# FSA Science Council

## Working Group 5

# Review of the FSA's research programme on food hypersensitivity

## Final Report

## June 2021

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## i. Glossary

| | |
|---|---|
| ACNFP | Advisory Committee on Novel Foods and Processes |
| AI | Artificial Intelligence |
| ARIs | Areas of Research Interest |
| BAME | Black, Asian and Minority Ethnic |
| EFSA | European Food Safety Authority |
| FAIR | Food Allergy and Intolerance Research |
| FBOs | Food business operators |
| FHS | Food Hypersensitivity |
| FSA | Food Standards Agency |
| GDPR | General Data Protection Regulation |
| HS | Horizon Scanning |
| JLA | James Lind Alliance |
| PSE | Priority Setting Exercise |
| PSP | Priority Setting Partnership |
| RAG | Red-Amber-Green |
| REA | Rapid Evidence Assessment |
| SC | Science Council |
| SME | Small and Medium Enterprises |
| UKRI | UK Research and Innovation |
| WG5 | Working Group 5 |

## ii. Acknowledgements

The Working Group would like to thank Alisdair Wotherspoon (Independent contractor, previous Head of Science Delivery in the FSA) and Katherine Cowan (Independent contractor and Senior JLA Adviser) for their very significant contributions to the work outlined in this report. We are also grateful to Ian Kimber (External Programme Advisor to the FAIR Programme) and the following FSA staff for their support: Alisha Barfield, Chun-Han Chan, Natalie Coles, Manisha Hartigan, Paul Nunn, Ayah Wafi, Rachel Whiteside, Ross Yarham.

The Science Council would also like to thank the participants who attended the workshops carried out during this review.

# 1. FOREWORD

The overarching mission of the Food Standards Agency (FSA) is to the ensure that food is safe, food is what it says it is and that consumers can make informed choices about what to eat. These are of central importance to consumers with food hypersensitivity (FHS).

Food hypersensitivity (FHS) encompasses both immune-mediated food hypersensitivity (food allergy and coeliac disease) and non-immune food intolerances. FHS is a complex, multifactorial disease of concern to multiple stakeholders including consumers with FHS, their families, clinicians, regulatory agencies and policy makers, scientists, food manufacturers and food business operators. It affects around 5-8% of children and 2-3% of adults in the UK, and although rare, can be fatal. Public concern over FHS has grown in recent years. In the UK and elsewhere, food recalls due to the presence of undeclared allergens feature predominantly in food alerts; legislation over food labelling has become clearer, and consumers and producers are more aware of FHS.

The FSA has been a major funder of research into FHS for over 2 decades, and the outputs of the research programme has had significant impacts at a national and global scale, most notably in the area of the prevention of FHS in children and the presence of declared and undeclared allergens in food products.

Strengthening protections for consumers with FHS is a top priority for the FSA. The FSA has established a Food Hypersensitivity Programme Board to oversee and coordinate its work in this area. The working group was tasked with reviewing the research into FHS supported by the Food Standards Agency to date, and prioritising those priority areas where the current scientific evidence is limited and therefore should be a focus for future research investment. The aim – to make the UK the best country in the world for consumers with food hypersensitivity.

## 2. EXECUTIVE SUMMARY

In May 2019, the Science Council was asked by the FSA Board to undertake a review of the FSA's research programme on food hypersensitivity (FHS), incorporating food allergy and food intolerance. Much of this work has historically been undertaken through the FSA's Food Allergy and Intolerance Research (FAIR) Programme.

The Science Council appointed a working group led by Dr Paul Turner and Prof John O'Brien. This extensive review was divided into 2 parts:

I. A review into the previous and current research programme, including an assessment of best practice in undertaking such a programme;

II. Work to inform the FSA's future research direction and strategy. This involved two activities: a comprehensive and robust Research Priority Setting Exercise (with associated rapid evidence assessment) to establish more immediate research priorities, and a Horizon Scanning activity.

**Part I: Previous and current research programme**

An Interim Report was delivered to the FSA Board in September 2020, describing the process and outputs relating to PART I. The Science Council found the FAIR programme had been well-managed and influential, with great success in delivering quality research with national and international impact on policy.[1] These successes were clearly linked to the dedication of FSA staff and contractors, and the pivotal role of the regular and extensive stakeholder meetings and external reviews, which unfortunately ceased after 2012. This appears to have been a consequence of resource limitations, which adversely affected capacity/capability within FSA, together with a shift in emphasis away from a focus on childhood food allergy to adults.

