Review of allergen analytical testing methodologies: Stakeholder engagement

UK food suppliers were contacted and answered questions regarding their allergen testing procedures, either during an interview or in response to receiving the questions in a questionnaire format. The responses are tabulated and enclosed. Identifying information has been removed from the responses so that the answers cannot be traced back to individual companies or employees. For this reason, products produced by each company are simply referred to as ‘own brand’ in the documents.

A questionnaire was issued to each of the stakeholders. The provided table of responses is included on the following pages.

Company A

Question	Response
Overview of business	Global manufacturer. Respondent works in strategy, policy and incident management.
Can you describe your allergen management regime	Allergen management regime is primarily based on the HACCP, on which Risk Assessments (RA) are based. This included quality policies and involves every stage of manufacture from the procurement of raw materials, to goods received, to controls in manufacture, packaging and distribution. Effort is made to maximise choice and minimise risk. A significant part of minimising risk involves cleaning of the production lines and validating this cleaning process. Critical Control Points on the lines have been identified. The company only uses PAL if it has been determined by the RA that sporadic cross-contamination may arise. The company has introduced a programme for labelling guidance based on research data from working with stakeholders such as the Anaphylaxis Campaign, that 30% of consumers ignore labelling. The company has a maximum level of allergen carryover that it permits.
Which specific allergens from the 14 food allergen groups does your company test for?	Most of the 14 groups are tested for, testing for allergens known to be in the foods prepared. Testing is performed following intelligence such as Horizon Scanning data or information from Trade Associations, but most testing is conducted on the production line during validation to verify cleaning processes so test for the allergens known to be included in those products (see later). So mostly peanuts, tree nuts (almond and hazelnut), milk, eggs and, in some factories, crustacea.
Which allergens are not tested for and why?	Most allergen testing occurs to validate and verify cleaning of the production line. For example, if the predominant (in terms of quantity) allergen in Product X is egg, following cleaning, products prepared at 8 times points following cleaning between Time=0 and Time=60 minutes will be tested for presence of egg. This way, if egg is not present, the cleaning process has been successful in terms of removing egg and there is confidence that allergens which may have been present at lower levels in Product X will also have been removed during the cleaning process.
What factors do you consider when determining which items will undergo testing for allergens?	A risk-based approach is adopted. For a production line, the product which will be prepared on that production line with the highest allergen loading will be used for the basis of validation of a Critical Control Point (CCP) study. Following production of that product, various swabs will be taken at various points on the production line by a specialist sanitation team, including swabbing of different materials which are present on the line such as rubber and stainless steel. The next product to be prepared on the line is also tested at 8 timepoints from T=0 to T=60 minutes on three different occasions to prove that PAL is not required. This risk assessment stays in place until something changes and verification checks are also performed annually. Regarding products with 'free from' claims, these are prepared in a dedicated facility only handling 'free from' ingredients so no environmental monitoring is needed but raw materials are tested on site by ELISA.
For a given product, how do you decide which allergens to test for?	The allergen testing is targeted to the predominant allergen which has been present on the production line (see above). Following a consumer complaint, as much detail is established as possible, including clinical diagnosis of allergic status and testing is performed on the outcomes of this investigation. Suppliers must provide details of allergens handled on their sites, provide certification of audit which is carried out by a third party inspector organised by Company A and suppliers must provide details of allergens handled by their previous supplier, so that stock is traced 'one step back' before the supplier to the respondent's company.

