	-
Wells and Jeong (2017)	Y	-	-	-	-	-
Kiyota et al. (2017)	Y	Y	Y	Y	-	-
Schembri (2017)	-	-	-	-	Y	-
Zhang et al. (2018)	-	-	-	-	-	-
Ortiz et al. (2018)	-	-	-	-	Y	-
Zhang et al. (2019)	-	-	-	-	-	-
Galan-Malo et al. (2019)	Y	Y	-	-	Y	Y
Bedford et al. (2020)	Y	Y	Y	-	-	-
Aleksić et al. (2020)	-	-	-	-	Y	-
Remington et al. (2020)	-	-	-	-	Y	-
Chen et al. (2022)	Y	-	-	-	-	-
TOTAL NUMBER PER SURFACE TYPE	12	9	2	1	8	3

Y = surface type included in the study; - = surface type not included in the study

11.9 Journal articles and theses detection method summary

Publication reference	Visible	ELISA	LFD	ATP	Protein	PCR
Perry et al. (2004)	-	Y	-	-	-	-
Jackson et al. (2008)	-	-	-	-	-	-
Röder et al. (2008)	-	Y	-	-	-	-
Spektor (2009)	Y	Y	-	-	-	-
Wang, Young and Karl (2010)	-	Y	-	Y	Y	-
Jackson and Al-Taher (2010)	Y	Y	-	Y	Y	-
Schreder et al. (2013)	-	-	Y	-	-	-
Watson, Woodrow and Stadnyk (2013)	-	Y	-	-	-	-
Hashimoto, Yoshimitsu and Kiyota (2014)	-	Y	Y	-	-	-
Zhang (2014)	-	-	-	-	-	-
Watson, Woodrow and Stadnyk (2015)	-	Y	-	-	-	-
Courtney (2016)	Y	-	Y	-	-	-
Wells and Jeong (2017)	-	-	Y	-	-	-
Kiyota et al. (2017)	-	Y	-	-	-	-
Schembri (2017)	-	-	Y	-	-	-
Zhang et al. (2018)	-	Y	-	-	-	-
Ortiz et al. (2018)	-	Y	Y	-	-	-
Zhang et al. (2019)	-	Y	-	-	-	-
Galan-Malo et al. (2019)	-	-	-	-	-	-
Bedford et al. (2020)	-	-	Y	-	-	-
Aleksić et al. (2020)	-	-	-	-	Y	-
Remington et al. (2020)	-	-	-	-	-	-
Chen et al. (2022)	-	-	Y	Y	Y	-
TOTAL NUMBER PER DETECTION METHOD	2	12	8	3	4	0

Y = detection method included in the study; - = detection method not included in the study

11.10 Cleaning methodology categories referenced within guidance documents

Guidance	Country	Wet	Dry	Push-through	CIP
Food Standards Agency, 2006	UK	Y	Y	-	-
Campden BRI, 2009	UK	-	-	Y	Y
Catalan Food Safety Agency, 2009	Spain	Y	Y	Y	
Campden BRI, 2013	UK	-	-	Y	-
Centers for Disease Control and Prevention, 2013	US	Y	-	-	-
Alberta Agriculture and Rural Development, 2014	CANADA	Y	Y	-	Y
ASSIFONTE, 2018	EU	Y	Y	-	Y
Brazilian Health Regulatory Agency, 2018	Brazil	Y	Y	Y	
Farmhouse and Artisan Cheese & Dairy Producers European Network, 2018	EU	Y	-	-	-
Codex Alimentarius, 2020a	Global	Y	Y	Y	Y
FoodDrinkEurope, 2020	EU	Y	-	-	-
Peanut and Tree Nut Processors Association, 2020	US	Y	Y	Y	Y
European Hygienic Engineering and Design Group, 2021	EU	Y	Y	Y	Y
Food Allergy Canada, 2022	CANADA	Y	Y	-	-
FoodDrinkEurope, 2022	EU	Y	Y	Y	-
USDA Food Safety and Inspection Service, 2022	US	Y	Y	Y	Y
US Food and Drug Administration, 2022	US	Y	Y	-	Y
Food Allergy Research and Resource Program, no date	US	Y	-	-	-
TOTAL NUMBER PER CLEANING METHODOLOGY	N/A	16	12	9	8

Y = Cleaning methodology mentioned, - = Cleaning methodology not mentioned.