The interim report made the following **key recommendations**:

[1] Research outputs included: intervention studies and an extensive systematic review of the literature which has informed both national and international guidelines on infant feeding; data on allergen presence in foods and clinical thresholds of reactivity, which have informed the UK position at CODEX and EFSA; changes in advice in the UK management of coeliac disease; input to a House of Lords Science and Technology Committee on food allergies in the UK.

i. Research Outputs

   a. **Additional resources should be allocated to maximise the use of routinely-collected data** across the FSA (e.g. post-incident analyses). This will help **avoid the situation where operational and analysis roles are combined**, resulting in limited capacity for data analysis. This has previously been flagged by the Science Council to the FSA Board.[2]

ii. Uptake and Impact

   a. **Improving the internal and external visibility of previous and existing outputs and impacts** will help the FSA build a compelling narrative to inform future business case planning.

   b. **A clear process should be developed for data sharing,** allowing monitoring by FSA of secondary outputs and impacts. Monitoring of impact should be an integral part of the regular external reviews, which ceased in 2012 due to resource constraints.

iii. Management and Governance

   a. There is a **critical reliance on "lynchpin" individuals**. This must be addressed through adequate internal resources (e.g. use of expert Project Managers), succession planning and strategies to capture best practice and protect institutional knowledge.

   b. The FSA should consider **complementary methods to develop tender calls** relating to more complex areas of future research (e.g. sandpits).

   c. **Guidance on applying for FSA research funding should be developed for the non-commercial sector**, to clarify differences in the FSA's tendering process compared to applying for UKRI funding.

   d. Steps should be taken to **minimise the impact of GDPR and associated legislation on research activities**.

iv. Review and learning mechanisms:

   a. **The FSA should consider re-instituting a mechanism for external review**, not just to capture best practice, but also monitor its success in applying this learning to future work.

[2] Science Council Report on Capability and Assurance, July 2018. https://www.food.gov.uk/sites/default/files/media/document/science-council-working-group-on-capability-and-assurance-final-report.pdf

**Part II: Future research strategy and direction**

The Science Council has completed Part II of the review and makes the following comments and recommendations:

**1. Internal Co-ordination**

i. The establishment of a Programme Board to improve internal coordination of research and policy activities in the area of FHS is a positive development. However, the Science Council recommends that **the process by which science and data are brought to the Programme Board should be made more resilient**, with a more structured approach to provide a "science push" while the Programme Board creates "policy pull".

ii. In addition to explicit research outputs, there are several additional FSA activities (e.g. Food & You, routinely-collected data pertaining to food incidents/root-cause analysis) that may not be considered or classified as "research". The value of such data may not be fully recognised, and **a small investment might enable more rapid analysis of incidents data, deliver improvements in incident prevention, and facilitate real-time analysis** as changes to food supply chains occur in the future.

**2. Research priorities for the next 5 years**

The Research Priority Setting Exercise (PSE) identified the following 10 priority areas, where uncertainties in the evidence exist. Seven of these are closely aligned to the FSA Areas of Research Interest (ARIs) with respect to FHS (see Annex D), with 3 (vi, viii, x) not included in the existing ARIs.

i. Risks posed to people with FHS by new/novel foods and/or processes
ii. Improving traceability of allergens in the food supply chain
iii. Risks posed due to shared production of foods, and how these can be mitigated
iv. Communicating risk, so that consumers with FHS can be confident that the food they are provided is safe
v. How to improve the utility of allergen labels, including precautionary allergen ("may contain") labelling
vi. How to better facilitate notification of incidents involving FHS to the FSA (and improve surveillance of allergen incidents in general)

vii. Impact of co-factors on reaction severity
viii. Impact of socioeconomic factors (including race/ethnicity) on FHS
ix. Impact of environmental exposures on risk of developing FHS
x. Current knowledge of FHS amongst the general public

The underlying evidence for these themes was found to be limited, and particularly poor for the following areas:

1) **Improving surveillance of FHS reactions occurring in the community**, to inform both current policy and allow the detection of new allergen risks (either arising from novel allergens/processes, or changes in the consumption patterns of existing allergens).[3] Establishing a serum biobank (for example, using blood samples from participants currently enrolled in FSA-funded research) would facilitate any future need to evaluate allergenicity arising from new/changing exposures to food proteins.
2) The **assessment and communication of allergen risk throughout the food chain** is challenging. New tools (including data sharing) and solutions should be evaluated to provide consumers with better information with which to make safe food choices.
3) Research to better understand the **impact of socioeconomic factors**, both with respect to the development of FHS and its management. The latter will require collaboration with other government departments, because socioeconomic factors impact on access to health advice which in turn informs consumer choice and risk avoidance behaviours.
4) The current **level of knowledge amongst the general public of FHS** is largely unknown. The FSA should consider whether work to address this could be undertaken alongside existing FSA projects (e.g. Food and You), and how this can inform public education strategies.
5) Identification of the **biological mechanisms that affect the development of FHS or loss of tolerance** that result in food allergy. This is a challenging area, and would require wide stakeholder input and novel approaches to develop cost-effective proposals that will deliver impact.

[3] The Science Council notes that the FSA is funding a UK-wide Anaphylaxis Registry to collect data pertaining to allergic reactions in the community, and developing a Food Allergic Reaction Reporting Mechanism to better capture food incidents.

The Science Council recommends that the FSA consider these 5 areas as potential research priorities over the next 5 years

## 3. Longer term research priorities

Predicting future research needs is challenging but the horizon scanning activity undertaken by the Science Council provided some insights for future work, identifying the following priorities (which have implications for both research and policy) which the Science Council recommends are considered in terms of future-proofing the FSA's regulatory capability:

i. Define the **requirements of a digital framework** (and associated data standards) **to communicate allergen risk throughout the food supply chain**, including on how such data might be accessed by consumers with FHS. The FSA should continue to engage with FBOs and other relevant stakeholders to achieve this.
ii. Investigate *proactively* the process by which FSA may need to engage with **social media and information platforms** on the presence of misleading or incorrect information with respect to FHS, and consider approaches to online food fraud which may be more difficult to manage than conventional food outlets.
iii. Continue to engage with multiple stakeholders involved in FHS, to **maintain an ability to address emerging drivers of change** which might affect consumers with FHS.

These drivers and trends are subject to, and a consequence of a complex interplay and interdependency of factors – developments are unlikely to be linear, and will occur at differing speeds and be subject to unexpected/unpredictable events and behaviours. In terms of policy/regulation and science/evidence, the **Science Council recommends that the FSA continues to develop a capability and capacity to act (and at pace where needed)**. This is likely to require a combination of approaches, such as legislation and enforcement, as well as "soft" tools (e.g. guidance, codes of practice, educational and advocacy strategies) to ensure that the interests of the FHS community are appropriately addressed in the challenges and opportunities ahead.

## 4. Funding

Attempts to co-fund projects with other funders have had limited success. In 2007, the House of Lords Science and Technology Committee identified a clear gap in funding for translational research into FHS in the UK. This situation has persisted, although the FSA has historically helped to address this through the FAIR programme.

**The management of FHS at a public health level involves multiple government departments and not just the FSA**. The advent of cross-governmental Areas of Research Interest (ARIs) provides a fresh opportunity for greater cooperation and research integration, with greater visibility of FHS research across government agencies. **The FSA is well-positioned to lead this, and the Science Council encourages the FSA to do so**.

## 5. Stakeholder engagement and review

**The Science Council recommends that the FSA reinstate regular stakeholder and quinquennial external reviews, to ensure ongoing evolution and external monitoring of the FHS research environment.** This would also facilitate:

- more structured (and regular) horizon scanning
- wider dissemination of research programme outputs and impact
- development of more strategic relationships with other funders and stakeholders to maximise potential for collaborative working/funding and sourcing of high-quality proposals, particularly in new/complex areas
- assurance to FSA with respect to the quality of the programme, its future direction and that the necessary oversight is in place.

In response to this report, the Science Council recommends that:

- The FSA considers a strategy which will address the recommendations and priorities outlined, with clear responsibilities, timelines and resources.
- The FSA provides a report to the FSA Board and then subsequently the Science Council on the implementation of the above recommendations, within 12 months of submission of this report.