Question	Response
What do you test for allergens?	Most testing is of environmental monitoring samples and final products. Less emphasis on testing of intermediate products as allergen monitoring is risk assessed for the final product, as described above.
Can you describe your sampling procedure.	In terms of the HACCP standard, the number and location of swabs taken for environmental monitoring are dictated in this document. Data generated from respondent's horizon scanning activities of incidents and vulnerabilities (e.g. due to commodity shortage) in the supply chain and data from Trade Bodies and trade consortia (including nation bodies for allergy research) feed into intelligence and may incite testing. In the cleaning of the lines, a 'worst case scenario' approach is taken to determine that allergens used on the production line has been removed by cleaning processes (as described above).
How many replicates of each sample are tested by each testing laboratory?	At least duplicate analysis, further replicates are dependent on the protocols of the testing lab.
What factors do you consider when selecting a testing laboratory?	The laboratory must provide suitable data for spike recovery testing on matrices provided by Company A. For new matrices, spike recovery data must be generated. Spike recovery data must be within 80-130% of the spiked level. Company A also sends a Quality Control sample with each sample for testing which contains the allergen to check that allergen is detected in that sample by the testing lab. Laboratory must be accredited to ISO 17025 and the laboratory's performance in FAPAS® proficiency testing rounds is considered. These criteria are checked annually by the respondent's company.
Are the data qualitative or quantitative?	Quantitative, but the respondent's company recognise there is uncertainty of measurement with data generated by ELISA. Company A has also organised testing performed by RT-PCR in the past but it is difficult to interpret since there is no direct quantitative link between PCR copy number and the level of allergen present so PCR is only used for information and ELISA is relied on for quantitation.
What are the units of measurement	mg/kg of allergen (mg/kg of allergen protein, where available)
Is there a particular LOD or LOQ that you require of the test.	Low ppm required. Company A are concerned if the LOD or LOQ is lower than 1-2.5 ppm since such tests run the risk of detecting artefacts. The respondent's company insist that the laboratory verify their own LOD and LOQ when using the test kit, rather than relying on the LOD and LOQ the kit manufacturers state should be yielded.
Which technologies are used in your testing of allergens?	ELISA only, with some information generated by RT-PCR but confirmed by ELISA. The respondent's company does not trust data generated by lateral flow device (LFD), which is qualitative only). Some matrices are difficult to analyse, e.g. chocolate, in which the fat and polyphenols interfere with LFD testing so ELISA is preferred over LFD.
What measures do you have in place for Quality Control?	Testing laboratories must take part in FAPAS® proficiency testing rounds and must perform as expected, supplying this data on the test report. Matrix validation studies must be completed by the testing lab and spike recovery testing must yield data within the 80-130% tolerance of the expected level. The testing lab must be accredited to ISO 17025 and use RMs. If a conversion factor has been used to convert the test data to the level of total allergen protein detected, this must be detailed in the report.
Who is responsible for interpreting the data and how is it decided whether a sample is determined as safe for consumers? How does this differ for ingredients versus final product testing (if applicable)?	For routine CCP verification, colleagues in food safety/sanitation interpret the data. Data resulting from testing resulting from an incident is interpreted by the most senior colleague in Incident Management, who performs a risk assessment to determine if there is a safety risk for consumers. For testing for claims on a 'free from' product, the food safety team interprets the data.
Do you use action levels/VITAL® reference eliciting doses to determine safe levels?	Yes, maximum/indicative levels are based on VITAL® 3.0 reference doses. In the future, the respondent is hoping that Codex recommend use of VITAL® 3.0 data and that the UK regulations will reflect this.
How do you decide when to recall a product?	A food safety risk assessment is prepared, based on information including the number of affected units outside of the company's control, the prevalence allergy in the affected geographic area, severity of reaction (known from clinical studies, where >ED10 tends to give more severe reactions and ED05 gives non-severe reactions which do not require medical intervention). The respondent's company use ED05 as a cut off value. Market action is taken depending on these considerations. FAO and WHO use ED05 as their recommended level for PAL so this is a conservative/precautionary level. The cost of recall to the company is cognisant that food allergy and acute reactions are high on the company's agenda which is why this company uses guidance from research for labelling allergens as safety is non-negotiable to the company.
Do you use any tools or calculations to interpret the data?	The data is added to the RA or HACCP. Trends are compared to determine annual performance to identify any areas of risk.
We are interested to learn about the costs involved in testing for businesses. How affordable is the testing regime. When you consider the costs in allergen testing, where do the direct costs to your business lie?	Cost of testing is £50-80 per sample, therefore the cost of each CCP is £1,200-1,920. Testing is undertaken when risk assessment dictates it is required, along with annual verifications. Testing products with claims of being free from allergens is higher so is undertaken in-house.
What considerations do you take into account when deciding how much to invest in allergen mitigation?	Safety and testing requirements are non-negotiable.
Could you estimate approximately what % of net profit is invested in monitoring for food allergens?	Outside of the respondent's remit.
What type of assessments do you generally perform and do these differ by product / allergen?	Probability Risk Assessment and Deterministic Risk Assessment.

Question	Response
Are there any other challenges you face when considering the possible allergen content of your products?	Biggest challenge is the requirement of approved testing labs. The differences in commercial testing kits used by these labs is also a big challenge as the performance of the kits is different when analysing cooked and processed goods compared to less processed or raw goods, so the Quality Control samples are very important. The respondent considers themselves fortunate not to deal much with matrices for which there is known cross-reactivity of the test kits such as mustard cross-reactivity with oilseed rape. The respondent states that there is a role for the lab to play in open dialogue with its customers, being transparent about the evidence gaps and challenges to the performance of the test kits they are using and that this open dialogue should be encouraged. Another challenge is the need for the lab to be able to report results in mg/kg allergen protein, this is straight-forward with some ELISA kits, with others a conversion factor is required and this is not possible for allergens tested by PCR. There is also a need for more incurred RMs to be commercially available for labs to use as part of their QC considerations. There is a need for all testing laboratories to be transparent about the kit they used, the conversion factor, QC used and to provide the data from the QC.
Considering allergen management, are there any gaps in food testing services which you wish were available or different to support your business? Are there any products for which you find it challenging to find a testing service?	It would be ideal if it would be possible in the future to have a low cost, instant, quantitative dipstick-type point-of-use test which would allow a faster turnaround time in allergen testing. Usually, testing takes 10 working days, or can pay for priority testing when required. Also, chocolate is a difficult matrix for testing and more quality controls should be available for this matrix.
Do you have any points you would like to raise, or further comments?	It would be ideal if the regulations could include a requirement for the use of VITAL® 3.0 data for setting acceptable allergen levels in foods. A regulatory system is required for PAL, based on VITAL® 3.0 data. There should be harmonisation between the regulations by UK, EFSA and FDA to facilitate international supply of raw ingredients and final products.

