Risk analysis and Precautionary Allergen Labelling:

Insight from UK micro, small and medium sized food business

A report for the Food Standards Agency by Basis Social

BASIS SOCIAL

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1. Executive Summary

1. This research aimed to understand the extent to which allergen risk analysis is conducted by micro, small, and medium sized (SME) food businesses, and whether this informs the use of Precautionary Allergen Labelling (PAL). It had a specific focus on whether risk assessment and the identification critical points of allergen cross-contact were undertaken.

2. The research involved interviews with 42 food businesses from England, Wales, and Northern Ireland, between January and March 2022.. Of these, 37 were SMEs working across the following sectors: manufacturing, retail, catering, and institutions. A further five interviews were conducted with large food businesses selected as exemplars of good practice in risk analysis for comparison and learning purposes (referred to as 'gold standard' businesses).

3. Across the sample, all 14 allergens regulated by UK food law were used by SME businesses in some form. The most common allergens used across sectors were gluten, eggs and milk, while peanuts and treenuts (collectively referred to as nuts) were the most top of mind allergens.

4. Use of allergens by SMEs varied across sectors and typically comprised 2-3 for manufacturers, 4-7 for retailers (though higher in convenience stores), with the greatest number allergens used across institutions and particularly catering establishments.

5. After microbiological risks, allergens were seen as the next highest food safety risk to consumers by SME food business. This was followed by physical risks, with chemical risks not routinely discussed. Allergens were seen as a particularly high risk in institutions and certain catering establishment.

6. Food safety training was common for SMEs, and greater for manufacturing and retailers in our sample. Training generally focused on wider food hygiene practice, with allergens a lesser focus. When allergens were covered in training, it often related to ingredient labelling requirements rather than cross-contact risks.

7. There was a good understanding of the concept of ‘risk assessment’ across sectors, and a moderate range of risk assessment conducted by businesses in the study. Risk assessment was greater in manufacturing sectors (across a range of business sizes), medium sized retail businesses, and, to a lesser degree, medium sized institutions. Risk assessment focused on microbiological risks and was driven by HACCP plans. Despite not being designed for this purpose, HACCP was broadly seen to manage all food safety risks, including allergens. There were minor instances of allergen risk assessment being directly integrated into HACCP plans.

8. The practice of allergen risk assessment was limited for SME food businesses involved in this study. When undertaken, assessment was piecemeal, rather than a part of a defined and systematic process. Typically, such assessments focused on select allergens, rather than the potential risks from all allergens present during the food production process. It also did not proceed through a stepwise understanding of different control points but focused on tasks more top of mind for cross-contact – particularly during preparation and cleaning. A lack of ability to identify and verify supply chain risks were also cited as a particular concern for manufacturers and retailers.

9. An intuitive, “cautious approach” to food safety to prevent allergen cross-contact, built from experience in working in a kitchen, was particularly prevalent in catering businesses. Given the very wide range of allergens present in these kitchens, it is likely that such practices miss important steps for potential cross-contact.

10. It was common for schools, colleges, and care homes to know the dietary requirements of food hypersensitive pupils and residents. This knowledge meant that, even in the absence of risk assessment, the ability to manage allergen risks was likely to be effective.

11. Overall, allergen testing by SMEs as part of risk analysis process was minimal. There was some testing of pathogens and particularly cleaning validation for

micro-organisms for manufacturers. There were two examples of an allergen being tested to validate a free from claim. There were no examples of allergen cross-contact being tested to support the use of PAL, either as cleaning validation or a product test.

12. Allergen risk management was more comprehensive across SMEs. For smaller manufacturers, actions typically focused on physical separation and secure storage of ingredients. For medium sized manufacturers, separate running of product lines, cleaning between production runs, and managing the packaging, labels and transport of products was common.

13. For retailers making pre-packed foods for direct sale, there were reasonably sophisticated processes of separation, food preparation, cooking, and cleaning to manage allergen cross contamination. For certain retailers (for example bakeries), cross-contact risk was perceived as greatest at point of sale when products were out in the store.

14. Areas for allergen risk management in catering included delivery and labelling, together with separate storage and preparation areas (dependent on kitchen size). While separate boards and utensils were used ubiquitously, there was often a ‘one board fits all allergens’ approach. Cleaning (via a dishwasher) was seen as fundamental to manage allergen risks. Airborne risks were seen as very challenging to manage. Institutions often had tailored approaches to manage cross-contact risks, based on the dietary requirements of individuals.

15. This relatively comprehensive set of management actions led to confidence across all sectors that allergen cross-contact risk was dealt with effectively. However, there were numerous instances of businesses being prone to biases when managing risk, including familiarity bias (a focus on top-of-mind allergens such as nuts), over-confidence bias (a belief processes are adequate as customers have never previously experienced an adverse reaction), status quo bias (a focus on the adequacy of HACCP plans), and messenger effects (an unquestioned belief in chefs). This means allergens risks may only be partially understood and managed.

16. The understanding of PAL was very mixed for business. While knowledge that it related to a ‘may contain’ warning was relatively high, businesses were confused about its voluntary status and its distinction from allergen ingredients labelling. Importantly, no SME business engaged in this study understood the requirement to undertake a formal allergen risk assessment before applying PAL.

17. PAL application was driven by a mixture of supply chain versus on premises risks. In terms of supply chain, it was typical to “trust the manufacturer” and pass on may contain warnings. There were certain instances of PAL warnings being placed into ingredients lists for more risk adverse businesses. For caterers, institutions and certain retailers, cross-contact risks during food preparation were seen as extremely hard to manage and, where used, PAL warnings were routinely applied for major allergens.

18. An FSA tool to support the use of PAL had a cautiously positive reception. There were concerns around the complexity, cost, and ability to use the tool. Integrating examples and developing a more meaningful way of communicating risk (based on intuitive ‘dose levels’ such as a teaspoon) may have a supportive role in its adoption.

19. There was only modest support for sharing results of allergen risk analysis across the supply chain, with concerns about the complexity of any reporting process, and the burden for small businesses. Overall, the focus needed to be on building trust and compliance in the regulatory system, rather than over engineering reporting requirements.

20. In gold standard businesses, there was a notably stronger food safety culture relative those observed in SMEs. This included a focus operational excellence in food sourcing, processing and distribution, a systematic approach to the allergen risk assessment and management, supply chain support, and resources placed into testing and validation.

21. While SMEs would struggle to adopt all ‘gold standard’ practices, given obvious differences in size and resources, there is learning (e.g., training protocols) and frameworks (e.g., risk management templates) that can be built on by the FSA and integrated into support for businesses, such as Safer Food, Better Business.

22. Overall, a lack of common standards, simple risk assessment/management templates, integration into HACCP, plus clearer communication on the need to conduct allergen risk assessment will be needed to drive forward practice. Awareness raising of the FSA risk analysis checklist may help, though the Orange Guide, developed by the FSA in 2006 by to establish principles for risk analysis, was also cited by gold standards businesses as instructive.

23. Finally, it should be noted that whilst each gold standard business had very effective controls, there were small but significant differences in practices across each manufacturer and retailer, from how to approach risk assessment to the requirements for labelling. This lack of standardisation creates problems for allergen management across the food system as a whole. Standards - both for thresholds and risk analysis practice – are key areas to address in future FSA guidance.

2. Introduction to this research

2.1 Background

Precautionary Allergy Labelling (PAL) is a voluntary statement that food businesses can choose to apply to food products where there is a risk of cross-contact with an allergen. It is **commonly seen as "may contain allergen x" or "not suitable for someone with x allergy"** on pre-packaged food products. For non-prepacked and loose foods, precautionary allergen information can be written (such as on a menu or website), provided verbally by staff, or visually on signs at the premises, we have used 'PAL' as a shorthand for Precautionary Allergy Labelling and Precautionary Allergy Information in this report.

PAL is currently a key focus for the FSA's hypersensitivity programme, as part of its wider mission to protect UK consumers from the health risks posed by food hypersensitivity (including food intolerances and coeliac disease). More broadly, the FSA aims to ensure UK consumers have high quality information to enable informed decision making around food.

The use of PAL is voluntary. When used, it must not mislead the consumer, be ambiguous or confusing and, where appropriate, be based upon scientific data, according to provisions within the Food Information for Consumers Regulation. However, if precautionary allergen labelling is not applied and a consumer has an adverse reaction to an allergen present due to cross-contact there could be a breach of General Food Law.

Importantly, **PAL should only be used when, following a thorough risk assessment, an unavoidable risk of allergen cross-contact is identified that cannot be sufficiently controlled through careful risk management actions**.

Additionally, PAL should make specific reference to one or more of the 14 allergens regulated by UK food law that are unintentionally present in the food and should not be used in combination with a 'free-from' statement for the same allergen.

Research for the FSA exploring the understanding and application of PAL by UK micro, small and medium sized (SME) food businesses identified that allergen risk assessment was often overlooked by such businesses.[1] Consequently, risk management procedures were often focused on processes to manage microbiological risks, which may not be adequate to minimise allergen cross-contact.

[1] Basis Social and Bright Harbour (2022). Precautionary Allergen Labelling: Insight from UK micro, small and medium sized food businesses and consumers.

2.2 Aims and objectives of research

Building on the previous study, the aim of this research is to understand in greater detail the extent to which allergen risk analysis is conducted by SME food businesses and whether this informs their use of PAL.

Objectives for the research were to explore:

- How SME food businesses understand the risk of allergens relative to other food safety risks
- The extent to which SMEs undertake a risk assessment to identify the potential risk of allergen cross-contact, together with the critical points involved in any assessment
- The extent to which Hazard Analysis and Critical Control Point (HACCP) plans are used in general, and specifically to assess allergen risks
- Whether the presence of any allergens resulting from cross-contact is quantified or cleaning is validated through testing
- How allergen risk management processes are developed, and the extent to which they are linked to any risk assessment processes
- Whether training on allergen risk analysis is adopted
- The understanding and use of PAL by SME food businesses, in relation to any risk analysis conducted

2.3 Sample

Research with 42 food businesses was undertaken between January and March 2022 to provide insight into the understanding and practice around allergen risk analysis. Of these, 37 were SMEs working across the following sectors: manufacturing, retail, catering, and institutions.[2] A further five interviews were conducted with large food businesses (i.e., those with more than 250 staff) selected as exemplars of good practice in risk analysis, for comparison and learning

[2] Institutions covered schools, colleges, hospitals, universities and care homes. Such catering services were provided in-house or by a third-party business.

purposes. These ‘gold standard’ businesses included 4 manufacturers and one retailer.

SME food businesses were recruited by Acumen, an independent market research fieldwork agency. A screener was used to target businesses and ensure quotas were met. To help enrich findings, 15 of the SME sample involved businesses that had taken part in the prior PAL research – selected across sectors and reflecting different practices around PAL. The remaining SME businesses were recruited free-find. The ‘gold standard’ businesses were recruited directly by Basis Social, through contacts provided via the FSA.

An incentive of £100 was offered to all businesses taking part in the research. The sample specification is provided in Table 1.