11.11 Principles of cleaning validation for food allergens referenced within guidance documents

Guidance	Country	P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	P11	P12	P13	P14
Food Standards Agency, 2006	UK	Y	-	Y	-	Y	Y	-	Y	Y	-	-	-	-	-
Campden BRI, 2009	UK	Y	Y	-	Y	Y	-	Y	Y	Y	Y	Y	-	Y	Y
Catalan Food Safety Agency, 2009	Spain	Y	Y	Y	-	Y	Y	-	-	Y	Y	-	-	Y	Y
Safe Quality Food Institute, 2012	Global	Y	Y	-	Y	Y	-	-	Y	Y	-	-	Y	Y	Y
Campden BRI, 2013	UK	Y	Y	Y	-	Y	Y	-	Y	Y	Y	Y	Y	Y	Y
Alberta Agriculture and Rural Development, 2014	Canada	Y	Y	-	-	Y	-	-	Y	Y	-	-	Y	-	Y
Neogen, 2016	US	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Brazilian Health Regulatory Agency, 2018	Brazil	Y	Y	Y	-	Y	Y	-	Y	Y	Y	-	Y	Y	-
Canadian Celiac Association, 2018	Canada	Y	-	Y	-	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Dairy Food Safety Victoria, 2018	AUS	Y	Y	Y	-	Y	Y	Y	Y	Y	Y	-	Y	Y	Y
Codex Alimentarius, 2020a	Global	Y	Y	Y	-	Y	Y	-	-	-	-	-	-	Y	-
Peanut and Tree Nut Processors Association, 2020	US	Y	Y	Y	-	Y	Y	Y	Y	Y	Y	-	-	Y	Y
Australian Food and Grocery Council, 2021	AUS/NZ	Y	-	Y	-	Y	Y	-	Y	Y	-	-	-	-	-

Guidance	Country	P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	P11	P12	P13	P14
European Hygienic Engineering and Design Group, 2021b	EU	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	-	-	Y	Y
British Retail Consortium, 2022	Global	Y	Y	Y	Y	Y	-	Y	Y	Y	Y	Y	-	Y	Y
European Commission, 2022	EU	Y	-	-	-	Y	Y	-	-	Y	-	-	-	-	-
Food Allergy Canada, 2022	Canada	Y	-	Y	Y	Y	Y	Y	Y	Y	Y	Y	-	Y	Y
FoodDrinkEurope, 2022	EU	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	-
International Life Sciences Institute Europe, 2022	EU	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Japan Food Safety Management Association, 2022	Japan	Y	Y	-	-	Y	Y	-	-	-	-	-	Y	-	-
USDA Food Safety and Inspection Service, 2022	US	Y	Y	Y	Y	Y	-	-	Y	Y	Y	Y	Y	Y	-
Food Allergy Research and Resource Program, no date	US	Y	Y	-	-	Y	-	-	-	Y	-	-	-	-	-

Y = Principle recommended, - = Principle not mentioned

Principle 1: Validation of cleaning to remove allergens is required;

Principle 2: Cleaning procedures should be defined and thoroughly documented;

Principle 3: Consider the physical form of the allergen;

Principle 4: Validation should consider a ‘worse-case scenario’;

Principle 5: Validation should involve appropriate allergen analysis, where feasible and appropriate;

Principle 6: Validation should include checks for visual clean;

Principle 7: Validation should demonstrate that cleaning is effective on multiple separate production runs;

Principle 8: Re-validation of cleaning procedures should be conducted periodically and if significant changes take place;

Principle 9: Appropriate sampling/swabbing procedures should be determined;

Principle 10: Focus sampling on hard-to-clean areas that may trap product residues;

Principle 11: Include positive controls when sampling;

Principle 12: Select an appropriate analytical method;

Principle 13: Analytical methods should be validated;

Principle 14: Analytical results should meet acceptable criteria.

