Review of the literature and guidance on food allergen cleaning: Executive summary

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

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

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

The results of studies into the efficacy of routine cleaning procedures described in peer-reviewed journal articles were consolidated into summary tables detailing the study design and key findings. For guidance documents and codes of practice, information on each cleaning methodology was summarised and key principles of validation and verification were extracted, collated and discussed. Summary tables were produced for most other literature sources and the information is reported in the results section of this report. A database of relevant literature sources has also been produced.

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

- Foodstuff: soil type, physical form and food matrix – e.g. generally sticky paste residues are more difficult to remove than dry residues.
- Surface: material and its properties – e.g. stainless steel is generally the easiest surface to clean, whilst wood and cloth are the most difficult.
- Equipment: accessibility – e.g. inaccessible equipment may need to be dismantled or cleaned using techniques such as ‘push-through’ (the use of an inert material, physical

object (‘pigs’) or foodstuff that does not contain any allergenic proteins).
- Cleaning parameters: time, mechanical action, chemical properties (of detergents or cleaning chemicals applied) and temperature.

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

In terms of other cleaning methodologies, controlled wet cleaning (use of commercial ‘wet wipes’ or cloths, which may be wetted with a specific cleaning chemical or antibacterial solution, to clean a surface in a controlled manner) was found to be effective in some scenarios. Dry cleaning techniques were shown to be capable of visually removing dry powder, but soil containing allergens was often still detected by analysis of the visually clean surfaces. Using a material that does not contain allergenic foodstuffs (‘push through’) was found to be variously effective; again, this depended on multiple factors. Clean-in-place (CIP - where cleaning chemicals and rinses may be pumped through equipment (such as pipe work and vessels), without first dismantling it, to remove food residues and contamination) was shown to be effective in the one study in which it was investigated using rigorous protocols.

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

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

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

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

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

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

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