Table 1: Sample for the research

SME Business Characteristic	Detail	SME Achieved sample (n=37)
Sector[3]	Manufacturers	10
Sector	Catering	12
Sector	Retail	7
Sector	Institutions[4]	8
Business size	Medium (51-250 staff)	10
Business size	Small (11-50 staff)	13
Business size	Micro (less than 10 staff)	14
Main type of food sold	Pre-packed food	11
Main type of food solid	Pre-packed for direct sale	13
Main type of food solid	Loose food	13
Location	Wales	7

[3] The size of business across each sector was split between medium, small, and micro businesses.

[4] This included schools, colleges, universities, and care homes, with food services provided either in-house or by a third-party catering company).

SME Business Characteristic	Detail	SME Achieved sample (n=37)
Location	Northern Ireland	5
Location	NW England	5
Location	NE England	5
Location	Midlands	5
Location	London and South East	6
Location	South West England	4
Adoption of PAL	Adopting PAL	28
Adoption of PAL	Not adopting PAL	9
Food hygiene score	4-5	30
Food hygiene score	1-3	7
Large, gold standard businesses	-	**N=5**
Sector	Manufacturers	4
Sector	Retail	1
How food prepared	Pre-packed food	4
How food prepared	Pre-packed, pre-packed for direct sale, non-pre-packed and loose	1

2.4 Research approach

All research was conducted as 1-hour, online interviews via the Zoom platform. To ensure consistency, interviews followed of a discussion guide, with questions covering the topics areas highlighted in the objectives above (see section 1.1). A copy of the full discussion guide is provided in appendix 1.

Interviews were video and audio recorded, where consent was given. Live notes were taken during the interviews and checked against recordings. Responses were analysed in matrix framework, with different themes coded, enabling similarities and differences across business size and sector to be explored. Anonymised quotes are used to illustrate findings.

2.5 Terminology

There are a range of terms used throughout this report, which are defined as follows:

- **Cross-contact and cross-contamination:** are used interchangeably and refer to the unintentional incorporation of a food allergen into a food.
- cross contamination**Risk analysis:** the overall process of assessing, managing, communicating and reviewing food safety risks.
- **Risk assessment:** the systematic process of identifying and assessing potential food safety risks.
- **Risk management:** the process of taking actions to control food safety risks.

3. Findings

3.1 Range of businesses involved in the research

As noted above, there were four food sectors involved in the research: manufacturers, retailers, catering businesses, and institutions. These were spread across a range of businesses sizes and food categories, together with different ways in which food is sold across pre-packed, pre-packed for direct sale (PPDS), and non-prepacked, and loose foods. These factors - sector, size, category, and packaging - shape the range of allergens used by businesses, the potential for cross-contact, and subsequent use of PAL.

In order to help contextualise findings, details on the range of businesses interviewed within each sector are as follows.

Manufacturers covered a wide range of categories including savoury snacks, speciality breads, sauces, confectioners, sandwiches, ready meals, and craft breweries. In micro businesses, the range of foods manufactured was often limited to a few products, and it was common for these businesses to cook from domestic properties. Small businesses had a wider range of products and produced food in professional setting. Medium sized businesses produced food on a significantly larger scale, had the most systematised processes and structures (for example teams with specific responsibilities) to support production. While most food produced by manufacturers was pre-packed, PPDS products were also sold (particularly by micro businesses, for example, via farmers markets). Online sale direct to the public was also common for micro and small businesses and mixed for medium sized business.

Retail SMEs included medium sized convenience store chains selling a range of branded products, plus smaller businesses such as bakeries, vegetarian stores, and sandwich shops, and micro-businesses including a chocolatier and food supplement business – which sold a more limited range of products, often produced on site. PPDS foods were sold by all respondents, though certain businesses also sold non-prepacked and loose foods, such as bakery items. The range of products sold

increased in line with business size, extending up to c.200 products for the medium sized convenience stores.

Catering businesses covered a wide range of foodservice, including restaurants, delis, cafes, pubs, hotels, takeaways, and wider catering services. The majority of caterers were micro and small businesses, with medium sized businesses represented through chains and those supplying catering services. Food was predominantly sold non-prepacked as meals, though there were modest amounts of PPDS sold in delis and pubs. The range of products sold was less driven by business size for this sector, and more a factor of cuisine and menu range.

Institutions involved in the study included care homes, schools and colleges, university caterers, and charitable organisations – for example, those providing services to children and young people. While covering a range of business sizes, they tended to be small or medium sized enterprises. They were most similar to the catering sector in terms of cuisine and how food was sold. However, relative to the catering sector, it was more common for institutions to be part of a larger group business supplying services - in turn with dedicated training and supply chain management practices.

4. Types of allergens used and perception of allergen risks

4.1 Types of allergens used

Across the sample, **all 14 allergens regulated by UK food law were used by businesses in some form**. The most common across sectors was gluten, eggs and milk, and while peanuts and treenuts (collectively referred to as nuts) was the most top of mind allergen, nuts were also the most common ingredient to be excluded from a food production process or a kitchen. Lupin was the least common allergen used.

The variety of allergens used by any given manufacturer was limited relative to other sectors – and typically comprised 2-3 per organisation. For example, a manufacturer of pies and savoury rolls only used gluten, egg, and milk on the premises, whereas a brewer used gluten and sulphides. However, this varied by category and allergen use was greater for a confectionary and deserts manufacturers. It was common for manufacturers to exclude allergens from their site where not needed for the production process. As noted above, this was most often nuts (including consumption by staff at meals), but of all sectors **controls over ingredients allowed on the premises was tightest for manufacturers**. Even in micro businesses cooking from domestic kitchens, there was an attentiveness to controlling the environment where products were made.

Given the wide range of retailers involved in the study, the range of allergens used (both within and across businesses) varied significantly. **Convenience stores had the greatest range of allergens**, but much of this was pre-packed, came from a limited number of trusted suppliers and not thought to pose a significant risk. **Smaller retailers used a narrower range of allergens, typically between 4-7**. This food was made in open environments in store before packaging, creating greater opportunity for cross-contact. Use of soya was particularly noted by retailers, relative to other groups. The smallest use of allergens were retailers with a very limited range of products, such as a micro food supplement business. **Given the PPDS focus of retailers, recent changes to allergen labelling regulation were top of mind for his group.**

> "We use nuts, soya, mustard and celery and sulphites. Soya is main allergen as it's in all sauces. Mustard in a lot of sauces and celery in ketchup. Since Natasha law, we make sure it’s all on the label ingredients and we have a dedicated printer to help."
> Small retailer, Vegetarian foods

All allergens (including lupin) were stated as being used across the range of catering businesses interviewed, and most had multiple allergens as part of their menu. Common allergens were eggs, milk, gluten, soya, celery and sulphates, with use of fish, crustaceans, treenuts and peanuts more varied (with the latter often

avoided as an ingredient). It was also noted that customers have sometimes highlighted allergies to ingredients not on the list of 14, including garlic and onion. **The use of allergen matrixes was common for catering businesses to identify mandatory allergen ingredients in different dishes (rather than to warn about 'may contain'). Overall, managing allergen cross-contact on site (rather than via supply chain) was a bigger concern for caterers**.

Institutions were similar to catering businesses, with all 14 allergens used. There was focus on eggs, gluten, celery, milk, and fish, but crustaceans, molluscs and lupin were less commonly mentioned. **Removing allergens such as nuts and tree nuts was very common in schools, and there was greater focus on tailoring menus to the dietary requirements of specific groups**.

4.2 Perception of allergen risks in the wider context of food safety

There was a **hierarchy of perceived food safety risks across business in the study, with microbiological risks highest, followed by allergen risks, then physical, with chemical risks not routinely discussed**. The relative balance of the risks varied across sector, with different critical control points identified (this is discussed in depth in section 4.2 and 4.3). Table 2 summarises the perception of risk from the SME food businesses in our sample.

Table 2: Perception of different food risks by SMEs

Food risk	Risk perception	Notable differences by sector	Critical control points
Microbiological[5]	Very high	None, though greatest for those working with raw foods.	Delivery, use by dates, storage at correct temp, cross contamination from raw foods, cleaning.

[5] This was generally described in terms of food poisoning, rather than specific pathogens, though listeria and salmonella were directly mentioned as risks from fish and chicken respectively.

Food risk	Risk perception	Notable differences by sector	Critical control points
Allergen	Quite high	Greater for catering and institutions, and lesser retailers.	Cross-contact at food preparation, cleaning, storage, ingredients, and supply chain.
Physical	Moderate	Greater for manufacturers.	Accidents on production line.
Chemical[6]	Low	Greater for certain manufacturers, for example, brewing.	Transportation and handling down the supply chain (primary production was not mentioned).

For SME manufacturers, overall, allergen cross-contact risks were not seen as particularly significant, because their risk assessment and management processes were deemed to be effective. Specifically, the supply chain was noted as being well managed,[7] they only used a limited number of ingredients, and food was produced on secure lines. **This is not to say that allergens were seen as unimportant - but rather that the likelihood of a problem was small compared to a microbiological risk,** and physical risks caused by accidents (such as objects in food). For breweries, there were also concerns around hygiene from the on-trade, with limited scope to control this.

> "I can control my beer very well but once in kegs and casts, if line clean hasn't been verified in bars, that's when people are at risk".
> Medium sized manufacturer, brewing.

[6] Chemicals were the least discussed risk and specifical chemicals were not mentioned.

[7] Manufacturers management of the supply chain was acknowledged as less effective when discussing cross-contact risks in detail.

For medium sized retailers, the primary risk to consumers concerned food hygiene and microbiological risks. Legal compliance was key for these businesses, and they worked closely with EHOs to define their responsibility. Given the regulatory force of managing microbiological risks, most effort was focused here. While allergen risks were noted as an issue for medium sized retailers, it was hard to manage cross-contact from the food service parts of the business.

> "It’s the law which sets the standard, and anything that's contained within the regulatory structure is taken seriously. We have developed our HACCP document in concert with the primary authority, but this is mostly focused on food hygiene. I don't believe it is possible to have an allergen safe environment - we would need clean areas and dedicated suppliers, which is not easy to accommodate given the current structure of the business. Medium retailer, convenience store.

For smaller retailers, particularly PPDS businesses selling breads, sandwiches, and confectionary - allergens were seen as a more significant risk to consumers. Managing such risk, particularly airborne risks of flour or sesame seeds falling off products during packing and sale, were not viewed as possible to meaningfully control. Whilst this was of concern for respondents, it was also viewed fatalistically and not seen as something they could manage effectively.

For catering businesses, the spontaneous mention of allergens as the key food risk was the highest of all food sectors involved in this study, followed by “cooking food correctly” and microbiological risks. As will be explored later, management of allergen cross-contact risk was seen as very challenging for catering business. Rather, **greater focus placed was on allergen risk communication -** from understanding a food hypersensitive customer’s needs, to making sure the customer knew the risks of eating in the premises.

Similarly, **allergen cross-contact was also noted a high risk for institutions** and the top risk in schools[8] – though there were effective controls to manage this risk in many institutions as individual dietary requirements were known. More generally, institutions placed a significant focus on considering microbiological risks, particularly ensuring deliveries of food are refrigerated at the correct temperature, and the risks of reheating foods.