Company B

Question	Response
Overview of business	UK retailer, selling fresh, frozen and ambient foods. Products are both branded and unbranded and there are different processes for each regarding allergen management. We also sell imported foods and have cafes/counters.
Can you describe your allergen management regime	For own brand goods, RA and HACCP are in place and all testing is conducted by UKAS-accredited laboratories. Cleaning processes are validated. All suppliers for 'own label' products must be working to at least BRC A grade for unannounced audits. Allergen management of branded goods is the responsibility of the supplier. Minimum standards are set for suppliers and suppliers of high-risk matrices (e.g. raw meat, cured/dried meats, pufferfish, or supplied by microbusinesses) must be working to at least BRC A grade for unannounced audits when taken on by the respondent company. Cleaning processes are validated and all testing is performed by UKAS-accredited laboratories. A HACCP must have been put in place by the supplier and the respondent has issued a food safety manual with a section on management of allergens and on preparing products with ‘free from’ claims and vegetarian and vegan products. Suppliers must also risk assess their labelling process and determine if PAL is needed. Suppliers must provide data showing that their cleaning process is validated. A risk assessment is prepared regarding the Finished Product Surveillance System. Suppliers must use UKAS-accredited testing laboratories. Emerging risks are assessed in-business. Incident management is both local (supplier-specific) and can also involve discussions with FSA. Allergen management of branded goods is the responsibility of the supplier. All suppliers must comply with legislation.
Which specific allergens from the 14 food allergen groups does your company test for?	All allergen groups are tested for if there is a risk. Lupin is the least tested for since few of the respondent's products carry a lupin risk.
Which allergens are not tested for and why?	None. All allergens are tested for if required by the RA. The respondent only tests own brand products.
What factors do you consider when determining which items will undergo testing for allergens?	Risks arising from cross-contamination, PAL labelling, products with free from claims, if emerging risks have come to light, previous supplier performance, previous testing results for this matrix.
For a given product, how do you decide which allergens to test for?	Test for allergens of risk in that supply chain, considering allergens handled on site and at the raw material site. Also perform random due diligence testing for allergens not handled on the site.
What do you test for allergens?	Finished products mainly, although consider risks for raw materials and may implement testing according to RA.
Can you describe your sampling procedure.	A routine surveillance programme occurs. A prescribed number of products per category are selected using random selection techniques by a third party and tested each period. The randomisation can be deliberately skewed if required, e.g. due to emerging issues or intelligence.
How many replicates of each sample are tested by each testing laboratory?	One sample is taken for testing and an audit sub-sample is retained in case results require confirmation at a later date. The number of replicates of the sample depends on the standard procedure of the laboratory.

Question	Response
What factors do you consider when selecting a testing laboratory?	Laboratory must meet spike recovery parameters prescribed by the respondent company. Testing is repeated if data are close to the LOD of the kit. Laboratory and method must be UKAS-accredited. Reliability of lab, history of performance, inclusion of QCs, as required for UKAS.
Are the data qualitative or quantitative?	A mix. Quantitative data is preferred, majority of methods are semi-quantitative (ELISA). Celery is determined by PCR due to concerns about cross-reactivity but there is a challenge in interpreting these results.
What are the units of measurement	Depends on the units of measurement provided by the particular kit used by testing laboratory. Reported in mg/kg of protein or mg/kg of allergen protein. Units in which data are reported impacts on the RA.
Is there a particular LOD or LOQ that you require of the test.	The LOQ of any test used must be achieved in a repeatable manner, so repeatable, reliable and statistically accurate. Seek most accurate LOD, not the lowest. In products with a 'free from' claim, a maximum LOQ is set and the LOQ must be stated in the report - this LOQ is dictated by gluten Regulation in the case of gluten. For other allergens, maximum LOQ limits have been set following consultation with numerous labs and supply bases to establish 'the norm'.
Which technologies are used in your testing of allergens?	Prefer to use ELISA. Use PCR for celery detection only and also to support investigations if an ELISA kit cross-reacts with certain ingredients.
What measures do you have in place for Quality Control?	Those required for UKAS accreditation. Key Performance Indicators - poor quality relating to a testing lab is flagged. Any known cross-reactivity of the testing kit used must be reported in the results.
Who is responsible for interpreting the data and how is it decided whether a sample is determined as safe for consumers? How does this differ for ingredients versus final product testing (if applicable)?	Data is interpreted from a central perspective. Data can also be interpreted by managers in relevant product areas. If an allergen is reported as 'not detected' this sample data is determined as 'safe' by the teams. If a positive result is reported, the risk assessment is referred to and factors are considered concerning, for example, if whether the data is quantitative or qualitative, cross-reactivity of the testing method, supplier's historical test record, consideration of how and likelihood that cross-contamination has occurred, consider target consumer (particularly if this is a product with ‘free from’ claims, threshold data from WHO/EFSA. Ultimately the team managing that category of food type make the decision of how to interpret data.
Do you use action levels/VITAL reference eliciting doses to determine safe levels?	Yes, used as a tool as part of the RA described above, including VITAL® 3.0, EFSA and WHO limits to set safe levels.
How do you decide when to recall a product?	Based on the RA, considering likelihood of risk, target consumer, any complaints relating to the product, test results, VITAL® 3.0 data and if expiry is still within date.
Do you use any tools or calculations to interpret the data?	Use tools to determine the amount of allergen (in mg) which may have been consumed and compare this to VITAL® 3.0 acceptable level.
We are interested to learn about the costs involved in testing for businesses. How affordable is the testing regime. When you consider the costs in allergen testing, where do the direct costs to your business lie?	One colleague manages all testing and allergen management is also a third of the role of another colleague. Technical managers and technical leadership team also feed into this. The team operates to a budget but this budget is for all testing so it is difficult to calculate how much is spent on allergen testing. The testing labs source the samples from the retailer's stores and charge them for the samples and for the testing. Between 650 and 700 samples are tested per year, equivalent to 10% of the total product range. Costs are £52 per ELISA sample for quantitative testing, £48 for semi-quantitative ELISA testing, £80 for lactose-free testing, £65 for qualitative PCR testing and £120 for semi-quantitative PCR testing.
What considerations do you take into account when deciding how much to invest in allergen mitigation?	Consider risk to business so test more products with ‘free from’ claims and have annual audits of suppliers of products with ‘free from’ claims suppliers. Testing of other products is risk-based. The whole testing programme has its own budget, including microbiology testing, so it's difficult to state the exact amount spent on allergen testing, although allergen testing is an important part of this budget.
Could you estimate approximately what % of net profit is invested in monitoring for food allergens?	Difficult to estimate (see response above). Annual testing costs exceed £150K, then there are the costs of staff and auditors.
What type of assessments do you generally perform and do these differ by product / allergen?	Test products, taking into account the target consumer and whether there is a PAL or if the product is prepared on a shared line in the factory. 'Free from' products carry more weight in terms of the number of products tested. Sulphites and gluten are tested against the defined limits.
Are there any other challenges you face when considering the possible allergen content of your products?	There is no threshold for the amount of soya in the final product, there is a threshold in the risk assessment conducted by the FSA in September 2014 which used a probabilistic approach for the action level of soya flour (236 ppm) but no threshold for the amount of soya, which is unhelpful. Challenges relating to the potential cross-contamination of wheat with mustard. Allergen-free manufacturing carries many challenges around validation of cleaning processes - testing of the line with a swab may give a positive result but this doesn't reflect the amount of an allergen contained in the final product. If this retailer has any detection of allergen in the swabs for products with a ‘free from’ claim, they don't sell the product as ‘free from’. There are challenges regarding how to know if cleaning processes are sufficient. The supply base struggle to know how many steps back in the supply chain to require checking of their raw materials - more guidance on this would be beneficial. The respondent does not specify the cleaning validation process for suppliers, other than the swabs must be analysed by UKAS-accredited labs. Guidance on this would also be beneficial.
Considering allergen management, are there any gaps in food testing services which you wish were available or different to support your business? Are there any products for which you find it challenging to find a testing service?	Cross-reactivity of testing kits is a real challenge. The respondent feels that the kit manufacturers should be looking into this more and publishing this information. Concerns with mustard in wheat flour. The fact that celery can currently only be reliably determine by PCR is a concern, given the disadvantages of PCR data for allergen data interpretation.