11.12 Principles of cleaning verification for food allergens referenced within guidance documents

Guidance Document	Country	P1	P2	P3	P4
Food Standards Agency, 2006	UK	Y	Y	Y	-
Campden BRI, 2009	UK	Y	-	-	-
Catalan Food Safety Agency, 2009	Spain	Y	Y	Y	-
Safe Quality Food Institute, 2012	Global	Y	Y	Y	-
Campden BRI, 2013	UK	Y	Y	Y	Y
Alberta Agriculture and Rural Development, 2014	Canada	Y	Y	Y	Y
Neogen, 2016	US	Y	Y	Y	Y
Brazilian Health Regulatory Agency, 2018	Brazil	Y	-	-	-
Canadian Celiac Association, 2018	Canada	Y	Y	Y	-
Dairy Food Safety Victoria, 2018	AUS	Y	Y	Y	-
Codex Alimentarius, 2020a	Global	Y	Y	Y	-
Peanut and Tree Nut Processors Association, 2020	US	Y	Y	Y	-
Australian Food and Grocery Council, 2021	AUS/NZ	Y	Y	Y	-
European Hygienic Engineering and Design Group, 2021b	EU	Y	Y	Y	-
British Retail Consortium, 2022	Global	Y	-	Y	Y
European Commission, 2022	EU	Y	Y	Y	-
Food Allergy Canada, 2022	Canada	Y	Y	Y	Y
FoodDrinkEurope, 2022	EU	Y	Y	Y	Y
International Life Sciences Institute Europe, 2022	EU	Y	Y	Y	Y
Japan Food Safety Management Association, 2022	Japan	Y	Y	-	-
USDA Food Safety and Inspection Service, 2022	US	Y	-	Y	Y
Food Allergy Research and Resource Program, no date	US	Y	Y	Y	-

Y = Principle recommended, - = Principle not mentioned

Principle 1: Allergen cleaning verification is appropriate to check efficacy of cleaning;

Principle 2: Ensure the ‘visibly clean' standard is achieved (check for visual clean);

Principle 3: Allergen analysis is appropriate for verification;

Principle 4: Select the appropriate analytical method (i.e. LFD rather than ELISA).

11.13 Information provided within industry and professional body publications

Industry/ Professional body publication	Author(s)	Year	Author organisation and country	Validation	Verification	Wet	Dry	Push-through	CIP
Food Safety Magazine	Baumert and Taylor	2013	University of Nebraska, US	Y	Y	-	-	-	-
Food Quality	Teng	2013	University of Otago Wellington, New Zealand	-	-	-	Y	-	-
International Food Hygiene	Lopez and Morales	2015	AIB International, US	Y	Y	Y	Y	Y	-
Quality Assurance Magazine	Zerva	2015	AIB International, US	Y	Y	-	Y	Y	-
International Food Hygiene	Easter	2015	Hygiena International Ltd, UK	Y	-	Y	Y	-	-
Food Safety Magazine	Kochak	2016	Auburn University Food Systems Institute, US	-	-	Y	Y	-	-
Food Safety Magazine	Haley and Brouilette	2018	Commercial Food Sanitation, US	Y	-	Y	Y	Y	-

Industry/ Professional body publication	Author(s)	Year	Author organisation and country	Validation	Verification	Wet	Dry	Push-through	CIP
International Food & Meat Topics	Brown	2019	Fortress Technology, UK	Y	-	Y	-	-	-
New Food	Smith	2019	Vikan, UK	Y	-	-	Y	-	-
Manufacturing Confectioner	Franzmeier	2019	Sollich KG, Germany	Y	Y	Y	Y	-	-
Food Processing, UK	Gill	2020	Deeside Cereals, UK	-	-	Y	Y	-	-
Food Safety Magazine	Schaffner	2020	Rutgers Food Innovation Center, US	Y	Y	Y	-	-	-
Food Science and Technology	Littleton, Walker and Ward	2021	Christeyns Food Hygiene Ltd, UK	Y	Y	Y	Y	Y	Y
Food Manufacture, UK	Ridler	2022	Food Manufacture, UK	-	Y	-	-	-	-
Food Processing, USA	Demetrakakes	2022	Food Processing, US	Y	-	Y	Y	-	Y

Industry/ Professional body publication	Author(s)	Year	Author organisation and country	Validation	Verification	Wet	Dry	Push-through	CIP
TOTAL NUMBER PER CATEGORY	N/A	N/A	N/A	11	7	10	11	4	2