4.3 Training

Training was common for all manufacturers and retailers. However, this was focused on food safety (typically level 2 or 3), together with HACCP. **Allergens were only explicitly covered in certain instances** and, where done, allergen training focused on ingredients lists and labelling requirements for PPDS products. **There were very few examples of allergen cross-contact being covered through such training.** For all but the larger businesses which had resources for in-house support, training was typically provided by an external party together with online courses and refreshed every 1-2 years. Environmental Health Officer (EHO) recommendations were particularly noted as important by retailers, and there were minor instances of using online FSA training for this group.

Training was the most mixed across caterers, ranging from comprehensive courses on food hygiene and allergen management, through to limited training with no provision for allergens at all. While this was to some extent a function of size of business, with greater provision in larger caterers, there were micro businesses that invested significantly in training. In this context, relative to other sectors, training specially on allergens was more likely to be undertaken by catering businesses alongside food safety courses. Training was generally undertaken when

[8] Allergen risk in schools was seen high relative to the risk from raw foods due to frequency (range of allergens in kitchen versus limited preparation of raw foods from scratch) and impact (risk of severe allergic reaction versus risk of food poisoning due to undercooking). Allergens were also a known risk (for example, specific children had food hypersensitivities) whereas food poisoning was only a potential and manageable risk.

staff joined, with periodic refreshers (from quarterly to a year plus) together with additional information updates (for example, changes to guidance) as required. Training was provided via a mixture of online and face-to-face sessions, using external agencies or the local authority. Several businesses mentioned using an FSA online training module on allergens to complement these formal courses. Again, training focused on management action to reduce risk of cross-contact, rather than risk assessment.

All institutions in the sample adopted training, with this typically being delivered internally or via the parent catering group, together with online support. **While allergens were often subsumed with wider food hygiene training, it was common for them to be covered via a distinct module** (though by no means universal). Allergen training covered a raft of issues, from good food preparation techniques to the use allergen matrixes - though **risk assessment of cross-contact and the use of PAL was not covered**. Despite this, there was a perception that training was adequate to manage allergen risks in the kitchen. There were also notable attempts to make training feel 'real' and more engaging, with certain institutions adopting food hygiene quizzes.

5. Risk assessment

While there was a good understanding of the concept of "risk assessment" across sectors, the practice of allergen risk assessment was extremely limited for SME food businesses involved in this study. It should be noted that risk assessments were used but these focused on microbiological risks.

Specifically, when risk assessment was undertaken, HACCP defined the process in SME food businesses. While HACCP was designed to focus on microbiological, chemical and physical risks (rather than allergen risks) they were seen to manage food risks generally.

Consequently, all food risks were assumed to be assessed through broader HACCP frameworks, with the potential that specific allergen cross-contact risks are missed. Allergens rarely formed a distinct part of any HACCP plan.

Beyond HACCP, there were other, limited examples of allergen 'risk assessment'. When undertaken, these were piecemeal, rather than a part of a defined and systematic process. Specifically, such an assessment tended to focus on one or two allergens, rather than the potential risks from all allergens present during the food production process. It also did not proceed through a stepwise understanding of different control points but focused on those more top of mind cross-contact opportunities – particularly during preparation and cleaning.

In the next section, how SMEs understand and use risk assessments in general and the specifics of how they assessments of the risk of allergen cross-contact at critical points is explored in depth. In addition, in section 5, we provide a series of pen portraits illustrating how allergen risk assessment and management was undertaken by specific businesses involved in the study.

5.1 How risk assessment is understood by SMEs

SMEs engaged in the study were generally able to define 'risk assessment' and understood this as distinct from risk management practices. However, the level of sophistication of definitions varied in across and within sectors, with responses ranging from "it's the assessment of risk", to a more detailed understanding of the processes involved in evaluation.

> "It means that I keep risk to a bare minimum. I do things properly."
> Micro catering business, cafe

> "It's an analysis of where there are risks in the food production process, and in terms of products and ingredients."
> Medium Manufacturer, savoury meals.

The **ability of manufacturers to define risk assessment was the strongest of all groups** and viewed in terms of critical points (as informed by HACCP plans). Specifically, it was viewed as an analysis of risks in terms of suppliers, ingredients, storage, food production process, cleaning, and transport. It was seen as distinct

from management – which was defined a proactively acting to prevent a risk, once it had been identified.

Understanding of the concept of risk assessment was also high for retailers, and near to the levels for manufacturers. It was variously defined as:

> "An awareness of the environment to identify and mitigate the threat."
> Medium retailer, convenience stores

> “A need to look at your environment and making sure it’s not cross contaminating." Small retailer, bakery

> “Assessing the environment for risks, as separate from managing those risks."
> Micro Retailer, food supplements

Though not as pronounced as with manufacturers, there was some association of risk assessment with HACCP for the retailers involved in this study.

While not as sophisticated as retailers and manufacturers, **there was generally a good understanding of the concept of risk assessment by catering businesses**. Overall, assessment was defined as the process of thinking about where risks could materialise, versus management which focused on the actions to mitigate the risk.

> "Risk assessment is looking at the business as a whole and thinking about risks to customers, staff. It can be anything from slips and trips to food safety. It covers who is at risk and how you would mitigate. Risk management is how you implement everything that is in your risk assessment."
> Small caterer, restaurant.

There were minor instances of micro catering businesses struggling to define risk assessment or conflating the definition with risk management.

Institutions also had a good conceptual understanding of risk assessment, which was defined as the process to 'understand whether a risk may happen'. There was a greater focus on risk assessment in terms of food preparation for this sector - specifically the checks made prior to cooking.

> "I think it means how you understand whether a risk may happen, and the checks you make before starting to make the food."
> Small Institution, School

5.2 Overall food safety risk assessment

The most sophisticated risk assessment practices for SMEs in this study were by manufacturers and to a lesser extent retailers. It was less well-advanced institutions, though strong risk management practices were noteworthy for this group. Catering risk assessment was relatively low. **Risk assessment focused almost exclusively on microbiological risks, rather than those from allergen cross-contact**. Assessment processes are briefly reviewed below before allergens are explored in greater depth.

All manufacturers in our sample stated they conducted risk assessments, together with the majority of retailers.[9] Relative to other groups, HACCP was cited as a fundamental part of this process and typically followed a step-by-step process from sourcing ingredients, to point of sale. Visual assessment of cleaning (including certain instances of validation swabbing) was common in small and medium sized manufacturing business, and medium sized retailers. While not common, certain manufacturing and retail businesses had adopted allergen risk assessment as part of their HACCP plan.

[9] As noted on p. 8, retailers fell into two broad groups: larger convenience stores, which sold branded goods, own label and also had butchers or food service outlets, plus retail outlets predominantly selling PPDS. While risk assessment often focused on foods prepared ‘in store’, there was some governance of branded goods in the supply chain.

Institutions had mixed practices around conducting risk assessments, and it was generally greater in medium sized businesses, where there was central support. Where undertaken, assessments ranged from “every six months” to “if supplier changes”. Significant menu changes would also prompt a review of risk assessment. Overall, risk assessment documents were not a touchstone for good hygienic practice in institutions and, to some extent, were seen as the responsibility for management or “someone else in the business”.

Whilstthe majority of catering businesses mentioned that they conducted a risk assessment, details on these were extremely patchy and in reality, it was often conflated with risk management tasks. There were minor instances of catering businesses working with external consultants (e.g., ex-EHOs) to help prepare their risk assessments, but again these were focused on wider food safety rather than allergens.

5.3 HACCP

HACCP plans were stated a being in place for most businesses and across all sectors involved in the study. Other than in a couple of instances, HACCP was not used to inform allergen risk assessments.

As noted, **HACCP plans were seen as adequate to manage allergen cross-contact risks**, particularly for manufacturing business (where most of the risks seen to reside in the supply chain, rather than on site). This was because of the controlled nature of their production process, the limited rage of ingredients, and limited range of products made.

> "We do have a HACCP plan and we would revise twice a year in consultation with consultant. But allergens not considered in the HACCP and never been locked at via EHO. We do use a PAL, but it links to nuts in factory where the flour is made - so we pass this info on to consumers from suppliers. There's no risk of cross-contact on site".
> Medium business, manufacturer, savoury meals

> “HACCP means that everything is just so well managed at our site… Cleaning would already be in place, but not because of [an allergen] risk assessment” Small manufacturer, ready meals

For retailers, the HACCP was particularly linked to Food Hygiene Rating Scheme (FHRS), though managing allergen cross-contact was not seen as material to FHRS scores (but it was noted that EHOs had started to discuss allergen ingredients labelling).

Overall, **HACCP plans played a less central role in risk assessment and management for caterers relative to other groups** - rather, established food hygiene practices and 'common sense' were used to manage risks. This is discussed in greater depth below. HACCP use in institutions was mixed, often driven centrally, and not seen as a part of day-to-day allergen management.

5.4 Risk assessment of allergen cross-contact

While not as comprehensive or step wise as for microbiological risks, **there was a level of allergen risk assessment by manufacturers involved in the study**, **focused on cross-contact risk from the supply chain**. Assessment included conducting audits and reviews of supplier management processes – though the limitations of this were acknowledged and suppliers were ultimately seen as “someone you need to rely on”. The idea of assessing and eliminating risk at source was particularly important and any new product lines or change in suppliers were given significant attention.

> "We would normally shut down any product which introduces a new allergen straight away as it's too much work. We then discuss whether it requires new equipment". Small manufacturer, snacks

As noted above, there were limited instances of manufacturers integrating allergen risk assessment into their HACCP plans and undertaking a more comprehensive allergen risk assessment across critical control points. When done, delivery, storage, preparation, cooking and cleaning were all looked at in terms of allergen cross-

contact risk. Manufacturers adopting this tended to have larger number of product lines, and greater risk of cross-contact.

More typically **for manufacturers, the focus for controlling allergen risks fell not on assessment, but wider hygienic production processes and their extensive experience making the product**.

> "Allergen risks are not formally assessed by the business. We have tried and tested manufacturing processes and have only had minor changes to the menu over last 100 years. We make our own pastry, and it's done in a consistent way. We're not at mercy of the supply chain."
> Medium sized manufacturer, savoury foods

For retailers, risk assessment of allergens was extremely patchy, and it was common for them to describe risk management actions rather than formal assessment processes during the interview. When pushed on allergen risk assessment, a lack of advice and templates was noted as missing for the sector, together with the integration of processes into HACCP.

> "The examples do not exist by sector - especially when it comes to allergens - where are the templates? It's just 'do a risk assessment', based on what? We are happy to be compliant, but it's hard to find the info, I feel like I've done my best"
> Small retailer, sandwiches

> "Allergens should be a section of the HACCP - we are doing it anyway, it's about simplifying processes. We are updating our HACCP all the time. If FSA want a quick win, they should just make it part of the HACCP"
> Micro retailer, chocolatier

Given the pre-packed nature of most of their products, retailers were concerned about the allergen risks in the supply chain. **However, retailers felt they had limited ability to actively manage cross-contact risk within their supply chain,**

given its complexity and the wide range of products on sale. As such, PAL labels passed through the supply chain were generally taken at face value.