Question	Response
Do you have any points you would like to raise, or further comments?	There is no industry-wide agreement on threshold data for allergens. The respondent stated that more research is required on threshold data and feels that more weight should be placed on WHO limits compared to VITAL® 3.0 data. More guidance from the FSA would be beneficial on validation of line cleaning processes and how to interpret data reported in mg/cm3 to mg/kg. The respondent states that more research is required on the affect of food processing on allergenicity. Since the retailer prefers not to use PAL unless absolutely necessary, to support their food-sensitive consumers, VITAL® 3.0 data is required for processed products.

Company C

Question	Response
Overview of business	Retailer selling fresh, grocery, formulated non food and constructed non food across stores within UK and Northern Ireland. Some own brand products produced on our behalf, some by our own manufacturing as well as via production in store of PPDS products.
Can you describe your allergen management regime	Labelling policy compliant with 1169 Allergen policy Allergen training Allergen council Incident management process (including out of hours) Surveillance programme Supplier approval and ongoing management Specifications approved and auditing programme in place Complaints management
Which specific allergens from the 14 food allergen groups does your company test for?	Main focus on nuts, egg, cereals, fish, milk, sulphur dioxide, crustaceans, mustard, sesame and soya as these are commonly handled within processing environments
Which allergens are not tested for and why?	Lupin as not used on factory sites within our supply chain and customers unfamiliar. Celery not used significantly within our supply chain. Small impact within UK population.
What factors do you consider when determining which items will undergo testing for allergens?	Product labelling ; contains vs may contains 'Free from' Claim on product What is handled within the factory environment Industry incidents
For a given product, how do you decide which allergens to test for?	Product labelling ; contains vs may contains 'Free from' Claim on product What is handled within the factory environment Industry incidents
What do you test for allergens? E.g. finished products, ingredients, production lines, other.	Finished products and raw material sampling – own brand suppliers are tasked with conducting their own allergen risk assessment and then testing programme
Can you describe your sampling procedure.	Risk assessed surveillance testing programme with result trending. Horizon scanning to determine raw material testing programme.
How many replicates of each sample are tested by each testing laboratory?	Our testing is surveillance for due diligence so we would test one product from the shelf and then test further samples (same or different date codes) if an issue was detected as well as follow up with the supplier on their test results
What factors do you consider when selecting a testing laboratory?	ISO 17025 accreditation (lab and method), methodology used and specialist skill set
Are the data qualitative or quantitative?	Both
What are the units of measurement of the testing procedures?	Depends on the method used but normally ppm
Is there a particular LOD or LOQ that you require of the test.	Use lowest LOQ available for allergen testing method
Which technologies are used in your testing of allergens?	Mainly ELISA and PCR
What measures do you have in place for Quality Control in the allergen testing?	Method must be part of lab ISO 17025 accreditation, internal auditing and EQA (which is part of 17025).
Who is responsible for interpreting the data and how is it decided whether a sample is determined as safe for consumers? How does this differ for ingredients versus final product testing (if applicable)?	Same process for raw materials and final products. The data interpretation will be conducted by a combination of the laboratory, the supplier, technical manager for the product category and food safety supply manager
Do you use action levels/VITAL® reference eliciting doses to determine safe levels?	Yes VITAL 3 as part of risk assessment
How do you decide when to recall a product?	Risk assessment completed (using VITAL as one of the tools) by technical manager and multi-disciplinary team. Incident meeting held as required.
Do you use any tools or calculations to interpret the data?	Yes VITAL 3
We are interested to learn about the costs involved in testing for businesses. How affordable is the testing regime. When you consider the costs in allergen testing, where do the direct costs to your business lie?	Routine testing costs are manageable however in an incident, where you need a quick turnaround, the price can increase significantly.
What considerations do you take into account when deciding how much to invest in allergen mitigation?	Not cost driven. Risk assessment driven.
Could you estimate approximately what % of net profit is invested in monitoring for food allergens?	Not cost driven. Risk assessment driven.