## 3. INTRODUCTION

The FSA is reviewing its strategy on FHS to ensure it has access to the best available science and evidence and to support the delivery of appropriate and effective actions to ensure food safety and consumer choice. The FSA has an established policy team and science-led research programme on food allergy and intolerance.

The FSA Board set the direction for the Executive to develop "a comprehensive strategic framework [for food hypersensitivity] for discussion with the Board in autumn 2019. This will include a review of the evidence base and the development of appropriate outcome measures through which to judge progress."

In May 2019, the Science Council was asked by the Board to:

i. Consider and advise on future research priorities and direction in respect to FHS.

ii. Conduct a review of the science and evidence base for addressing FHS.

iii. Advise on the role the FSA should play to enhancing scientific knowledge.

At the Science Council's open plenary meeting of June 2019, it was agreed to establish a working group (Working Group 5, chaired by SC member Dr Paul Turner) to undertake a review in response to the FSA Board's request. The Terms of Reference were established in November 2019. The Working Group presented and agreed a workplan at the Science Council open meeting in December 2019:

I. A review into the previous and current Research programme (WG5.1), including an assessment of best practice in undertaking such a programme (WG5.3).

II. Work to inform the FSA's future research direction and strategy, through:

- A Priority Setting Exercise, inspired by the James Lind Alliance methodology with wide stakeholder input, to identify research priorities for the FSA in the area of FHS (WG5.2), and a review of the existing literature associated with these identified priorities (WG5.4).
- Identification of future research priorities in a 5 to 15-year timeframe through a horizon scanning activity. (WG5.5)

An Interim Report was delivered to the FSA Board in September 2020, describing the process and outputs relating to PART I, making the **following key recommendations**

i. **Overall strategy and direction**: The FSA has historically funded a significant amount of research into FHS in the UK, with great success in delivering quality research with international impact on policy. Since 2017, there has been a shift towards a greater focus on adult food allergy, which the FSA Board stated at its March 2017 meeting that should not be at the expense of other research activities on FHS. There has been a decrease in investment in the FAIR programme since 2010. The reduction and turnover in personnel, together with the cessation of annual stakeholder meetings, may have limited the ability of FSA to identify and launch new research activities. With the introduction of cross-governmental ARIs, **the Science Council recommends that FSA Board provide a steer as to the role FSA (as opposed to other research funders) should play in commissioning broader research into FHS (for example, whether research into the treatment of food allergy or potential environmental causes of food intolerances falls within the FSA remit)**.

ii. **Food Hypersensitivity Programme Board**: A new Programme Board was established by the FSA in Summer 2018 to bring together FSA work in the area of FHS under the direct oversight of the Executive Management Team. The Science Council considers that the process by which science and data are brought to the Programme Board should be made more resilient. **Without wishing to compromise the benefits of the informal horizontal system currently in place, we recommend a more structured approach (with appropriate staff resourcing) to facilitate this, perhaps in the form of a multi-disciplinary forum alongside the Programme Board to provide "science push" while the Programme Board creates "policy pull".**

iii. **Maximising outputs from existing data**: The FSA should consider allocating additional resource to **maximise use of routinely-collected data across the FSA (e.g. post-incident analyses) and avoid the current situation where operational and analysis responsibilities may be undertaken by the same personnel, limiting capacity for data analysis.**

This has been previously flagged by the Science Council as a recommendation to the FSA Board (Science Council Report on Capability and Assurance, July 2018).

iv. **Capturing best practice, supporting staff and building resilience**: There has been a critical reliance on “lynchpin” individuals. **The Science Council recommends this should be addressed through adequate internal resources, succession planning, handover checklists and strategies to capture best practice and protect institutional knowledge.**

v. **Regular external reviews:** The FSA should consider **reinstating regular stakeholder and quinquennial external reviews** to ensure ongoing evolution and external monitoring of the FHS research environment, something which would also facilitate horizon scanning, dissemination and collaboration.

vi. **Tendering process for contracted research**: **The FSA should consider complementary methods to develop tender calls** relating to more complex areas of future research e.g. sandpits. Guidance on the tender process should be developed to clarify the differences between contracted research and that funded, for example, through UKRI. We advise that data management plans should be required as part of the tender process, to incorporate details on data flow to facilitate compliance with GDPR and associated legislation.

vii. **Maximising impact**: Improving the internal and external visibility of previous and existing outputs and impacts will help the FSA build a compelling narrative to inform future business case planning. **The Council recommends that a clear process should be developed for data sharing, allowing monitoring by FSA of secondary outputs and impacts. Monitoring of impact should be an integral part of the regular external reviews, which ceased in 2012 due to resource constraints.**

This final report outlines the second part of the review, highlighting the direction and strategy the FSA should consider in terms of future research commissioning in the area of FHS.