> “I think many retailers are struggling to manage allergens through the supply chain, a full audit is just not possible."
> Medium retailer, convenience store

Even for smaller retailers with a more limited stock, supply chain management was an issue. As micro business selling food supplements noted, some of their ingredients came from Russia and (without costly testing) it was impossible to verify beyond asking for various paperwork.

For retailers that made food in store, cross-contact risk was predominantly identified at points of delivery, the separation and storage of foods, cooking, and particularly cleaning. Additionally, airborne cross-contact risk was identified as a major issue for bakeries.

Allergen risk assessment in catering was almost non-existent. When probed on assessing cross-contact risk, whilst a very large number of measures were highlighted, they focused almost universally on allergen risk management actions. Areas covered included allergen food separation and storage (including labelling), the risk of cross-contact when allergenic foods were prepared (framed as the use of separate utensils or boards), and cleaning - which was seen as the main way of controlling risk. Other than in takeaways, cross-contact risks associated with serving foods was not spontaneously mentioned.

An intuitive “cautious approach” to food safety, built from experience in working in a kitchen, typically guided catering businesses to prevent allergen cross-contact.

> "We always try and minimise any element of cross contamination through separate storage and cleaning practices. It’s all about being extra cautious."
> Medium sized catering business, restaurant chain

> “It's up to the chefs. They make sure that standards don't slip. We are pretty tight on process, so I think there's minimal potential for cross contamination risk.”
> Small catering business, fast food restaurant

> “I just use common sense to go through the process of managing allergens”.
> Micro catering business, café

Given the very wide range of allergens present in these kitchens, it is likely that such practices miss important steps or allergens of interest.

While the systematic appraisal of allergens risks in institution was also very limited, **it was common for schools, colleges and care homes to know the dietary requirements of food hypersensitive pupils and residents**. **This advance knowledge meant that even in the absence of allergen risk assessment the ability to meaningfully manage risk was effective**.

The main exception to this was in universities. Here practice resembled catering businesses, with allergen control predicated more on experience and professional knowledge, than risk assessment. Finally, charitable organisations interviewed - for example, those providing catering services to youth clubs or community day centres - neither undertook allergen risk assessments nor had deep “catering expertise” to guide practice. Rather, as much of the food served was pre-packed and brought through supermarkets, allergens risks were believed to have been managed via the supply chain.

6. Pen portraits

To bring to life the issues discussed above, we highlight four ‘pen portraits’ to illustrate the culture and practice of allergen risk analysis in across a range of SME food businesses sectors. For confidentiality, the names of the businesses and staff have been changed, though the cuisine, size and sector are as reported.

Portrait 1: Micro catering business with limited risk assessment processes and poor allergen cross-contact controls

Royal Kebabs and Burgers is a small, family run fast food business, serving popular late night takeaway meals. The owner Sheila runs the back-of-house admin side of the business, whilst her husband, John, cooks. Sheila is largely in charge of the allergen information they provide to their customers. She's currently going through the labels on all their ingredients to understand what allergens and ingredients were on their premises – and unsure how many allergens are currently present in the kitchen.

Sheila's understanding of risk analysis is patchy, and she uses the terms 'assessment' and 'management' interchangeably. In relation to the cross-contact of allergens. They are not carrying out a risk assessment and generally felt it is hard to identify and control allergen risks, given the open and busy nature of the kitchen:

"It's quite difficult to be able to control [allergens] with the type of thing we're providing, you know, if we have our staff cooking pizzas, kebabs"

Overall, Sheila felt the business adopted good food hygiene safety practices. Implicitly these were seen to manage all food risks in the kitchen, including that from allergens.

"We do say keep your hands clean... and we encourage our staff to wear gloves when handling raw foods, so it doesn't cross contaminate. We just try to encourage staff to cover their face, wear gloves, wash their hands frequently, keep the shop clean when it's not busy"

In the absence of a risk assessment, they apply a blanket PAL label on their menus, ("if you have any allergies let us know") in order to make sure that they are covered in the event of an allergic reaction. PAL was conflated with allergen labelling for ingredients and seen as a legal requirement, used both to warn customers and to help protect the business from legal challenge.

"Nowadays it’s a requirement so that if a customer does have an allergic reaction, the labelling was there in the first instance"

Managing allergen cross-contact is seen as particularly challenging for Sheila and John for a host of reasons. Separating allergens for storage is not possible because of the physical layout of the kitchen. Needing to cook multiple meals in a short space of time also limits the scope for thorough cleaning between food preparation.

At their last food hygiene inspection, the business was rated 1 because the premises was “in need of repairs and alterations”. In spite of this, they believe they are compliant with the FSA guidelines, and allergen risks are being managed effectively.

Portrait 2: Small catering business with good understanding of assessment processes and mixed allergen cross-contact controls

The Clocktower Café is a small high street establishment owned by Mary. She describes it as a “community hub, and a place everyone could come to.” They serve “typical British food” fresh to order. They have an emphasis on catering to everyone regardless of dietary or allergy requirements and allow customers to adapt items on their menu board to accommodate them accordingly. Mary is aware of the risk from allergens because of her own gluten intolerance.

“Allergy awareness is something I'm quite strong on… I’m really aware of the risks involved”

Mary has a good grasp on what a risk assessment is, and how it differs to risk management. For Mary risk assessment is about understanding where there are potential points of danger in her business, whereas the management side of things was about putting in practices and procedures to address them. She understands risk assessment as something that extends beyond food preparation and is important across the business as a whole.

“It’s not just about food it’s also about practical safety... risk assessment is for the

whole business. For me, assessment is making sure you are aware of the risk... the management side of things is making sure procedures are put in place and followed"

Mary has specific risk assessments for allergens that involve looking at their supplier's practices, the storage of food, where and how its prepared, how it is packaged, cleaning practices, and even airborne risks such as gluten particles. She also checks her risk assessment regularly and updates it with any necessary changes as and when its needed.

"We highlight the potential allergens that are airborne... also if products have been brought in, we look at where they've been made. It's reviewed once a month to make sure there haven't been any changes"

While her risk management procedures are also fairly comprehensive, they are limited by the nature of her business, and her capability to reduce the risks involved of handling and preparing multiple allergens in a small kitchen. Whilst they have a separate set of utensils for allergens, they are all washed in the same dishwasher, and Mary believed that this was fine in addressing cross-contact risks due to the high temperatures. She also lacked the storage space to fully separate allergens, but she did try and keep them apart in the fridge she had.

"All of our items are fresh and separate, however we have an allergen folder so we can talk through to the customer. We manage it the best that we can do but ultimately it's up to the customer to decide if its right for them"

Whilst Mary has a good understanding of risk assessment, she is constrained by the nature of the business in managing the risks. While risk assessment was relatively comprehensive, it did not follow a formal, step wise process. Likewise, although her staff did receive some formal online food hygiene training provided by the FSA when they joined, often allergen information trickled down informally through her.

Portrait 3: Micro retailer with a reasonable understanding of risk assessment and a belief that allergen cross-contact controls were effective

Gita owns and runs Chocolate Kitchen, a micro retail business that makes artisan chocolates. She is proud of her 5-star food hygiene rating. As a chocolatier, she works with a limited number of allergens during the making process, with milk and gluten most common. Certain allergens are occasionally used as toppings, but she tries to exclude nuts from the manufacturing process, and they are only used upon request for personalised orders.

"We try and stay away from having any peanuts or any nuts in the area because of cross contamination risks."

Gita has a good understanding of risk assessment and conducts a thorough risk assessment based on HACCP principles, though this is commonly focused on microbiological risks. She carries this out herself, with advice from her local environmental health officer. While allergens are not formally part of her HACCP plan, she believes she has an intuitive understanding of managing these risks.

“Risk assessment is assessing all the different types of risk and managing is ensuring the management is in place. In terms of risk in general for chocolates it’s just assessing cross contamination, assessing allergens”

Gita has a range of management processes in place, and focuses on separation and cleaning practices to avoid cross-contact. The chocolate is almost always made from scratch using raw ingredients to reduce the amount of risk coming from the supply chain. On the occasions that nuts are involved in projects, they try to only cook those products on separate days or weeks from the rest of their products. She does not test for allergens, does not conduct any cleaning validation, and did not highlight the persistence of milk in terms of cross-contact. Rather, the focus was nuts.

"While we use things like milk every day, we always try and allocate a specific week to do all orders that relate to nuts... but once those orders are done, we make sure everything is cleaned down and the nuts are taken off the premises"

Gita has an allergen folder and allergen information readily available to customers, so they can ensure all ingredients and labels are properly listed, meaning they don't have to use a PAL.

Portrait 4: Medium sized manufacturer with a good understanding of risk assessment but broad allergen cross-contact controls

Piotr is a Quality and Food Safety Technician for a company called Savour, who manufacturer ready meals predominantly for hospitals. They work from one site that is effectively a large commercial kitchen, rather than a food processing site that larger companies in this sector would use. They create pre-packaged meals and use a wide range of ingredients and allergens, with the exception of nuts.

Their risk assessment was focused on identifying microbiological risks (given the risks to vulnerable patients), with allergens seen as a secondary risk. Assessing allergens was difficult in their business, because they relied on so many ingredients from the supply chain, which was difficult to govern.

"We are serving vulnerable people [in hospital]. Food safety is at the forefront...there is so much temperature control in our processes. It is easy to look at our allergen handling and think it's uncontrolled. Suppliers are the issue. They switch brands of products and that is the risk. There is a risk of sending a meal out unwittingly that might contain an allergen"

Piotr has developed a HACCP plan to assess and manage food risks and the business is STS accredited (STS are an independent Certification Body in the UK and have a technical food safety standard for food manufacturers and distributors).

Cross-contact is managed by use of a system in which products that contain allergens are made in an 'allergen area'. They were advised by the EHO that everything that is produced in this area is accompanied with PAL. Piotr himself was disappointed about this practice and felt PAL was being used without a tailored assessment and management of the actual risk.

"We have PAL on products produced in a certain area of the site. One area - anything that contains any allergen - it gets a PAL. It gets a PAL for any of the allergens that are used in that room. I don't really like (PAL) because I don't think it is useful for people with allergies, it is a cop out from businesses. It says you might not be managing your allergen management well"

Piotr's has HACCP training and level 3 'supervising food safety' training. He even describes himself as a 'nerd' for food safety. However, the risk management of allergen practices are limited in that they cannot confidently audit the supply chain, because of the high number of ingredients they work with, and they don't have the resources to set up more effective assessment and management systems.

7. Risk management

7.1 Risk management of allergens

Overall, the processes underpinning risk management in SMEs were more comprehensive than risk assessment and adopted to varying extents by all businesses interviewed in this study. As noted earlier, while certain management actions were specifically to manage allergen cross-contact, others were general, effective food safety practices, used to manage a variety of risks in the kitchen.

For smaller manufacturers, the risk of allergen cross-contact was seen to reside in the supply chain, and management actions typically focused on physical separation and secure storage of ingredients. For large manufacturers, on-site cross-contact was of greater concern, and practices such as the separate running of product lines, cleaning between production runs, and distinct processes to support packaging, labelling and onward transport were more common.