Question	Response
What type of assessments do you generally perform and do these differ by product / allergen?	For own brand product will review supplier allergen management programme and their risk assessments. Supplier scorecard completed for products with a Free From claim.
Are there any other challenges you face when considering the possible allergen content of your products?	There are several industry issues currently and I will use wheat and mustard as an example – natural cross contamination in the field, a variety of mustard types and no test method. Are all the mustard strains allergenic? Once product leaves the factory then down to customer and their understanding – how do they handle in home, particularly in a multiple household where only 1 person has an allergy. Loose food management.
Considering allergen management, are there any gaps in food testing services which you wish were available or different to support your business? Are there any products for which you find it challenging to find a testing service?	Not all allergen methods are available eg : wheat - you can test for gluten but that is not the same as a wheat allergy. Not all allergen methods can give quantitative results – problem if Codex thresholds come in. There are several industry issues currently and I will use wheat and mustard as an example – natural cross contamination in the field, a variety of mustard types and no test method. Are all the mustard strains allergenic?
Do you have any points you would like to raise, or further comments?	Support codex thresholds and mandatory minimum levels however we must have industry guidance on what, where and how much to test.

Company D

Question	Response
Please can you provide a brief overview of your business	Retailer operating in Great Britain and the Republic of Ireland.
Can you describe your allergen management regime	Not directly applicable as we do not directly manufacture product. The manufacturers would be responsible for implementing an allergen management regime in line with our requirements.
Which specific allergens from the 14 food allergen groups does your company test for?	Beta-lactoglobulin (?-LG) Casein Crustacean (Tropomyosin) Whole Egg Protein Gluten Tree nuts: Hazelnut, Walnut, Almond, pistachio, cashew, pine Mustard Peanut Sesame Soya SO2 Lupin Molluscs Fish Celery Hydrolysed gluten
Which allergens are not tested for and why?	We can test for all allergens; some allergens are more commonly tested for than others.
What factors do you consider when determining which items will undergo testing for allergens?	Products making claims e.g., milk free, nut free, gluten free etc. would be prioritised for testing. Also, products may be tested in response to industry issues e.g., peanut in soya lecithin.
For a given product, how do you decide which allergens to test for?	Claims on pack would be considered e.g., gluten free, milk free or suitable for coeliac.
What do you test for allergens? E.g., finished products, ingredients, production lines, other.	Finished products
What type of assessments do you generally perform and do these differ by product / allergen?	As a retailer we test finished products, audit production sites, review and approve product specifications and artwork for labels.
Can you describe your sampling procedure.	Product samples are purchased from store by an independent third party and transported securely to the nominated laboratory. Once at the laboratory food samples are homogenised by the laboratory using blenders before testing (if needed), unless it is a powder or homogeneous liquid/sauce.
What factors do you consider when selecting a testing laboratory?	Reputation, accreditation, capability to handle the volume of testing required for our business, competitive pricing.
Which technologies are used in your testing of allergens?	ELISA and PCR
How many replicates of each sample are tested by each testing laboratory?	1 extracted sample, with duplicate ELISA measurement.
Are the data you receive from testing in a qualitative or quantitative format?	Quantitative data for food samples.
What are the units of measurement of the testing procedures?	Mg/kg (ppm) allergen (commodity) or allergen protein, depending on the test.
Is there a particular LOD or LOQ that you require of the test?	Food samples are analysed quantitatively. The laboratory we use applies a lower LOQ as the reporting limit. Each method has an upper LOQ which is the maximum LOQ. The maximum limit can be increased through dilutions testing.

