

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

4.1 Food Standards Agency project specification

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

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

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

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

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

4.2 Background

It is estimated that 2.6 million people in the UK live with a diagnosed food allergy (Acharya, 2021), i.e. an immune-mediated food hypersensitivity (Codex Alimentarius, 2020a). The amount of allergenic foodstuff that can cause an allergic reaction differs between individuals, however, it has long been known that very small amounts of allergenic protein (in the milligram range) can cause a severe or possibly even fatal reaction (Taylor et al., 2002). For food-allergic individuals this necessitates the adoption of a strict avoidance diet to prevent consumption of foodstuffs to which they react. Such individuals, as well as those associated with them, for instance their family, friends, and caregivers are therefore obligated to be vigilant for allergen information on product labels of prepacked food and for food sold loose, for example in food service situations, when preparing or purchasing food. Allergic individuals face a significant food safety hazard of consumption of food allergens. To enable them to make safe, informed choices, it is vitally important that the correct allergen information pertinent to the risk from consuming a food is conveyed clearly at the point of decision-making for consumers, i.e. information that accurately describes allergen content whether deliberately added or potentially present due to the risk of a food containing allergenic foodstuffs through adventitious cross-contact.

All food businesses have a legal responsibility to produce safe food. The general food law (retained Regulation (EC) No. 178/2002) provides the overarching principle that food shall not be

placed on the market if it is 'unsafe', which is considered to be 'injurious to health' or 'unfit for human consumption'. Article 14 goes on to state that when determining whether food is 'unsafe' regard shall be had to the information provided to the consumer regarding the avoidance of specific adverse health effects from a particular food or category of foods. Food containing undeclared allergens would therefore not be considered safe.

Food business operators (FBOs) are obliged to put in place procedures based on Hazard Analysis and Critical Control Points (HACCP) principles (as laid down in Article 5 of retained Regulation (EC) No. 853/2004) and verify that food law requirements are met (as required by Article 17 (1) of retained Regulation (EC) No. 178/2002). HACCP risk analysis confirms that exposure to (undeclared) food allergens for specific sensitive populations is a risk requiring deliberate allergen risk management procedures with controls, validation, verification and monitoring in place. Cleaning is a critical step in preventing contamination or re-contamination of products; physical, chemical and biological cleanliness is a prerequisite for food safety (Schmitt and Moerman, 2016). Cross-contact can occur in food processing and food service environments when allergenic foodstuffs are handled, prepared or processed on surfaces or equipment or using utensils that are not then cleaned appropriately before preparation of a food product that does not contain those allergenic ingredients, or following spillage in food handling, storage and transport environments which is not cleaned up effectively. Such contamination raises concerns around consumer safety for allergic individuals and FBOs alike.

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

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

Currently, in UK there is no specific legal requirement to provide PAL or precautionary allergen information (PAI, for non-prepacked food) to indicate possible allergen cross-contact; although of course the over-arching requirement to provide safe food applies. Many FBOs, however, provide this information voluntarily to indicate the possible presence in food products of unintentional substances that people may be allergic to. The voluntary use of PAL is permitted; the basis for this is contained within Article 14 of retained Regulation (EC) No.178/2002, which refers to the information provided to the consumer concerning the avoidance of specific adverse health effects from a particular food or category of foods. In addition, Article 36 (2) to the FIC is relevant, as it is required that such voluntary food information shall not mislead the consumer, shall not be ambiguous or confusing for the consumer and it shall, where appropriate, be based on the relevant scientific data. Therefore, PAL should only be applied upon substantial risk of

unintentional allergen presence based upon scientific risk assessment and evidence.

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

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

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

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

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

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

Although cleaning is an important control measure to reduce or prevent allergen cross-contact, general evidence of its capability (in terms of validation) is lacking. Cleaning validation conducted in accordance with best practice (for example, Campden BRI, 2009) and defined as “the process of assuring that a defined cleaning procedure is able to effectively and reproducibly remove the allergenic food from the specific food processing line or equipment” (Jackson et al., 2008) involves analysis, which is too resource intensive for many FBOs.

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

4.3 Aims and objectives of this research

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

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

The FSA requirement for this project was for a desk-based literature and guidance review of the cleaning methodologies available for the 14 food allergens for which labelling is mandatory in the UK, including the key stages and principles of allergen cleaning and effective approaches, and to assess the extent to which they are underpinned by an appropriate evidence base. The request was to include:

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

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

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

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