Y = Topic mentioned, - = Topic not mentioned

11.14 Information provided within webpages and other information

Organisation/Author	Country	Validation	Verification	Wet	Dry	Push-through	CIP
Emport LLC, 2015	US	-	-	Y	Y	Y	-
Smith, 2015	UK	-	-	-	-	-	-
Gloves by web, 2016	US	Y	Y	Y	Y	-	-
Howlett, 2016	Ireland	Y	Y	-	-	-	-
Smith, 2016	UK	-	-	-	-	-	-
The Acheson Group (TAG), 2016	US	Y	Y	-	-	-	-
Food Allergy Research and Education (FARE), 2017	US	-	-	Y	-	-	-
Food Safety Experts, 2017	Canada	Y	-	-	-	-	-
Jackson, 2017	US	Y	Y	Y	Y	Y	Y
Food Safety Authority Ireland (FSAI), 2020	Ireland	-	-	-	-	-	-
Romer Labs, 2019a	UK	Y	-	-	-	-	-
Romer Labs, 2019b	UK	Y	Y	Y	Y	-	-
Campden BRI, 2020a	UK	Y	Y	Y	Y	-	Y
Canadian Food Inspection Agency, 2020	Canada	-	-	-	Y	-	Y
Christeyns, 2020	UK	Y	Y	Y	Y	-	Y
Romer Labs, 2020a	UK	-	-	Y	Y	-	Y
Diversey, 2021	US	-	-	Y	Y	-	Y
Hygiena, 2021	UK	-	-	Y	Y	Y	Y
Rochester Midland Corporation, 2021	US	Y	Y	Y	Y	-	-
Singapore Food Agency, 2021	Singapore	-	Y	-	-	-	-
AIB International, 2022	US	Y	Y	Y	Y	-	Y
Canadian Food Inspection Agency, 2022	Canada	Y	Y	Y	Y	Y	Y

Reading Scientific Services Ltd (RSSL), 2022	UK	Y	Y	-	-	-	-
Biocel, 2022	Ireland	Y	-	Y	Y	Y	Y
Food & Allergy Consulting & Testing Service (FACTS), 2022	South Africa	Y	Y	-	-	-	-
Food Standards Agency, 2022	UK	-	-	-	-	-	-
Hygiena, 2022	UK	Y	Y	-	-	-	-
Uğurcan, 2022	Turkey	-	-	Y	-	-	Y
Allergen Bureau, 2023	AUS/NZ	Y	Y	Y	Y	-	Y
Food Allergy & Anaphylaxis Connection Team (FAACT), 2023	US	-	-	-	-	-	-
Food Safety Standard App, 2023	India	Y	-	-	-	-	-
TOTAL NUMBER PER CATEGORY		18	15	16	14	5	11

Y = Topic mentioned, - = Topic not mentioned

11.15 Information provided within book chapters

Author(s)	Country	Validation	Verification	Wet	Dry	Push-through
Stone, Jantschke and Stevenson, 2009	US	Y	Y	Y	Y	Y
Burrows, 2010	US	-	-	Y	Y	-
Gowland, 2010	US	-	Y	Y	-	-
Stone and Yeung, 2010	US	Y	Y	Y	Y	Y
Cochrane and Skrypec, 2014	UK	Y	Y	-	-	-
Nikoleiski, 2015	UK	Y	Y	Y	Y	Y
Moerman and Mager, 2016	UK	-	-	-	-	Y
Crevel, 2016	UK	Y	Y	-	-	-
Holah, 2016	UK	-	Y	-	-	-
Jackson, 2018	US	Y	Y	Y	Y	Y
Marriott, Schilling and Gravani, 2018	US	Y	Y	Y	Y	Y
Eisenberg and Delaney, 2018	US	-	Y	Y	-	-
TOTAL NUMBER PER CATEGORY		7	10	8	6	6

Y = Topic mentioned, - = Topic not mentioned

11.16 List of webinars with links to the source

Organisation	Country	Webinar title and link
International Food Safety and Quality Network, 2017	Ireland	Validation of Cleaning & Sanitation programs
Romer Labs, 2020b	UK	Identify. Control. Eliminate. New developments in allergen management and cleaning
Anaphylaxis Campaign, 2020	UK	The Role of Cleaning in the Management of Allergens
Romer Labs, 2021a	UK	Effective food allergen management for businesses and consumers
Romer Labs, 2021b	UK	How do you manage allergens in gluten free production
Food & Allergy Consulting & Testing Services, 2021	South Africa	Validation vs Verification in a Food Factory