# 4. BACKGROUND TO THE FSA'S RESEARCH PROGRAMME IN FOOD HYPERSENSITIVITY

The Food Allergy and Intolerance Research (FAIR) programme was originally established in 1994 by what was then the Ministry of Agriculture, Fisheries and Food, to investigate the causes and mechanisms of severe food allergy, with emphasis on peanut allergy, in order to reduce the incidence and severity.

Since then, the programme has evolved, informed by external programme reviews in 2003, 2008 and 2012, to incorporate funding of research projects to address other areas of policy needs, including the prevalence of food allergy in the UK, identifying risk factors associated with the development of food allergy, and research to review evidence on thresholds for sensitivity to gluten in the context of coeliac disease.

The FAIR Programme has to date encompassed over 60 contracted research projects. (see Annex 2, Interim Report). Table 1 shows the budget of the FAIR project since its formation in 1995.

| Projects Starting | Amount Spent (£) | Total Spend since 1995 (£) |
|---|---|---|
| 1995-1999 | 3,829,269 | 3,829,269 |
| 2000-2004 | 5,077,841 | 8,907,110 |
| 2005-2009 | 5,045,753 | 13,952,863 |
| 2010-2014 | 2,558,100 | 16,510,966 |
| 2015-2019 | 2,791,823 | 19,302,789 |
| 2020 | 644,739 | 19,947,528 |

**Table 1**: Research funding to the FAIR programme from 1995 to 2020. Figures reported are not reflective of the financial year spends but of total project costs, allocated into time brackets based on their start date.

# 5. SHORT-TERM RESEARCH PRIORITIES IN FOOD HYPERSENSITIVITY

**Methodology**

The Working Group undertook a Priority Setting Exercise (PSE) with associated Rapid Evidence Assessment, to establish the current and short-term research priorities for the FSA. The PSE was inspired by the James Lind Alliance (JLA) method and principles. The JLA is a non-profit making initiative funded through the National Institute for Health Research (NIHR), established in 2004. It brings patients, carers and clinicians together in Priority Setting Partnerships (PSPs) to identify and prioritise the uncertainties in evidence, or 'unanswered questions', that they agree are the most important for research in their topic area. Traditionally, PSPs have focused on uncertainties about the effects of treatments, but some PSPs have chosen to broaden their scope beyond that. The aim of a PSP is to help ensure that those who fund health research are aware of what really matters to patients, carers and clinicians. Industry stakeholders are usually excluded from PSPs. However, in context of the FSA's remit to protect consumers with respect to risks posed by FHS, it was essential to include Food Business Operators and other stakeholders involved in the food supply chain. For this reason, the Science Council worked with a senior JLA coordinator to adapt the PSP methodology to undertake a Priority Setting Exercise which met the FSA's requirements.

The **aim** of the PSE was to identify and prioritise the current knowledge gaps in providing safe food to individuals with FHS in the UK from key stakeholder perspectives, including (but not limited to) consumers (both allergic and non-allergic), healthcare professionals, regulators, industry and wider stakeholders.

There were 5 parts to the PSE, as shown in Figure 1:

i. **Initiation**: Establish a Steering Group to draft a protocol,[4] oversee the PSE activity and identify potential stakeholders.

[4] Protocol available at: https://science-council.food.gov.uk/sites/default/files/wg5pseprotocolfeb20v1.pdf

ii. **Consultation**: Undertake a public, stakeholder survey to identify "unanswered questions" and knowledge gaps (referred to as "evidence uncertainties") relating to the provision of safe food to consumers with FHS.

iii. **Analysis**: refinement of responses generated in (ii) to formulate summary questions.

iv. **Prioritisation**: the PSE workshop itself.

v. **Development of research questions** and subsequent Rapid Evidence Assessment of the literature relevant to the identified questions, to help the FSA understand the existing evidence base and thus the need for future research.