For retail outlets where most food was pre-packed with limited preparation on site, again the greatest risks were seen in terms of supply chain, together with storage and spillage risks onsite. Allergen cross-contact was less top of mind for this group.

For retailers preparing PPDS foods on site, there were reasonably sophisticated processes of separation, food preparation, cooking and cleaning to manage allergen cross-contact, together with structured routines to ensure standardisation. Despite the use of packaging, for certain retailers, the greatest cross-contact risk came at the point of sale when the products were out in the store.

> "Everything driven through consistency of making products. We create one type of product at a time for example, sourdough and then we clean down after that product - each product is only meant to have the ingredients it is meant to have. More risks can come about when food is displayed and packaged. Products with seeds are placed on the bottom shelf so none will drop on to others".
> Small retailer, bakery

Risk management of allergens in catering businesses were wide ranging. Critical points included delivery and labelling, separate storage and preparation areas (though this was dependent on kitchen size). **While separate boards and utensils were used ubiquitously, there was often a 'one board fits all allergens' approach**. Airborne risks were also seen as very challenging to manage.

> "We can't separate all food, its fresh and we don't have a big enough fridge. No we wouldn't do it, apart from smoked almonds, they are in a jar in an area of the dry store just for nuts, in secure tubs."
> Micro catering business, deli

> "We do physical separation, it's easy for us as we have a huge kitchen. We also use separate utensils. We use a white chopping board and white knife for burger buns. The chef will go and do that by himself and put them in a sealed container, wash his hands and put [the board and knife] in the dishwasher."
> Small catering business, restaurant

> "We have purple boards and utensils, which is used for allergens and washed separately"
> Small catering business, restaurant

There were **limited instances of catering businesses not undertaking any risk management actions to prevent cross-contact**. This was both due to the challenges of managing allergen risks given the environment, and also because allergen risks were not top of mind. Rather, for these businesses, there was a general focus on food hygiene and cleanliness.

Institutions generally had good processes in place to manage allergens cross-contact, particularly in schools where lanyards were provided with the allergy and other dietary requirements of individuals. Specific procedures were adopted around storage, cleaning and separation. Using (colour coded) utensils was seen as essential for managing cross-contact. Cleaning was generally done via commercial dishwashers, though 'industrial deep cleans' were undertaken in certain instances.

> "We have a brightly coloured allergen folder in every kitchen. It has an allergen matrix set up for each area and staff are completely briefed on their area... we work from a completely set menu".
> Medium sized institution, college

7.2 Quantification and allergen testing

There were two types of quantitative testing in food businesses.

- Product tests evaluated the amount of a pathogen, allergen, or ingredient within a final product.
- Swabbing and cleaning validation, which evaluated the amount of a pathogen or allergen residing on a food contact surface (for example, machinery) as part of the production or preparation process.

Overall, **quantitative testing was very limited across SME food business**.

Testing was greatest for manufacturers (though by no means universal), and generally focused on cleaning validation microbiology tests (e.g., listeria). There was no cleaning validation undertaken for allergens by manufacturers. One manufacturer

in our sample directly tested for allergen cross-contact, but this was to demonstrate 'gluten free' status, rather than to inform the application of PAL.

Overall, **smaller manufactures didn't see the need to test for allergen cross-contact given the limited production range and the opportunities for cross-contact being relatively small**. There were related concerns about the level of risk not justifying the costs.

> "We don't test for allergens in final product. We don't feel that it's necessary at the minute. We're quite strict with labelling... we will also tell consumers on the website there's a risk of an adverse reaction. The cost would also be expensive."
> Small manufacturer, confectionary

Very few retailers in our sample routinely tested products, and none tested specifically for allergen cross-contact. Where testing was done, it either related to microbiological swabbing and cleaning validation (for instance, in the butchery counter of a convenience store) or testing to verify the ingredients in a product. Consequently, it was driven by ad hoc events (such as a EHO visit or the development of new product), rather than as a routine part of food hygiene practice. The principle of **testing for cross-contact was not seen as practical for many of the larger retailers interviewed**, given the range of foods that were on the premises.

None of the catering businesses interviewed undertook testing for allergen cross-contact. There was one instance of allergen testing conducted by aa medium sized caterer to verify their free-from claim, and a microbiological test exploring product shelf life in a micro business. Overall, there was a very strong sense that **allergen cross-contact was inevitable in a catering kitchen and testing was relatively unhelpful in this context**.

> "In no world will I send a piece of brisket off for testing to see if there are particles of wheat in it. In restaurants there will always be a risk of 'cross-

contamination’. Don't eat here if you are worried, the consumer needs to take on responsibility as well. I don't need the hassle."
Small caterer, restaurant

Similarly, there was **no testing of allergens in institutions – which was seen as unfeasible in terms of costs, complexity, and expertise**. Microbiological testing was also rare, and where done, was where the business was part of a larger catering company. Overall, testing was seen more for manufacturers than food service businesses.

"No, we don’t do any testing. We would rely on our suppliers to do that. We don’t have the resources or the capability".
Micro Institution, charity

7.3 Confidence in risk management

Despite an absence of testing, SME food businesses across all sectors felt confident that their actions to control allergen cross-contact were sufficient to manage the risk.

Small manufacturers were particularly confident given the relatively **simple ingredients in their products, and the adequacy of risk management controls** underpinned by their HACCP plans.

Similarly, retailers felt that the **fundamentals of food hygiene were covered well, and this provided a level of protection for consumers with food hypersensitivities**. Both manufacturers and retailers used external accreditation processes, which provided reassuranceas to the high standards of food safety.

"I'm 99.9% confident [of managing allergen risks]. We are currently going through new certification called SALSA - which is essentially what you need to be able to sell products in retail. It goes the extra mile to ensure that everything is fine. We've had to go through massive structural changes to get the certification. The level of detail attached to risk management is crazy."

Small retailer, vegetarian foods

"There are certain processes you have to follow as a manufacturer. Lots of hoops you have to jump through to ensure you're covered, because of things like SALSA"
Small manufacturer, ready meals

In catering businesses and institutions, generally respondents felt "very confident" in the adequacy of their allergen risk management actions. This variously related to the **effective separation and cleaning processes, the professionalism and experience of staff, stable and/or limited menus, and never having a customer suffering an allergic reaction on their premises.**.

“I am very confident because the products I have are good. They don't change that often. Most things I have are kept separate and not many of my products have allergens”.
Micro caterer, café

“We come from such a professional [catering] environment. We are used to big kitchens. The EHO could walk in at any time, it's gleaming all the time , we always have labels and had docs up to date and ready”.
Micro caterer, private catering services

“I’m very confident. Every other week a professional cleaning company deep cleans both kitchens.”
Medium sized institution, school

There were **only limited instances of catering or institutions businesses not feeling confident about managing allergen risks**. These related to businesses where the risks were seen as impossible to control - either due to the wide range of allergens in the kitchen (e.g., restaurants), where space limited the ability to manage cross-contact (e.g., small kitchens or storage areas) or where there was significant opportunity for cross-contact (particularly airborne for those using flour). Additionally, risk was perceived to be greater where businesses had certain tasks subcontracted

and they were not in control of quality (for example, cleaning in medium sized institutions). Notwithstanding this, there were numerous instances of small, open, busy kitchens that were confident in their allergen management practices, despite evidence to the contrary.

7.4 FSA tool

As part of the interview, we discussed the potential for using a (hypothetical) FSA tool to help guide businesses in their use of PAL, based on businesses entering details concerning supplier information, on site risks, ingredients and portion sizes.

Overall, reception for the tool was mixed, with certain businesses either struggling to see the relevance or being concerned about its complexity. There were notable differences across sectors in this context.

There was only limited interest in the tool from manufacturers. They generally felt they had a good understanding of their supply chain and associated risks, so the tool was less relevant for their needs. Moreover, there was a sense that such a tool would be very general, and not specific enough for their distinct needs.

> "I don't think I could base a decision on that. Generally, FSA guidance is very vague, it’s for such a wide range of business - it's such basic guidance. We are complying with other standards like STS food safety that are more specific. I could use [the FSA tool] as a base but would have to do more research because we have different products and processes. But In terms of justifying what you are doing for external auditors it wouldn't think it’s a reliable source."
> Medium manufacturer, ready meals

Retailers showed greater, albeit cautious support for the FSA tool. Overall, better guidance on when to apply a PAL was welcomed, particularly anything that took the "guess work out of it". Nonetheless, there were significant concerns over how complex the process would be, and a lack of confidence concerning how to use and

interpret the tool, and (as with manufacturers) concern the tool "may be ambiguous and may not help me".

Of note was the experience of one small retailer who was currently using software that generated “may contain” codes based on ingredients. They found it very helpful.

> "If I'm developing new item, we take allergens from suppliers website, but sometimes we then get product the delivered, and the labelling can be different to what we found online - which shows how easy it is to get things wrong. Once we have all the information, we upload all the products and details into the software which generates the allergen codes and may contain codes. The production team keep the document of allergens, and all allergen documents are reviewed monthly".
> Small retailer, vegetarian foods

Views on the FSA tool amongst catering and institutions businesses was very mixed. There was no pattern of views in terms of business size or cuisine. Rather those businesses that were positive to the idea typically had greater openness to improve current practice, but still needed reassurance that it wouldn't be overly complex to use or require specialist training.

Those that were less receptive felt the tool would be cumbersome and costly to use considering the range of foods on the menu. They also couldn't understand how cross-contact risk in their kitchen would be meaningfully understood through the tool, given how complex this was.

> "It sounds quite labour intensive and complicated to work out. Would I use it? If it was optional, probably not"
> Micro caterer, café

> "Yes, I would use it if could understand it. I would struggle to do a risk assessment like this, so any type of guidance to help with this is beneficial...I would need something that would be downloadable, gives some examples to test yourself on".

Small caterer, restaurant

“I get the concept… I would try to do that, but might struggle”
Micro institution, charity

7.5 Willing to share risk analysis

Participants were also asked whether they would be willing to share results of risk analysis across the supply chain. Again, views on this were very mixed.

While to some extent manufacturers could see that it might be helpful, **there was a concern about the complexity of any reporting process, and burden for small businesses**. Overall, the focus needed to be on building trust in the system, rather than over engineering reporting requirements.

"There's a real risk of over complicating this and creating unnecessary burden on business. Consumers need to trust the brand and trust the regulation system. Asking people to provide info on risk assessments etc will overcomplicate things. EHOs need to do their job and people have faith that the regulations work".
Medium sized manufacturer, pies and savoury meal

There was modest support for sharing of risk analysis by smaller retailers, providing it was not too onerous, mainly as it showed you were an open business that could be trusted. For larger retailers, it was seen as "very complex and hard to do across the business". Rather, there was a view that **risk assessment was fundamentally seen as part of the HACCP plan, and that it should be reviewed as part of compliance by a relevant authority**.

