

Review of the literature and guidance on food allergen cleaning: Materials and methods

5.1 Search strategy

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

[Database of publications identified in the literature and guidance review on cleaning to remove food allergens](#)

The following sections describe the search strategies employed and generation of the database.

5.1.1 Food Science and Technology Abstracts (FSTA) search

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

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

To summarise the results of the FSTA screening process (see Table 2), of the 84 selected at initial scan phase, 64 were included in the database, of which 34 were categorised as journal articles, 25 industry and professional body publications, three book chapters and two guidance documents.

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

Search number	Search terms	Number of results
1	DAIRY PRODUCTS OR MILK OR PASTEURIZED MILK OR SEMI SKIMMED MILK OR SKIM MILK OR STERILIZED MILK OR UHT MILK OR WHOLE MILK OR PROTEINS MILK OR CASEIN OR WHEY PROTEINS OR LACTOGLOBULINS OR LACTOSE OR EGGS OR EGG WHITES OR EGG YOLKS OR ALBUMINS OR CELERiac OR CELERY OR LUPINS OR WHITE LUPINS OR NUTS OR BRAZIL NUTS OR CASHEW NUTS OR MACADAMIA NUTS OR PECAN NUTS OR PISTACHIO NUTS OR ALMONDS OR SWEET ALMONDS OR HAZELNUTS OR PEANUTS OR PEANUT PRODUCTS OR PEANUT PROTEINS OR ROASTED PEANUTS OR PEANUT PASTES OR PEANUT MEAL OR PEANUT BUTTER OR WALNUTS OR SOY PROTEINS OR SOYBEANS OR SOY PRODUCTS or FISH OR SHELLFISH OR CRUSTACEA OR MOLLUSCS OR MUSTARD SEEDS OR SESAME SEEDS OR SULFITES OR SULFUR DIOXIDE OR SO2 OR GLUTEN OR WHEAT GLUTEN OR RYE OR BARLEY OR OATS OR SPELT OR SPELT WHEAT (Descriptors) or khorasan (Topic) or nuts (Topic) or queensland nuts (Topic) or soy* (Topic) or soya (Topic) or sulphites (Topic) or sulphur dioxide (Topic)	151,894
2	ALLERGENS (Descriptors) or allergen* (Topic)	7083
3	CONTACT MATERIALS OR SURFACES OR CERAMICS OR ENAMELS OR WORKTABLES OR GLASS OR PLASTICS OR STAINLESS STEEL OR WOOD OR UTENSILS OR KNIVES OR EQUIPMENT OR DISHWASHERS OR COOKERS OR REFRIGERATORS OR PROCESSING LINES OR PROCESSING EQUIPMENT OR OVENS OR BAKING OVENS OR MICROWAVE OVENS OR PANS OR SIEVES OR FREEZERS OR CHILLERS OR BOILERS OR CATERING OR CATERING ESTABLISHMENTS OR CATERING INDUSTRY OR FOODS SERVICE OR HOTELS OR KITCHENS OR PUBS OR RESTAURANTS OR CAFETERIAS OR CANTEENS OR COFFEE BARS OR SANDWICH BARS OR RETAIL OR SHOPS OR SUPERMARKETS OR VENDING MACHINES OR WHOLESALE (Descriptors) or pottery (Topic) or china (Topic) or pyrex (Topic) or plastic* (Topic) or hospitality (Topic)	96,784
4	CLEANING OR CLEANING AGENTS OR CLEANING IN PLACE OR WASHING OR HYGIENIC QUALITY OR DISINFECTION OR SANITATION (Descriptors) or remov* (Topic) or validat* (Topic) or clean* (Topic) or cleaning chemical* (Topic) or wash* (Topic) or dishwash* (Topic) or handwash* (Topic)	82,084
5	1 and 3 and 4	1028
6	2 and 3 and 4	77
7	5 or 6 (duplicates and patents removed)	1083

Table 2: Food Science and Technology screening process

Screening strategy	Number of results
FSTA search strategy and initial titles scan conducted by project librarian. Relevant articles were selected for abstract screening.	1083
Initial abstract screening process completed by project researcher to identify relevant articles to be incorporated into the database.	84
Abstracts excluded after initial review and second review by project manager in total, of which:	20
Not relevant to the review	13
Focussed on development of a specific detection method, not relevant to cleaning	7

Screening strategy	Number of results
Results from FTSA search reviewed, of which:	64
Journal articles	34
Industry and professional body publications	25
Book chapters	3
Guidance documents	2

