Review of the literature and guidance on food allergen cleaning: 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.

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 R?der 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 (R?der 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 (Aleksi? 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. R?der 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 (Aleksi? 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.

R?der 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.

Publication reference	Relevant findings of the study
R?der 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.
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.

Publication reference	Relevant findings of the study
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.
R?der 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.

Publication reference	Relevant findings of the study
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 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.

Publication reference	Relevant findings of the study
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.
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 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 Hygienic 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, 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 U?urcan (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 10?C in a detergent solution, doubles the rate of chemical reactions involved in cleaning (U?urcan, 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 U?urcan (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 U?urcan (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 Scienti?c 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 dif?cult 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 veri?cation, 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.