Question	Response
What measures do you have in place for Quality Control in the allergen testing?	Analytical quality control sample (internal quality control), Blank of extraction, Calibration curve, Negative control, ELISA duplicate measurements consistency check Participation in external quality assurance (EQA) schemes – proficiency tests, Environmental monitoring, Calibrations, Segregation of areas (Sample preparation separate from ELISA lab) Documented procedures, including risk management.
Who is responsible for interpreting the data and how is it decided whether a sample is determined as safe for consumers? How does this differ for ingredients versus final product testing (if applicable)?	The laboratory conducting the testing determines whether the result indicates a food safety issue.
Do you use action levels/VITAL reference eliciting doses to determine safe levels?	VITAL thresholds may be used if required.
How do you decide when to recall a product?	Risk assessment which may consider: • If the product carries a “may contain” statement for the allergen in question • Level of contamination/potential to cause a reaction Where the product is in the supply chain - e.g., in store or in a storage facility
Do you use any tools or calculations to interpret the data?	The results which pass QC, are reported with a Red, Amber, or Green grade in line with our requirements.
We are interested to learn about the costs involved in testing for businesses. How affordable is the testing regime? When you consider the costs in allergen testing, where do the direct costs to your business lie?	Approximate cost per sample ranges from £40 to £85 for the most common allergen tests - gluten, egg, milk
What considerations do you take into account when deciding how much to invest in allergen mitigation?	Potential risk to consumers and what is reasonable.
Could you estimate approximately what % of net profit is invested in monitoring for food allergens? Please state if this is not plausible.	Not possible to answer, would vary for each manufacturing site and their product range
Are there any other challenges you face when considering the possible allergen content of your products?	Complex global supply chain for raw materials e.g., the Indian government’s investigation into peanut contamination in soya lecithin demonstrated the challenges UK businesses face when assessing cross contamination risks of small amounts of allergen being present in the final product. Food sensitivity varies in different parts of the world. A globally recognised list of the most common allergens would be helpful.
Considering allergen management, are there any gaps in food testing services which you wish were available or different to support your business? Are there any products for which you find it challenging to find a testing service?	Agreed action levels for allergen presence would be a useful tool to help understand risk and provide clarity for Regulators and industry.
Do you have any points you would like to raise, or further comments?	N/A

Company E

Question	Response
Please can you provide a brief overview of your business	Convenience store retailer with multiple distribution partners who manage the retail stores Central office function manages National Brand product supply Distribution Partners manage local brand source and supply
Can you describe your allergen management regime	For the Central Office National Brand function: All suppliers complete an allergen risk assessment (ARA). This covers; allergens handled at raw material site, allergens handled at manufacturing site, validation/verification programmes, process RA. The ARA is designed to determine risk of allergen cross contamination and alibi labelling requirements. All ARAs and evidence (lab reports / verification plans etc) are approved by QA technologist or Quality and Responsible Retailing Controller. All suppliers are required to comply with our internal Allergen management policies which details the testing requirements including methodology and frequency.
Which specific allergens from the 14 food allergen groups does your company test for?	Varies for each supplier. Most common include; Nuts, gluten, milk (?-LG/Casein), fish, egg but can be any of the allergens.
Which allergens are not tested for and why?	Allergen would not be tested for if it is not handled on same line as finished product in manufacturing site and/or raw material site.
What factors do you consider when determining which items will undergo testing for allergens?	Worst case scenario, the form of the allergen (powder is higher risk than solid product), finished product claims eg; free from, known risks eg mustard cross contamination into wheat products from the farm
For a given product, how do you decide which allergens to test for?	Allergens that are handled on the same line but not declared in final product packaging Final product testing to demonstrate positive result and requirement for alibi labelling If sulphites are used on site, test to demonstrate <10ppm in final product
What do you test for allergens? E.g. finished products, ingredients, production lines, other.	Finished products, production lines, rinse water
What type of assessments do you generally perform and do these differ by product / allergen?	Both external and internal lab analysis Rapid swabs can be used by sites internally to detect specific allergens. Labs can analyse swabs and final product samples
Can you describe your sampling procedure.	As per laboratory procedure.

Question	Response
What factors do you consider when selecting a testing laboratory?	All external labs accredited ISO17025
Which technologies are used in your testing of allergens?	For lab analysis, ELISA and DNA testing Environmental monitoring – rapid allergen swabs
How many replicates of each sample are tested by each testing laboratory?	As per laboratory procedure.
Are the data you receive from testing in a qualitative or quantitative format?	Both
What are the units of measurement of the testing procedures?	Ppm or LOD mg/kg
Is there a particular LOD or LOQ that you require of the test?	Legally Gluten <20ppm We do not state LOD/LOQ's required, we require validated test kits appropriate to the allergen of concern and quantitative and qualitative results in support
What measures do you have in place for Quality Control in the allergen testing?	All external labs accredited ISO17025, for internal site testing, all sites are BRC/GFSI accredited so working to international standard.
Who is responsible for interpreting the data and how is it decided whether a sample is determined as safe for consumers? How does this differ for ingredients versus final product testing (if applicable)?	Teams at supplier sites and our QARR team
Do you use action levels/VITAL reference eliciting doses to determine safe levels?	No, we do not accept calculations as a determination of presence of allergen
How do you decide when to recall a product?	When there is a risk of allergen cross contamination identified for a product on sale that has not been communicated to the consumer.
Do you use any tools or calculations to interpret the data?	No – VITAL is not included in our policy
We are interested to learn about the costs involved in testing for businesses. How affordable is the testing regime? When you consider the costs in allergen testing, where do the direct costs to your business lie?	Do not currently test ourselves
What considerations do you take into account when deciding how much to invest in allergen mitigation?	N/A
Could you estimate approximately what % of net profit is invested in monitoring for food allergens? Please state if this is not plausible.	N/A
Are there any other challenges you face when considering the possible allergen content of your products?	• Reliability of test methods available • Changes in supply chains • Production rota changes • The effect to processing eg – production processes eliminating the allergenic protein in the allergen raw material • Working with international suppliers where allergies and allergen management are considered a lesser problem than in the UK
Considering allergen management, are there any gaps in food testing services which you wish were available or different to support your business? Are there any products for which you find it challenging to find a testing service?	To be determined
Do you have any points you would like to raise, or further comments?	No