There were mixed views on the willingness to share risk analysis by caterers. Barriers included the time, complexity and the impracticality of such a process given the menu range, and the limited perceived value for customers, who "just need to trust a business to manage the risk". For those catering businesses who stated they would be willing to share, a “nothing to hide” mindset dominated, though even for this

group concerns were voiced about the effort involved in the process. Similarly, while in principle institutions stated they may be willing to share information of their risk analysis, there was significant concern over what this would involve and the consequences of getting it wrong.

8. PAL

8.1 Understanding of PAL

The overall **understanding of PAL across SME food businesses was patchy and often very limited.** While commonly associated with the words 'may contain' what this meant in practice was unclear for business. For the catering and institutions sectors especially, given most allergens were present in a kitchen, it was felt to be both unhelpful and unpractical to label every dish.

> "But you don't want to put may contain everything...I can't use it if I've made porridge in the morning and rice noodles in pm, would that mean I have to say 'may contain' milk? It just means people have restricted choice".
> Medium sized institution, university

PAL was routinely confused with PPDS labelling, with businesses not sure whether it was a legal requirement to use a PAL in this context.

> "PAL is now a requirement to inform your customers of the products you are producing and highlighting the allergens that may be in the products"
> Micro catering, café

Given this, **several catering businesses were confused as to whether PAL applied to non-prepacked or loose foods, or only pre-packed.**

Overall, **PAL was better understood by larger businesses and those in manufacturing**. Retailers also had better knowledge that PAL related to cross-contact, though several businesses associated its use only with pre-packed

ingredients via the supply chain, rather than cross-contact risk in their own kitchens. It was less well understood by catering businesses and micro businesses, and to some extent institutions.

There were however notable exceptions to these ‘rules’, including small caterers who could give detailed definitions. However, such increased knowledge did not relate to a propensity to use PAL statements.

> "It means ‘may contain’. An allergen ingredients label is 'definitely contains’. PAL means it's produced in an environment where ‘cross-contamination’ might occur. But I don't believe in using it. There will always be a risk of cross contamination in our business. Cut a bread roll and there will be micro-fine dust!"
> Small catering, restaurant

Most tellingly in the context of this study, none of the businesses interviewed understood the need to conduct a risk assessment to inform PAL use. The table below summarises the level of understanding of PAL for the sectors involved in the study

Table 3: Levels of PAL understanding across SME food sectors

PAL understanding	**Manufacturing**	**Retail**	**Catering**	**Institutions**
Relates to cross-contact/’may contain’	Good	Good	Moderate	Moderate/Good
Voluntary status	Moderate	Moderate/Poor	Poor	Poor
Distinct from allergen labelling	Moderate	Moderate/Poor	Moderate/Poor	Moderate/Poor

PAL understanding	Manufacturing	Retail	Catering	Institutions
Requires a risk assessment	Very poor	Very poor	Very poor	Very poor

8.2 Application of PAL

In terms of how PAL was applied by SME food business, it should be noted that our sample was structured to reflect a greater proportion of organisations adopting PAL. This includes both labelling on packaging, as well as other verbal and written statements.

Overall, **PAL was not applied consistently across or within sectors**. Given the lack of a thorough risk assessment of allergen cross-contact, **a range of heuristics were used to inform PAL application**, including:

1. Where the allergen cross-contact risk was seen to arise, specifically in the supply chain versus on the business premises
2. Ease of implementation within the business (particularly costs and practicality)
3. Extent to which information was seen as useful to consumers
4. What allergens were top of mind for the business
5. Concerns over business risks from not applying

Applications across sectors was as follows:

Use of PAL by manufacturers generally related to the ingredients used and cross-contact risks within the supply chain. There were only minor instances of it being used specifically due to their manufacturing process or cross-contact between lines, and this tended to be in medium sized businesses creating a wide range of products. "May contain" or "made in a factory that also makes" were the most common expressions for PAL for this group.

Given no manufacturer in the sample explicitly tested for allergens, when PAL was used, it was used to cover all products using an ingredient or products prepared in a certain area of the business.

> "We decided to put a PAL for sesame on all labels. Because sesame is used in 90% of bread suppliers, it's just impossible to isolate it; so for peace of mind, we decided to use PAL. We couldn't guarantee it and just couldn't prove there was no cross contamination."
> Small manufacturer, baked goods

> “We have a PAL on products produced in a certain area of the site. In this one area - anything that contains any allergen - it gets a PAL. It gets a PAL for any of the allergens that are used in that room - the EHO suggested we do this”.
> Medium manufacturer, ready meals

For those manufacturers not using PAL, this was predominantly due to the nature of the product, limited number allergenic ingredients used, the limited range of products produced, and the potential to 'put off' consumers. The cost of testing (relative to the perceived risk of an allergic reaction) was an issue in this context. Views were mixed as to whether they would use PAL in the future, ranging from those not really seeing the need, to those who may use it as the business grows. In this context, manufacturers not using PAL tended to be slightly smaller or micro businesses with a limited product range.

For **medium sized retailers, particularly those running convenience stores, PAL information was generally passed down from suppliers on pre-packed foods**. While very occasionally instances were noted of needing to re-label a product, generally they trusted that manufacturers were doing their job effectively and that EHOs are governing this process.[10] PAL was not used for PPDS products made on site in these stores.

[10] There was a lack of awareness that Trading Standards Officers were responsible for labelling, and this was unlikely to fall under the responsibility of an EHO.

For smaller retailers, there was a greater use of PAL in relation to cross-contact “in store”. Additionally, as they had responsibility for printing their own labels, there was generally greater attentiveness to the use of PAL statements. The role of precautionary allergen information, including signage and verbal information was also of importance for such retailers.

> "I bought a new label printing machines for 13 allergens. Every label we have is a credit card size - it's placed on the product at point of sale. We also allergen matrix for all products. We also have all our recipes online"
> Small retailer, bakery

> “We have all the information, but you have to chat to a member of staff. A customer must ask”.
> Small retailer, sandwich shop

For those retailers not applying PAL, reasons generally varied from the products sold are so simple they did not require a label, or that cross-contact is so likely that all products would need a label. For this latter group, **mandating PAL use, or producing complex guidance for compliance, was a very significant concern**. Overall, it was seen as very hard to have sufficient safeguards to protect those most vulnerable FHS consumers from a severe reaction in these businesses.

For **catering businesses engaged in the study, where PAL was used, it was either focused on passing on information from suppliers (rather than a full assessment of cross-contact in the kitchen) or used as a catch all to protect the business**. Use of PAL was mixed across a range of businesses sizes.

> "One of the bigger companies are brilliant at passing on allergen information. Everything comes listed on boxes, with allergens in bold.”
> Small caterer, hotel

> "On our menus we use may contain nuts or traces of nuts - as a blanket thing for the restaurant"
> Small caterer, restaurant

For those not using PAL, either it was because of a lack of knowledge, or the risks were felt to be well managed, or that it was impractical to have written statements covering all allergens.

> "We don't need to put PAL on because we have assessed and mitigated the risk - and this is based on what we do for the HACCP"
> Micro Catering, Private catering services

Verbal confirmation of dietary requirements and the **sharing of allergen information by customers was seen as a critical point to prevent an allergic reaction for caterers**. In this context, a larger catering business had developed an electronic point of sale (EPOS) system to support communications.

> “When a customer arrives, they are asked immediately if they have dietary requirements. If guest has an allergy, the waiter informs manager on duty. The Manager takes the allergen file to the customer, to help them make an informed decision. The waiter takes the order and there is a big button on the EPOS system to warn for an allergy. The order prints through, with the allergy warning in bold, red capitals to the kitchen. Food is prepared and ready to go to table and then the manager will carry food to the customer and announce with the dish that this is allergen free food”.
> Medium sized catering restaurant

PAL use by institutions was often undertaken in medium sized business and directed by the parent catering group. PAL use generally related to information passed down through the supply chain, rather than in terms of cross-contact in the kitchen. Overall, PAL was not seen to be a very helpful statement to consumers in institutions and viewed as 'covering the back' of the business. There was also the occasional 're-labelling' of PAL warnings as part of the ingredients list.

> “We would rather say that it contains something rather 'may contain'. We kind of treat any information from the supplier as part of the ingredients list. May contain does not sound convincing, so we'd rather be black and white about it. We don't want to put ourselves or customer at risk”.

Small Institution, university

As noted previously, there were other allergen risk assessment and management procedures for institutions such as schools and care homes, meaning that meals could be prepared and tailored to the FHS dietary needs of specific individuals. In this context, there was no use for a PAL statement. More generally, where PAL was not applied in institutions, it related to three reasons: it was not company policy; applying PAL meaningfully was seen as complex given the busy nature of kitchens; or there was a poor understanding of what to do. On the latter point, if guidance or training was provided, it was noted as potentially encouraging use.

9. ‘Gold standard’ large businesses

In addition to the SMEs, five large businesses were interviewed that adopted high standards of risk analysis help manage cross-contact of allergens. These businesses focused on manufacturers selling pre-packed foods, and included a large retailer who sold pre-packed, PPDS, loose and non-prepacked foods, including a variety of foodservice in stores. Of these gold standard businesses, four applied PAL and one did not.

The purpose of these interviews was to gain a better understand of ‘what good looks like’ in allergen risk analysis, explore differences with SME sample, and consider whether any learning could be adopted across sectors more broadly.

The following five areas emerged through the gold standard interviews.

1. **Food safety culture and importance of allergens**

All the **gold standard businesses had a very strong focus on food safety, that permeated culture and practice within the business**. Given the potentially fatal consequences should a FHS consumer have an adverse reaction to one of their products, allergen risk was seen as very important to assess and manage within the business – viewed as either the primary risk to consumers, or on a par with microbiological risks. The lack of international thresholds and standards across

allergens also heightened this risk. **This strong focus on allergens was distinct from any SME engaged in our sample.**
Allergens were also recognised as a very complex area to manage, given both supply chain risks, plus opportunities for cross-contact during manufacturing or in store. The magnitude of this was significant – all businesses had global supply chains and many hundreds of suppliers. Manufacturing ranges covered an extremely wide range of products, both branded and white label. The retailer stocked over 20,000 products.

Given this range and complexity, **there was a focus on high standards, and distinct policies and procedures governing the allergens** in supply chain versus the risk from cross-contact within the business. There were also **teams with specific roles and responsibilities to govern food safety** – often separated out between allergen, microbiological and chemical functions.

2. **Supply chain compliance, verification and support**

All businesses provided clear information and support to their suppliers on requirements for allergen risk assessment, management and labelling. For manufacturers, suppliers were typically asked to complete detailed allergen self-assessment forms, which were then subject to verification, through paperwork checks, visits and/or product testing. Stability of the supply chain was fundamental part of risk management and governance, with both core and 'back up' suppliers on an approved supplier list. It was also common for training to be provided to the supply chain.

Within retail, processes included third party audits, protocols detailing how suppliers should risk assess and manage allergens, as well as product assurance via testing. The retailer in our sample worked with the British Retail Consortium to help develop codes of practice and food safety manuals, including specific protocols for allergens. As well as vetting suppliers, all products were assessed in terms of the allergen status, both at line and ingredients level. It was acknowledged that the scale and nature of the business assisted this governance process, and that the risk changes

across sectors – not least in foodservice, where products are made in an open environment and the level of control significantly reduced.