The **scope** of the PSE included:

- Enabling safe food choices for consumers with food hypersensitivity
- Practices to handle and produce food safely for those with food hypersensitivity
- Behaviours surrounding food safety with specific reference to food hypersensitivity

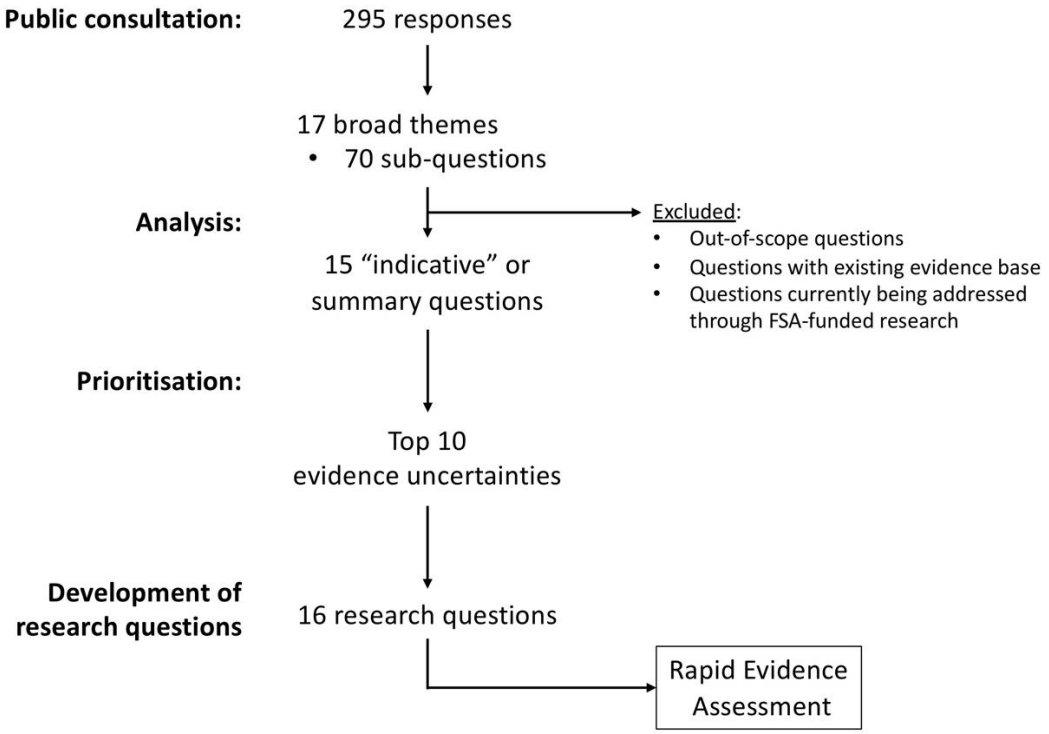


**Figure 1**: PSE methodology

Five themes were identified to provide structure to the PSE:

i. **Eating out**: the consumption of food prepared and served away from home, especially at a restaurant, café or take away establishment.
ii. **Buying Prepacked Food** i.e. food that has been prepared in advance of sale e.g. ready meals, packaged sandwiches etc.
iii. **Handling and Understanding Food** – helping consumers to make informed choices about buying safe food, which involves: food preparation, labelling, food/ingredients supply, preventing cross-contamination, effective cleaning, testing and monitoring to ensure food safety.
iv. **How we interact with food**, including changes in how and where consumers obtain food today e.g. new foods and novel allergens, food banks, food business practices, new and reusable packaging, online purchasing through the internet etc.
v. **Improving knowledge** including, for example, questions about the numbers of people in the UK affected by food hypersensitivity; or why some people develop food hypersensitivity but then outgrow their allergy or sensitivity.