Company F

Question	Response
Please can you provide a brief overview of your business	Global food manufacturer of herbs, spices, condiments, and flavours.
Can you describe your allergen management regime	Global allergen management procedure deployed to all plants this covers site risk assessment expectations, control of allergens, cleaning validation and verification program requirements. The procedure utilises industry best practice guidelines such as FDE allergen management guideline and FARRP. Raw material data / vendor data management process that includes allergens uploaded into internal systems to drive labelling and scheduling requirements.
Which specific allergens from the 14 food allergen groups does your company test for?	Typically, we test for gluten, egg, milk and sesame seed as part of our factory monitoring although from time to time we test for the presence of other allergens as well if we have intelligence or risk assessment information to suggest there is a concern.
Which allergens are not tested for and why?	Testing regimes are based upon risk which is why some allergens are not tested. Additionally due to the challenges of testing our product matrices for some allergens we do not routinely test them however have multi allergen test protocols in place if there was a specific concern.
What factors do you consider when determining which items will undergo testing for allergens?	Risk profile of the product, form of the raw material if any free from claims are made on the product.
For a given product, how do you decide which allergens to test for?	Based upon risk assessment, 'allergens' is a blanket term however we recognise that the profile for the allergen of concern will change according to the risk i.e. field level contaminant in a commodity vs factory cross contamination vs making a free from claim to target a vulnerable consumer group.
What do you test for allergens? E.g. finished products, ingredients, production lines, other.	Finished products where a claim is made or as part of validation study Raw materials – where a risk has been identified Product lines – As part of annual verification and validation studies, as well as positive release of manufacturing lines where a free from claim is being made

Question	Response
What type of assessments do you generally perform and do these differ by product / allergen?	We conduct raw material risk assessments looking at risk of contamination with allergens, factory assessments looking at cleaning and also airborne contamination. These assessments may be quantitative or qualitative depending on the input data.
Can you describe your sampling procedure.	Finished product – cleaning validation first off Finished product claim –3 samples taken through the batch and tested (x3) Raw materials – ISO sampling guidelines applied
What factors do you consider when selecting a testing laboratory?	Accreditation of lab and method. Validation studies completed on testing methods / kits used. Clear understanding on the challenges of testing spice matrix.
Which technologies are used in your testing of allergens?	Lateral flow devices / ELISA / PCR
How many replicates of each sample are tested by each testing laboratory?	Depends – typically there is one sample however we may make take multiple samples across the same batch.
Are the data you receive from testing in a qualitative or quantitative format?	Depends on the testing method used
What are the units of measurement of the testing procedures?	Depends on the testing method used – typically for ELISA it is PPM and for PCR it is report as positive / negative at the LOD of the test
Is there a particular LOD or LOQ that you require of the test?	We do not specify the LOD / LOQ for the tests we use, just that the sample matrix has been validated including where appropriate spike recovery testing.
What measures do you have in place for Quality Control in the allergen testing?	PCR / ELISA testing is conducted in an external laboratory that has undergone approval as per our process (Review of accreditation, procedures on testing including internal QC, kit validation) labs also need to participate in ring testing scheme. Lateral Flow devices – These are internally validated to ensure that they detect allergens at the LOD determined by the kit.
Who is responsible for interpreting the data and how is it decided whether a sample is determined as safe for consumers? How does this differ for ingredients versus final product testing (if applicable)?	Trained / competent personnel review data and make decisions on if the product is safe for consumer. Process utilises protein action levels.
Do you use action levels/VITAL reference eliciting doses to determine safe levels?	VITAL levels are utilised by trained / competent personnel to determine safe levels.
How do you decide when to recall a product?	If a risk to customers have been identified then product would be recalled.
Do you use any tools or calculations to interpret the data?	Calculator based on VITAL action levels is used. External allergen expertise is sought when required.
We are interested to learn about the costs involved in testing for businesses. How affordable is the testing regime? When you consider the costs in allergen testing, where do the direct costs to your business lie?	Generally, the cost of allergen testing is high when compared with micro testing, however it is a cost the business recognises needs to be spent. Our current regime fits within our cost model.
What considerations do you take into account when deciding how much to invest in allergen mitigation?	Our allergen mitigation programs are built on risk that recognise that testing is only one of the many mitigation strategies that can be utilised.
Could you estimate approximately what % of net profit is invested in monitoring for food allergens? Please state if this is not plausible.	Not plausible.
Are there any other challenges you face when considering the possible allergen content of your products?	Lack of understanding of allergens and protein action levels amongst regulators. Lack of harmony from a global perspective on action levels and labelling.
Considering allergen management, are there any gaps in food testing services which you wish were available or different to support your business? Are there any products for which you find it challenging to find a testing service?	Testing in a spice matrix for ELISA can be challenging and the use of PCR does not give a quantitative result to allow a VITAL risk assessment. Further research and development of Mass spec methods would be useful.
Do you have any points you would like to raise, or further comments?	None.