> “Generally speaking, as a retailer, it’s easier to manage the supply chain risks as you’re mostly dealing with packaged goods. It’s one factory supplying 1000s of shops. So, you can apply your effort to have the biggest impact. In foodservice operations, it’s not like that. You’re manging different permutations of risk, and this may vary from site to site”.
> Large retailer, ‘gold standard’ business

Despite all these protocols and procedures, ultimately, supply chain management was noted as challenging and there was only so much that a supplier could be expected to do – particularly given the globalised nature of the supply chain plus different standards and governance processes within the market. Spices were cited as an exemplar of this. In such contexts, the onus fell on the more on the manufacturer than the supplier to consider all the risks appropriately:

> “We use grinding houses in India for example. When considering risk, I need to consider not just what do I know but what I don't know or assume”.
> Large manufacturer, ‘gold standard’ business

3. **Detailed internal policies and practices, reinforced through training**

While all large manufacturers had a HACCP plan, it was common that allergens were covered through a distinct plan, given the different control points and protocols needed to prevent cross-contact.

Control points for allergen risk analysis included:

- The allergen declaration used (for example, free from, may contain, allergen as an ingredient etc)
- The raw ingredients and supply, including whether to test for validation
- The format of the ingredients (for example,, “a 100kg pack of flour creates much more dust than a smaller pack”)

- Delivery and transportation
- Where stored
- How foods are processed and produced
- How machines are cleaned, and the nature/persistence of the allergen (for example, milk proteins)
- Packaging and labelling
- Onward transportation

Allergen storage requirements were comprehensive, including enclosed containers and sealed bags, colour coded by allergen. Additionally, to help manage allergen risks when making processing foods, production runs were often staggered. For example, one manufacturer asked suppliers to categorised ingredients on a scale between 1-5, where 1 concerned no allergens, and 5 concerned multiple allergens. After verification, this coding was then used to phase the timing of different production runs in the factories.

> "These controls relate to our scheduling. We will take a retail order for the day, contact the ops team and then make the products in a certain order. Plain first, then breadcrumbs and gluten, then breadcrumbs plus marinates and so on. Time is allowed for cleaning between batches, and this is linked to historical validation data."
> Large manufacturer, 'gold standard' business

Across these processes, it was common for organisations to provide summary information to management staff on the risk assessment – for each production run highlighting the allergen of interest, nature of the risk, likelihood and impact.

Cleaning was extensively done after production runs. The form the allergen is in (e.g., solid or powder) influenced the type of clean. Wet cleans were typically done with detergent, disinfectant, or other sanitiser, and included a pre-rinse, scrubbing and a final post-rinse, as well as extensive drying to prevent micro-organism growth. Flushing was also used in certain contexts (for example, chocolate residues), though this was expensive due to down time of machinery. A dry cleans included brushing

down, vacuuming, filtration, ‘rinsing’ with crystalline products, and dry steam cleaning. For persistent proteins, such as milk, complex plant machinery was avoided as far as possible, as it was difficult to clean.

4. **Protocols that were easy to understand for others in the business**

As well as those more deeply involved in allergen risk analysis, it was important that all staff could understand and adopt good allergen hygiene and practice. Visual cues and the use of colour coding (from utensils to personal protective equipment) was common, and more generally anyone on site (from contractors to visitors) were briefed in terms of dos and don’ts - such as not bringing nuts or sesame into the buildings. Generally, training was mandated for all staff on food safety and allergens formed a specific part of this. For manufacturers, training was also targeted to teams involved in product development.

More generally, it was noted there was a need to find a better way of communicating the level of allergen risk to small businesses, which ultimately related to the amount of protein in the end product. Given the lack of testing, saying a threshold needs to be below so many parts per million is unhelpful. Rather, bringing the risks to life for people in a more intuitive and meaningful way was noted – for instance, if you use above a teaspoon of such an ingredient a product, you’ll need to use this label.

5. **A focus on testing, but reliance on good process**

It was common for all large manufacturers involved in the study to conduct quantitative testing. There were three elements to this.

- Testing on ingredients or products via the supply chain. This was to verify allergen claims, including whether products that contained a PAL actually needed one.
- Testing their own products. This was both to test production cycles overall for cross-contact, and, where produced, to verify free from claims.
- Testing/swabbing to validate whether specific cleaning of machinery had been effective.

Manufacturers both followed and advised on international standards, such the Voluntary Incidental Trace Allergen Labelling (VITAL) and wanted greater harmonisation of standards.

> "There are no established and consistent thresholds set, so we have to cobble together the best information we can from a variety of source to consider the level of the allergen. We use VITAL, we use WHO, we use the European Food Safety Authority sources to put together the levels. The FSA could really help the industry is by getting behind some reference doses."
> Large retailer, 'gold standard' business

While testing was acknowledged as an important part of the allergen risk analysis, it was also noted as very complex due to the range of factors influencing cross-contact. This included:

- particulate size
- whether any cross-contact was likely to be spread evenly throughout a product and the product range
- cross-contact across product lines (which is stochastic)
- how frequently a product exceeds an allergen threshold when sampled

In short, testing was not seen to pick up everything and was fundamentally not a substitution for careful risk analysis and management processes. As one respondent noted:

> "You should never try and test your way out of trouble. Testing is a fundamental part of the process, but it's not a substitute for effective hazard control systems. High standards and common processes are the key to safety. Testing is there to check." Large manufacturer, 'gold standard' business

Given this complexity, it was also noted that it was very challenging to get smaller businesses to test in the supply chain. Rather, as noted above, the larger

manufacturers would validate claims and provide allergen management and labelling advice to their suppliers in this context

Finally, when asked if they would like to make any further comments, several businesses mentioned the need to regulate PAL, to support compliance and drive standardisation across the supply chain. Setting allergen thresholds was also seen as a critical part of this process. There was debate as to whether this would require primary legislation, or the broadening of existing food law – such as that pertaining to health claims.

Process standardisation was also key. It was felt that high standards existed and there were workable systems in place for much of the food sector that could be built upon. The FSA's Orange Guide, produced in 2006 and covering Principles of Risk Analysis, was seen as a very useful start point in this context – though it was noted that awareness of this document in foodservice was low.

The pen portrait below provides more detail on the risk analysis processes for a large manufacturer. It not only highlights the protocols in place to identify and control allergen risks within the business, including validation testing, but also the governance and training support provided to the supply chain. As in the pen portraits for SMEs, the company and staff names have been anonymised for confidentiality purposes.

Delicatus is a large, international snack company, making a wide variety of products from chocolate bars to chewing gum. Jonathan is responsible for global food safety and oversees teams across a range of markets.

There is a strong culture of food safety in the business, and a structured approach to risk assessment driven by the seven HACCP principles. This includes stages for hazard analysis, identifying critical points, establishing limits or thresholds, monitoring, management, verification and record keeping. These steps cover every part of the manufacturing process, from the purchase of raw materials, to the dispatch of the finished product. Policies cover both internal and external manufacturing facilities, including the supply chain.

For example, for supplier approval, details on risk assessment and risk management processes are needed. This covers the steps in place to manage allergen cross-contact together with wider controls over raw ingredients, including transportation and packaging risks. To support this process, Jonathan's team review supplier data across the risk analysis process - from cleaning validation data to data on staff training.

Once at a manufacturing site, materials are segregated, and steps are put in place to ensure allergenic ingredients are evident to people working in the warehouses. A scanning system is used to make certain the right raw material is used for processing. Further controls are then put in place to identify and mitigate the risks or potential cross-contact - from equipment, people, or the environment.

Cleaning validation and testing is an important part of this allergen risk analysis process, with thresholds used to minimise risk to consumers.

> "If we do the risk assessment, and we believe that we can successfully remove the allergen from the line, we do three cycles of cleaning validation. And that would usually be a combination of equipment, swab, and finished products. If we have a situation that we've determined that there is a likely risk of cross contamination, we have a programme in place called our indicative level programme. This basically identifies the maximum concentration of carry over which is which is allowed, with thresholds based on work that we've done with external expert bodies. Our big fear is that people take risks with precautionary allergen labelling. So, it's about being in a position that if somebody does take a risk, or does make a mistake, we have a threshold that we wouldn't see the most severe of reactions".

To support allergen safety practice, much investment is put into training, including for suppliers. Supplier quality expectations are documented, and suppliers are informed of any updates though global webinars. Given the relatively 'dry' subject matter, training uses illustrations, scenarios, and pictures to bring themes to life. This level of support helps create a stable supply base, which in turn helps to manage risk. There

is also extensive training for staff in the business – covering people from procurement to R&D functions.

When thinking about the future of PAL, Jonathan would like to see the FSA setthreshold standards for allergens, because currently products labelled with the same‘may contain’ statement can contain very different levels of allergens present due to cross-contact.. Moreover, it was perceived to be difficult for common frameworks to be adopted across the food sector without some regulation of this area.

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10. Conclusions

There was a wide range of understanding and practice around allergen risk analysis across SME food businesses, driven by sector, size of business, range of products, cuisine, and how food was sold, across pre-packed and non-prepacked categories.

In terms of risks to consumers arising from food production and preparation processes, adverse reactions to allergens were seen as a relatively high risk, second only food hygiene risks, and in certain instances, the highest risk in a food business.

While the term ‘risk assessment’ is well understood and distinguished from risk management, there was only a moderate range of SME food businesses that conducted risk assessments. These focused on manufacturers (across a range of business sizes), medium sized retail businesses, and, to a lesser degree, medium sized institutions. It should be noted that while a majority of businesses claimed to undertake a risk assessment, in reality this mainly focus on risk management actions rather than any formal assessment process.

Where undertaken, risk assessment generally focused on microbiological hazards rather than hazards arising from allergen cross-contact. Risk assessment was particularly linked to HACCP plans. Routine risk assessment of allergens was extremely limited, and only undertaken by a handful of businesses. Given this, there were no specific patterns in terms of sector or size of business.

Testing of allergens was extremely rare and no businesses in our sample specifically tested for allergen cross-contact to inform their use of PAL (though there were a couple of instances of testing to verify free-from status). While there were some examples of cleaning validation tests, where undertaken, these focused on microbiological tests.

General barriers to testing included cost, complexity and expertise. For the few SME manufacturers that did test for pathogens, allergen testing was not seen as apriority. Rather, risks were generally thought to be well managed given the limited range of allergenic ingredients used, product range and opportunities for cross-contact, and

the adequacy of cleaning processes. This was very different from the large, ‘gold standard’ manufacturers engaged in the study. While in part this is an artefact of supply chain complexity and product range, it also relates to differences in food safety culture and the dominance of HACCP plans in identifying and managing microbiological risks in small businesses.

In the absence of a risk assessment process for allergens, a more intuitive, ‘common sense’ approach emerged in relation to identifying risks.

Medium sized retailers, specifically convenience store chains, and certain manufacturers predominantly focused on supply chain risks for allergen cross-contact. There was, however, limited governance and oversight of the supply chain, and again there is learning from ‘gold standard’ businesses that could be used to support this process – such as the use of allergen self-assessment forms, and the potential to share training material.