12. Glossary

Term	Definition
Acceptable Quality Limit (AQL) statistical sampling	The use of statistical sampling to determine whether to accept or reject a production lot of material based on how many 'defectives' are considered acceptable in a given sample.
Acid	A chemical substance with a pH of less than 7, which when dissolved in water, releases hydrogen ions (H+). Generally used in detergent formulations to assist in the removal of hard water scale (Campden BRI, 2020b).
Alkali	A chemical with a pH greater than 7 and generally used in detergent formulations to assist in the removal of fats and proteins (Campden BRI, 2020b).
Allergen	Means an otherwise harmless substance capable of triggering a response that starts in the immune system and results in an allergic reaction in certain individuals. In the case of foods, it is a protein which is found in food capable of triggering a response in individuals sensitised to it (Codex Alimentarius, 2020a).
Adenosine triphosphate (ATP)	A substance used in energy transfer in living cells and is, therefore, present in biological material. A rapid test for cleanliness of surfaces is based on ATP measurement as it is found in microorganisms and food (Campden BRI, 2020b)
Biofilm	Biofilms are surface-attached, structured microbial communities containing sessile bacteria and/or fungi embedded in a self-produced extracellular matrix

Term	Definition
	composed of polysaccharides, DNA, and other components (Coenye, 2013).
Cleaning	The removal of soil, food residues, dirt, grease or other objectionable matter (Codex Alimentarius, 2020b).
Cleaning-in-place (CIP)	A method used to clean equipment, often involving pipe work and vessels, without first dismantling it. Cleaning chemicals and rinses may be pumped through equipment to remove food residues and contamination (Campden BRI, 2020b).
Cleaning-out-of-place (COP)	Denotes systems and equipment that must be disassembled, relocated, or specially treated in order to clean and sanitise them (Food Safety Magazine, no date).
Control measure	Any action or activity that can be used to prevent or eliminate a hazard or reduce it to an acceptable level (Codex Alimentarius, 2020b).
Controlled wet clean	The removal of soil, including food residues, dirt, grease or other objectional matter using a limited amount of water and detergents and controlling the spread of the water used (Campden BRI, 2020b).
Critical control point (CCP)	A step at which a control measure or control measures, essential to control a significant hazard, is/are applied in a HACCP system (Codex Alimentarius, 2020b).
Cross-contact	Occurs when an allergenic food, or ingredient, is unintentionally incorporated into another food that is

Term	Definition
	not intended to contain that allergenic food (Codex Alimentarius, 2020a).
Detergent	A chemical, or mixture of chemicals, that facilitates the removal of food debris from surfaces (Campden BRI, 2020b).
Deoxyribonucleic acid (DNA)	The major constituent of genes and hence chromosomes.
Dry clean	Use of equipment for example brush, vacuum, dry wipe to physically remove food soil, without the need for any water, cleaning chemical, detergent or soap.
Enzyme-linked immunosorbent assay (ELISA)	Immunological assay used to measure, in the case of food allergens, proteins.
Flow cytometry	Analytical technique that measures the physical or chemical characteristics of individual cells and particles as they pass through single or multiple laser beams.
Food	Where 'food' is referred to in this report, the definition in Article 2 of retained Regulation (EC) No. 178/2002 is applied: 'food' (or 'foodstuff') means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans. 'Food' includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment.

Term	Definition
Food business operator (FBO)	The entity responsible for operating a business at any step in the food chain (Codex Alimentarius, 2020b).
Food Safety Management System (FSMS)	Prerequisite programmes, supplemented with control measures at CCP, as appropriate, that when taken as a whole, ensure that food is safe and suitable for its intended use. The FSMS is also the combination of control measures and assurance activities. The latter aims at providing evidence that control measures are working properly such as validation and verification, documentation and record keeping (European Commission, 2022).
Food Science and Technology Abstracts (FSTA)	Online database covering a wide range of food-related peer-reviewed articles.
Food service	Means a food business or institution that produces, prepares and serves food for direct consumption (Codex Alimentarius, 2020b).
'Grey' literature	Evidence not published in commercial publications. Grey literature in this report includes codes of practice, guidance documents, industry/professional body publications, corporate white papers, websites, blogs and reports.
Hazard analysis critical control points (HACCP)	A food safety management system, which identifies, evaluates and controls hazards that are significant for food safety (Campden BRI, 2020b).
Hook effect	The hook effect is observed when a very high amount of an analyte is present in the sample but the