Given the remit of the FSA, the following were considered out of scope for this PSE activity:

- Causality of food hypersensitivity
- Diagnosis and treatment of Food Hypersensitivity (including healthcare (NHS) provision)

An online public survey "Improving life for people with Food Hypersensitivity" was launched on 20th February 2020 (see Annex B) and communicated to over 250 organisations *via* social media channels, targeting the general public, food businesses, patient groups/charities, healthcare sector, academia, local authorities and professional bodies. The survey asked respondents to help identify knowledge gaps relating to FHS in each of the above 5 themes. Almost 300 responses were received when the survey closed (a month earlier than anticipated due to COVID-19) on 26th March. Ipsos MORI were commissioned to analyse the responses received, using a 4 stage process as shown in Figure 2. This generated 17 broad themes, encompassing a total of 70 sub-questions reflecting the survey responses (Annex C). The IPSOS MORI report is provided separately.

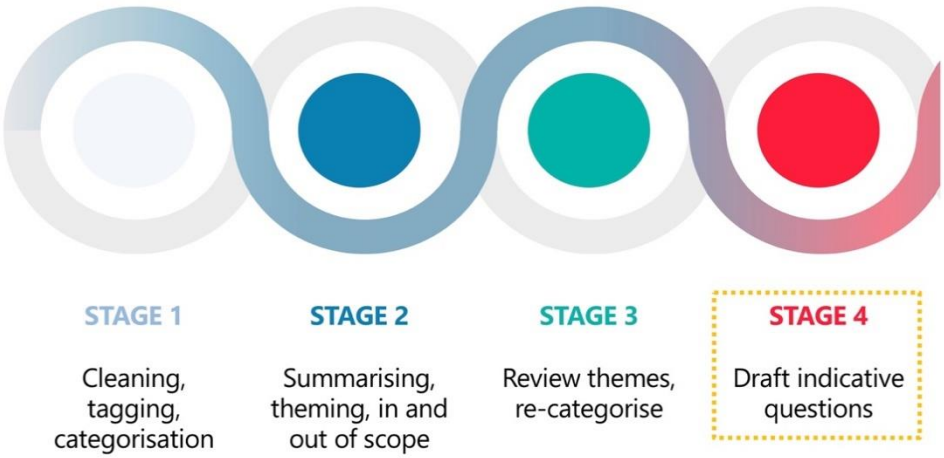


**Figure 2**: Analysis of survey responses into indicative questions for the PSE

The Steering Group subsequently reviewed these sub-questions (and, where needed, the original survey responses). After excluding out-of-scope questions or those areas in which FSA is currently commissioning research (Table 2), the Steering Group identified 15 summary or "indicative" questions which were then taken for prioritisation at a two-day workshop in September 2020 (virtual meeting, postponed from early 2020 due to COVID). Thirty-two stakeholders participated, representing food businesses, patient groups, healthcare and academia, local authorities and the FSA. The "top 10" priorities were then synthesised into 16 research questions (adopting a PICO (Patient/Population, Intervention, Comparison, Outcome) format) at a subsequent workshop. These were used for a rapid evidence assessment (REA), undertaken by RSM UK Consulting under contract from FSA. A systematic search protocol was used, which included details on the sources of evidence (academic searches, grey literature search, call for evidence, and manual searches), search terms used, and screening processes; the RSM report is provided separately. The Science Council working group then assigned a level of certainty to the available evidence as reported by the REA (Table 3).

| Out of scope | Addressed by current FSA research |
|---|---|
| What is the difference between an allergy and an intolerance? | How many people are affected by FHS? |
| Why do healthy eating options include so many allergens? | How many hospital/GP visits are due to FHS? |
| Gluten-free foods: Why do they cost more? Are they “better” for you? | What are the most common food allergies / intolerances? |
| Diagnostics: Waiting times, accuracy, access, novel diagnostics and genetics | National register or database for allergy incidents / people with FHS |
| Desensitisation treatment for food allergy, incl. interventions targeting the microbiome | Are food allergies/intolerances increasing? |
| Are staff in food establishments trained in how to use adrenaline autoinjectors? | Is there a link between childhood eczema and food allergy? |
| Are food allergies in adults treated with the same seriousness as those in children? | Thresholds for clinical reactivity<br>i.e. how much allergen is needed to trigger reactions |
| Is there a link between food poisoning and the development of FHS? | |
| What is the defined safe level of lead in game birds? | |

**Table 2**: Evidence uncertainties excluded from the PSE exercise

| Certainty of evidence | Explanation |
|---|---|
| High | We are very confident that the true effect lies close to that of the estimate of the effect. |
| Moderate | We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different. |
| Low | Our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect |
| Very low | We have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect |

**Table 3**: Certainty of evidence[5]

[5] https://gdt.gradepro.org/app/handbook/handbook.html

**Summary of Findings**

Fifteen indicative questions were identified by the Steering Group after excluding out-of-scope questions or those areas in which FSA is currently commissioning research (see Figure 1 and Table 2). At the PSE workshop, these were then prioritised, resulting in 10 evidence uncertainties, as listed in Table 4.