Allergen cross-contact on the business premises was a greater concern for smaller retailers selling PPDS foods, catering businesses and institutions. The range of foods sold, the nature of the allergens (particularly airborne risks from dust), and the open nature of the kitchen meant preventing this risk was seen as near impossible. Given this, in certain businesses, there is the potential that risks are not even attempted to be managed very effectively, given the inevitability of some cross-contact.

Trigger events (such as changing supplier or developing a new product or menu) also prompted an appraisal of allergen risk, but this was often in the context of changes to allergenic ingredients rather than in terms of the impact for cross-contact.

There were a wide range of management practice adopted by businesses to manage allergen cross-contact risk. They focused on ingredients (including avoidance of certain allergens), separation, labelling, the use of different utensils and in particular, cleaning (though as noted, cleaning validation was not undertaken for allergens). This range of management practice led to confidence across all sectors that allergen cross-contact risk was dealt with effectively.

Overall, the combination of an intuitive approach to risk assessment and belief in the adequacy of existing risk management has the potential to underestimate and misidentify the risk from allergen cross-contact. There was evidence of businesses being prone to biases when assessing and managing risks, including familiarity bias (a focus on top-of-mind allergens such as nuts), over-confidence bias (management processes are seen as adequate as customers have never previously experienced an adverse reaction), status quo bias (a focus on the adequacy of HACCP plans), and messenger effects (an unquestioned belief in chefs).

Despite a lack of formal risk assessment in institutions, in schools, care homes and other establishments where the dietary requirements of consumers are known, there are likely to be effective processes in place to manage allergen cross-contact risks.

Understanding of PAL by SMEs businesses was extremely mixed. While it was common to link PAL to ‘may contain’ and cross-contact, its legal status, its distinctiveness from allergen labelling, the categories of food to which it applied (particularly non-prepacked) all had modest levels of understanding. Importantly, no SME business engaged in this study understood the need to conduct an allergen risk assessment prior to using PAL.

When used, PAL was driven by a mixture of supply chain versus on premise risks. In terms of supply chain, it was typical to “trust the manufacturer” and pass on may contain warnings. There were certain instances of PAL warnings being placed into ingredients lists for more risk adverse businesses. For caterers, institutions and certain retailers, given cross-contact risks during food preparation were seen as extremely hard to manage, where used, PAL warnings were routinely applied for major allergens.

A hypothetical FSA tool to support the use of PAL received a cautiously positive reception, butthere were concerns around the complexity, cost, and the ability to use it. Integrating examples and developing a more meaningful way of communicating risk (based on intuitive ‘dose levels’ such as a teaspoon) could play a supportive role in its adoption. Routine sharing of risk analysis was seen less favourably, due to the complexities involved.

In gold standard business, there were notably stronger food safety cultures relative to that observed within SMEs. Whilst in part this is due to their size and structure, and the involvement of teams who are accountable for food safety , they also had a focus on operational excellence, a systematic approach to the risk assessment and management of allergens, and a commitment to managing and supporting the supply chain through training. There were also significant resources placed into testing and validation. While it is unreasonable to expect SMEs to adopt all of these practices, there is likely to be learning (e.g., training protocols) and frameworks (e.g., risk management templates) that can be built on by the FSA and integrated into existing support for businesses, such as Safer Food, Better Business.

Overall, a lack of common standards, simple risk assessment/management templates, integration into HACCP, plus clearer communication on the need to conduct allergen risk assessment will be needed to drive forward practice in this area. Awareness raising of the FSA risk analysis checklist may help to in this context, though the Orange Guide was also cited as a key document in this context.

Finally, it should be noted that whilst each gold standard business had very effective controls, there were small but significant differences in practices across each manufacturing and retail, from how to approach risk assessment, to the requirements for labelling. This lack of standardisation creates problems for allergen management across the system as a whole. Standardisation - both thresholds and risk analysis practice - is a key area to address in future FSA guidance.

Appendix 1 – topic guide

Introduction (5 minutes)

Thank you for making the time to speak to me today.

My name is XX, and I work for Basis Social, an independent research agency that is conducting a study on behalf of the Food Standards Agency. The FSA are an independent government department responsible for making sure that food is safe, and that food is what it says it is.

They have asked us to explore the experiences of small and medium sized businesses about their use of risk assessment and management processes that inform the use of “May contain…” food allergy labels and statements. These are also known as precautionary allergen labels. The work will inform future advice to businesses on the use of such statements.

We know from previous research that businesses adopt a range of practice in this area. This interview will explore this in more depth.

While the research is being conducted on the behalf of the Food Standards Agency, this interview remains strictly confidential to the research team and all findings will be reported anonymously.

Nothing you say will be attributed to you directly and we really encourage you to be honest with us in your responses. If you do not wish to answer any particular questions, feel free to ask us to move on.

There are strict regulations regarding data protection, and we take these very seriously. We hold your details securely, anonymise what you share with us, and delete all identifying information from any published materials. We have provided further information on how we treat your data and GDPR compliance in the project information and consent form we provided to you when inviting you to take part.

We would like to record this discussion but only if you are happy with this. The recording is used to ensure we have an accurate record of the discussion for analytical purposes. We don't share transcripts with FSA.

Do I have your permission to record the interview?

Finally, Basis are a company partner of a body called the Market Research Society and abide by their code of conduct. Participation in this discussion is completely voluntary and you can withdraw your consent to participate at any point in the process. This includes during this discussion, or up until the report is written at the end of March 2022.

Do you have any questions before we start?

About them and the business (5 minutes)

- To begin, can you say a few words about yourself and your role?
- What types of food does the business sell? And typically, how much of this is made on site vs pre-made?
- And how is food sold? [Probe pre-packed, pre-packed for direct sale, loose]
    - [Ask manufacturers producing more than one type of food ONLY: Are these foods produced in the same factory or same production line?]
- And roughly, how many suppliers do you have?
- And what allergenic ingredients are used by the business?
    - [NB for reference they are as follows]
        - Celery
        - Cereals containing gluten (for example, barley, oats)
        - Crustaceans (for example, prawns, crabs and lobsters)
        - Eggs
        - Fish
        - Lupin (an ingredient found in some flours)
        - Milk
        - Molluscs (for example, mussels and oysters)
        - Mustard

- Tree Nuts (for example, almonds, hazelnuts, walnuts, cashews etc.)
- Peanuts
- Sesame
- Sulphur dioxide (sometime known as sulphites)
- Soya

Risk assessment (15 minutes)

I now want to discuss how you assess and manage food risks in the business

- When you think about food risks to consumers in your business, what comes to mind?
- What would you say the main risks are? Probe
  - Microbiological risks
  - Allergen risks
  - Chemical
  - Physical
- What does risk assessment mean to you? How does this differ from risk management?

[Moderator to explain if unclear]

  - By risk assessment we mean thinking about the points at which a risk could happen by
  - By risk management we mean thinking about how to mitigate/manage a potential identified risk this is what we mean
  - Do you conduct a risk assessment to inform your understanding of risks in relation to foods?
  - Thinking now specifically about allergens, how are cross-contact risks from allergens assessed by your business?
  - What procedures are in place?
  - How do you assess risks from potential sources and stages of production?

- Open then probe

- incoming ingredients (sourcing/supply chain) [inc how communicated from supplier]
- Storage (of ingredients and intermediate/finished products)
- processing
- training of staff
- cleaning
- shared equipment
- re-work
- air particles in preparation area
- packaging
- transport
- any other sources or stages of production?

- Do you test the final product for the presence of allergens?

If yes.

- How do you do it [tested themselves, sent to a lab]
- Do you follow any guidance or use any tools to carry out allergen risk assessment? What are they?
- Overall, can you quantify the level of allergen cross-contact in a product?
  - [If yes] Please describe what they are
  - [If no] what are the barriers to quantification

If no.

If FSA made risk assessment guidance available to businesses which would involve you to carrying out calculations to inform your decisions on whether to apply PAL (for example, based on the levels of allergens that may be in the final product, the amount of product that will be eaten and the amount of allergen needed to cause an allergic reaction), would you use this?

- What support would need to be in place to help you use it:
  - Capacity
  - Data
  - Skills

- Do you use HACCP?
- Is your HACCP plan ever revised? When would this happen?
- Probe change in manufacturer, supplier, formulation.
- Is your HACCP plan used to inform the risk assessment of allergens?
- Has a Local Authority officer ever looked for allergen management within the HACCP plan?
- Has your FHRS score ever been affected by allergen management?
- Does HACCP inform your decision on whether to apply a PAL?

Risks Management (15 minutes)

- What risk management process are adopted in the business?
- Thinking about the different stages of food processing in your business we discussed earlier, how do you manage risks at these different stages [Open then probe]:
    - incoming ingredients (sourcing/supply chain)
    - Storage (of ingredients and intermediate/finished products)
    - processing
    - training of staff
    - cleaning
    - shared equipment
    - re-work
    - air particles in preparation area
    - packaging
    - transport
    - any other sources or stages of production
- How confident are you that:
    - The way you separate foods containing allergens from other is adequate to manage the risk?
    - Your cleaning procedures are adequate to manage the risk?
        - Probe: Is testing of environmental samples (for example, swabs) for allergens used to validate cleaning? Why/why not?

Training on risk assessment and management (10 minutes)

- What training have you had on allergen risk assessment and management?
- Do you run any in-house allergen training for staff in the business?

If yes:

- What roles do these staff work in?
- What do you cover in the training?
- Who provides this? Why were they chosen?
- How is it rolled out in the business?
- How often is training undertaken?
- What additional support might you need?

If no:

- Why not?
- What are the barriers to staff training?
- How do you ensure that key staff are aware of allergen management practices within the business?
- What would make it easier for you to provide allergen training for staff?
- Outside of formal training, how do you stay up to date with requirements around risk assessment, risk management and PAL?

PAL Labelling (10 minutes)

Now I want to turn to Precautionary allergen labelling

- What is you understanding of PAL?
    - Can you give me a definition of PAL?
    - What is your understanding of how PAL should be applied / rules surrounding it?
- Can you tell us about whether or not you apply PAL? Why?
    - Probe: how used in relation to risk analysis processes mentioned above
- [For those applying PAL] How is PAL applied in the business? What statements are used and in what formats? Why?
    - [For caterers and retail] How do staff check if customers have any allergenic requirements?
- When are these PAL statements reviewed?

    - [For those not applying PAL] Would anything encourage you to use PAL?
    - If you are supplied with food that bears a PAL statement, do you include that PAL statement on the food that you sell? If not, why not?
    - Would you be willing to make the details of risk-analysis of allergen cross-contact available to the public? For example, this may include what risk has been identified, and what you've done to manage the risk?
    - Why?
- That concludes the questions I have? Do you have any other comments around risk analysis and PAL you'd like to make?

Thank you. We're speaking to a range of businesses throughout January and February and will be writing a report in March. This will inform a consultation on PAL by the FSA that's currently being undertaken.

Are you aware of the consultation? Would you like details?

Moderator to reiterate confidentiality points, thank and close