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

5.1.1.1 Specific cleaning methodologies screening process for journal articles

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

- Wet: Application of water, whether alone, or in addition to a cleaning chemical, detergent or soap, either by carrying out a rinsing procedure or with a cloth.
- Controlled wet: Application of a commercial 'wet wipe', or cloth, to clean a surface in a controlled manner, which may be 'wetted' with a specific cleaning chemical or antibacterial solution.
- Dry: Use of equipment e.g. brush, vacuum, dry wipe to physically remove the food soil, without the need for any water, cleaning chemical, detergent or soap.
- Push-through: The use of an inert material, physical object ('pigs') or foodstuff that does not contain food allergens that are not intentionally added to the subsequent product, sometimes referred to in guidance as flushing.
- Cleaning-in-place (CIP): A method used to clean equipment, often involving pipe work and vessels, without first dismantling it. Cleaning chemicals and rinses may be pumped through equipment to remove food residues and contamination.

5.1.2 'Grey' literature search

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

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

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

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

5.2 Producing the bibliographic database

Results of the searches were collated into categories in a Microsoft Excel (Version 2301) spreadsheet with the following headings: Journal article; Thesis; Conference poster; Guidance/Code of practice; Industry/Professional body publication; Website page; Other information; Book chapter; Webinar.

Table 3: Literature categorisation descriptions and number of references

Literature categorisation	Description	Number of references found in initial searches	Number of relevant references added to database
Journal articles	Peer-reviewed publications in scientific journals, including conference abstracts	34	19
Guidance and codes of practice	Guidance produced by a relevant organisation/regulatory authority, published as a whole document intending to provide guidance on a specific topic	38	28
Industry and professional body publications	Articles included as part of an industry/professional body's regular specialist publication focussed on a specific industry (in this case the food, drink and associated industries) or specialised topics, providing industry perspectives, guidance, best practice and recommendations	30	15
Website pages	Company/regulatory authority website pages and blog articles	44	24
Other information	Literature that fell outside of the previously described categories and took the form of presentation slides or company-published information (e.g. white papers and reports)	19	7
Book chapters	Relevant chapters within published books	15	2
Theses	Published theses with a single author in association with the author's organisation	6	3
Webinars	Video recordings (without a script or presentation slides) that show presentations delivering general information on a specific topic	7	6
Conference poster	Poster used to present research findings at a conference	1	1

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

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

5.3 Data extraction

5.3.1 Data extraction method for each literature category

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

Table 4: Data extraction methods

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

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

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

Document Type	Inclusion criteria	Exclusion criteria
Journal articles, theses, conference poster	Applied a specific cleaning methodology and tested the efficacy using a relevant, analytical method (e.g. ELISA, LFD).	<p>Abstract-only articles that made reference to validation but had no specific study details, and were presented at a conference not attended by any member of the project team;</p> <p>Articles validating a specific detection method without applying a cleaning methodology;</p> <p>Articles applying a specific cleaning methodology but neither cleaning nor analysis conducted for allergens;</p> <p>Articles discussing cleaning methodology in the context of reducing microbiological hazards;</p> <p>General articles that discuss the topic of allergen management, however as no further details on a specific cleaning methodology provided these could not be reported on in the results section.</p>

Document Type	Inclusion criteria	Exclusion criteria
Guidance documents	Referenced any of the key words and contained extractable information relevant to the topic of 'allergen cleaning' and 'cleaning validation and verification'.	No mention of cleaning to remove food allergens; No mention of cleaning validation.
Industry and professional body publications, website pages and other information, book chapters, webinars	Referenced any of the key words and contained extractable information relevant to the topic of 'allergen cleaning' and 'cleaning validation and verification'.	Articles discussing general allergen-related topics e.g. allergen-free formulation, PAL without a specific reference to cleaning, testing and sampling (not directly relating to cleaning); Articles discussing hygiene, equipment or machinery but not in the context of allergen cleaning.

5.3.2 Specific cleaning methodologies screening process

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

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

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

5.4 Report structure

The following results section (Section 6: Results) and sub-sections present the information found and extracted by literature type (Journal articles, Guidance and codes of practice, Industry and professional body publications, Websites and other information, Book chapters and Webinars). Each sub-section describes the findings and pulls out specific considerations that were commonly mentioned by the literature type. The subsequent section (Section 7: Report Summary and Discussion) summarises the information found and discusses it in the context of other literature relevant to the topic of food allergen cleaning. It is recommended to read the results section first (before Section 7) to gain an understanding of the differences between each literature type as the results are not repeated for all sources.

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

articles, an overview for each study is given.