Company G

Question	Response
Overview of business	A retailer selling ambient and chilled products globally
Can you describe your allergen management regime	Alongside any legal obligations, we lay out specific standards our suppliers are expected to meet with regards to allergen management and specifically our free from product ranges. This covers both factory standards, allergen risk assessment and mitigations, as well as testing requirements that our suppliers must comply with
Which specific allergens from the 14 food allergen groups does your company test for?	As part of our independent product testing (IPT), we test products where a specific free from claim is made for that specific allergen e.g. gluten free rather than an ingredient label declaration
Which allergens are not tested for and why?	As part of our surveillance we are only testing for allergens where we are making a front of pack claim that the product is free from a specific allergen e.g. gluten free, dairy free
What factors do you consider when determining which items will undergo testing for allergens?	We target all products where a free from claim is made.
For a given product, how do you decide which allergens to test for?	Determined by the free from claim.
What do you test for allergens?	All product types where a free from claim is made.
Can you describe your sampling procedure.	Shopped from store against a planned schedule targeting products with a front of pack claim eg gluten free. Frequency altered by risk but aim to test all products twice per year.
How many replicates of each sample are tested by each testing laboratory?	One sample is tested.

Question	Response
What factors do you consider when selecting a testing laboratory?	We work directly with one service provider who assess testing laboratories on our behalf. They are assessed for performance, responsiveness, technical competence, sample preparation controls, reporting style, turn around times etc. Our contracted service provider has extensive experience of working with testing laboratories.
Are the data qualitative or quantitative?	Quantitative for ELISA, PCR/NGS are semi quantitative.
What are the units of measurement	Test and legal requirements dependent.
Is there a particular LOD or LOQ that you require of the test.	We target tests with defined LOQ where possible.
Which technologies are used in your testing of allergens?	We have access to a full range of methodologies.
What measures do you have in place for Quality Control?	All laboratories used are UKAS accredited to ISO 17025.
Who is responsible for interpreting the data and how is it decided whether a sample is determined as safe for consumers? How does this differ for ingredients versus final product testing (if applicable)?	We target finished product testing and results are interpreted by our service provider to determine “in spec” vs “out of spec”. Any out of spec result would be reviewed and interpreted by us and where applicable incident management procedures would be applied. We also have access to an expert toxicologist and expertise with our service provider to support and advise any risk based decisions.
Do you use action levels/VITAL® reference eliciting doses to determine safe levels?	Not answered
How do you decide when to recall a product?	We have an incident management procedure that covers information gathering, risk assessment and action for food safety incident. In the event of an identified issue information would be gathered from the supplier and an incident management team formed. The team would include business subject matter experts in relation to allergens if the incident was related to allergens. Gathered information would be reviewed and risk assessed to determine next steps. We would consider - • The allergen of concern and if there are known detection limits that would cause a reaction (e.g., gluten, sulphites), is it known to cause anaphylaxis? • Is the product being marketed to a vulnerable customer (e.g., a free from range) • Is the allergen hidden within the product (e.g., wrong ingredient used verses a clear mispack - would the customer see the issue? What is the alibi information on pack?) • Amount of product impacted and where it is in our supply chain (e.g., can this be isolated before it reaches the customer or not Has testing taken place? If so, is it accurate?
Do you use any tools or calculations to interpret the data?	Yes, we use an internally developed PPM calculator.
We are interested to learn about the costs involved in testing for businesses. How affordable is the testing regime. When you consider the costs in allergen testing, where do the direct costs to your business lie?	Testing costs are best obtained from the labs and service providers.
What considerations do you take into account when deciding how much to invest in allergen mitigation?	Testing costs are best obtained from the labs and service providers. Allergen management is one of a number of food safety risks that require effective management. Due to the potential severity of food allergens, we invest a significant amount of time and resources into the effective management of these. We employ a team of food technologist and subject matter experts to ensure that the risks from allergens are carefully managed.
Could you estimate approximately what % of net profit is invested in monitoring for food allergens?	Testing is only a part of the management of allergens. We complete ~700 supplier audits a year / employ a team of ~60 Technologists / develop and invest in systems to ensure product and supplier controls are in place. The total food safety programme is run at a cost of multiple millions of (£).
What type of assessments do you generally perform and do these differ by product / allergen?	Not answered
Are there any other challenges you face when considering the possible allergen content of your products?	When considering the manufacture of free from products we give careful consideration to the supplier, the processing environment and the procurement of raw materials. The supporting risk assessments and audits must support the decision to all production to commence from any new supplier.
Considering allergen management, are there any gaps in food testing services which you wish were available or different to support your business? Are there any products for which you find it challenging to find a testing service?	Rapid, accurate and cheap testing for raw materials intake would be advantages for our supplier to essentially positively release high risk raw materials onto site.
Do you have any points you would like to raise, or further comments?	Not answered