Term	Definition
	observed value is falsely lowered (Dasgupta and Wahed, 2014).
Lateral flow device (LFD)	Immunological test in a lateral flow format for the qualitative detection of protein of food allergens.
Limit of detection (LOD)	The lowest defined quantity or concentration of a particular substance that can be reliably detected (above analytical noise), but not necessarily quantified, in the specified method of analysis.
Liquid Chromatography-Mass Spectrometry (LC-MS)	Analytical technique combining liquid chromatography with mass spectrometry to identify and quantify compounds.
Lower limit of quantification (LLOQ or LOQ)	The lowest defined quantity or concentration of a particular substance that can be reliably measured with the specified method of analysis.
Mass spectrometry	Analytical technique that measures the mass-to-charge ratio of ions to evaluate the composition and structure of samples.
Maximum Residue Level (MRL)	Upper legal level of a concentration for a pesticide residue in or on food, based on good agricultural practice and the lowest consumer exposure necessary to protect vulnerable consumers (Regulation (EC) No 396/2005).
Neutral	A chemical with a pH of 7 (Campden BRI, 2020b).
Open-plant cleaning (OPC)	Machines and surfaces in a production area are thoroughly cleaned and, if necessary, disinfected ‘in situ’, this may involves conveyor belt removal for example..

Term	Definition
Operational prerequisite programme	Control measure or combination of control measures applied to prevent or reduce a significant food safety hazard to an acceptable level and where action criterion and measurement or observation enable effective control of the process and/or product. They are typically linked to the production process and are identified by the hazard analysis as essential, in order to control the likelihood of the introduction, survival and/or proliferation of food safety hazards in the product(s) or in the processing environment (European Commission, 2022).
'Pig'	Physical object sent through pipework to remove food residue.
Plate ELISA	Immunological assay based on the principles of the ELISA method that uses a multi-well plate.
Polymerase Chain Reaction (PCR)	Analytical technique used to amplify and replicate specific segments of DNA to enable the detection of genetic material.
Precautionary allergen labelling (PAL) or precautionary allergen information (PAI)	Voluntary statements or information indicating that a food allergen could be unintentionally present in a product. [The acronym 'PAL' is used throughout this report to refer to both PAL and PAI].
ppm	Parts per million, which is equivalent to mg/kg.
Push-through	A cleaning methodology incorporating use of an inert material, physical object ('pigs') or foodstuff that does not contain allergenic ingredients. [throughout this report the terms push-through and flushing have been used interchangeably; flush

Term	Definition
	therefore refers to the material used for push-through or flushing].
Quantitative risk assessment (QRA)	Is a tool that complements allergen management practices by enabling the risk presented to allergic consumers due to unintended allergen presence in a food to be estimated. It thereby can provide useful information as input into risk management decision making, such as whether Precautionary Allergen Labelling (PAL) is appropriate (ILSI-Europe, 2022).
Quat	The abbreviation used for quaternary ammonium compound disinfectants.
Real-time Polymerase Chain Reaction (rtPCR)	Analytical technique based on PCR that monitors the amplification of DNA in real time.
Settle plates	Passive air sampling devices (for example empty petri dishes that can be swabbed or that contain a known quantity of extraction solution or a foodstuff that can be analysed for the presence of airborne food allergens that have settled onto the surface during a defined period of time).
Small and Medium Sized Enterprise (SME)	In the UK is defined as a business with under 500 employees and an annual turnover under £100 million (Foreign, Commonwealth and Development Office, 2023).
Soil	A complex mixture of food product, water and microorganisms to be cleaned off surfaces (Campden BRI, 2020b).
Standard Operating Procedure (SOP)	Instructions developed by a FBO to help trained staff to carry out routine operations.

Term	Definition
Surface Plasma Resonance (SPR)	Optical technique that measures changes in refractive index at the interface between a metal film and a sample and can measure molecular interactions in real time.
TACT	An acronym for Time, Agitation, Concentration and Temperature.
Validation	Obtaining evidence that a control measure or combination of control measures, if properly implemented, is capable of controlling the hazard to a specified outcome (Codex Alimentarius, 2020b).
Verification	The application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure is or has been operating as intended (Codex Alimentarius, 2020b).
Visibly clean	Means having no visible food, debris and other residues (Codex Alimentarius, 2020a).
Wet clean	Application of water, whether alone, or in addition to a cleaning chemical, detergent or soap, either by carrying out a rinsing procedure or with a cloth.
Wet wipe	A small piece of wet cloth or paper that is used once for cleaning, may be wetted with cleaning or sanitising chemicals.

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