Sixteen research questions were then formulated, encompassing these 10 uncertainties, and used as the basis for the Rapid Evidence Assessment (REA). The Science Council working group then assigned a level of certainty to the available evidence, the outcomes of which are presented in Table 5. In general, the underlying evidence base was found to be limited, and particularly poor for the following areas:

i. Methods underpinning surveillance of FHS reactions occurring in the community, to inform both current policy but also allow the detection of new allergen risks (either arising from novel allergens/processes, or changes in the consumption patterns of existing allergens) which pose a hazard to consumers with FHS.
ii. The assessment and communication of allergen risk throughout the food chain.
iii. Research to better understand the impact of socioeconomic factors, both with respect to the development of FHS and its management.
iv. The current level of knowledge amongst the general public of FHS.
v. Identification of the mechanisms that affect the development of FHS or loss of tolerance that result in food allergy.

**Table 4**: Priority Research questions identified by the PSE, mapped to the FSA's areas of research interest (ARIs)

| **Indicative uncertainty** | **Research Question** | **Notes** | **Overlap with ARIs identified by FSA with respect to FHS** |
|---|---|---|---|
| Risks posed to people with FHS by new/novel foods and/or processes | 1) In consumers with FHS, what measures are needed to monitor for reactions due to:<br>• new uses of known allergens?<br>• novel proteins which might induce sensitisation and thus clinical reactivity?<br>2) What protocols should the FSA use when assessing the risk to consumers with FHS posed by novel foods/ processes/packaging?<br>3) What data exist as to the likelihood of allergenic proteins in biobased food contact materials migrating into foods? | e.g. the use of pea protein in protein concentrates, which is often declared only as "vegetable protein" in ingredients listing.<br>e.g. wheat-based starch in packaging, or latex-based binders in packaging and sustainable cutlery. Does not refer to risk of occupational allergy due to biobased food contact materials. | What existing or new analytical methodologies can identify potential new food allergens and their characterisation from novel and GM foods for risk assessment and management and how can they be used?<br>What is the allergen risk associated with biologically-based food contact materials? |
| Improving traceability of allergens in the food supply chain | 4) How should allergen information be communicated (through the food supply chain) to consumers with FHS, to:<br>• improve consumer confidence in terms of possible allergen content?<br>• reduce the incidence of unintended allergen exposure? | The sensitivity and reliability of analytical tests was also discussed, but development of these and the responsibility to ensure such tools are used appropriately was felt to be outside the FSA's research remit. | How can advanced approaches for food labelling be used to protect UK consumers with FHS?<br>How can the FSA enhance the quality of life for consumers with FHS and help them manage the risks that come with it? |

| | | | |
|---|---|---|---|
| Risks posed due to shared production of foods, and how can these be mitigated | 5) What are the health risks to consumers with FHS due to allergen cross-contact during food production?<br><br>6) How effective are different control options in reducing these health risks? | e.g. shared production in small kitchens. Use of shared ovens (e.g. gluten-free foods cooked in the same oven as gluten-containing foods)<br><br>e.g. different cleaning strategies | How can the FSA enhance the quality of life for consumers with FHS and help them manage the risks that come with it?<br><br>What are the best allergen cleaning methods and how can their effectiveness to protect the allergy sufferers be validated?<br><br>How can allergy threshold doses be defined most effectively and applied? |
| Communicating risk, so that consumers with FHS can be confident that the food they are provided is safe | 7) What are the most effective ways for FBOs to communicate a level of competence (with respect to allergen risk management) to consumers? | | How can advanced approaches for food labelling be used to protect UK consumers with FHS?<br><br>How can the FSA enhance the quality of life for consumers with FHS and help them manage the risks that come with it? |
| Allergen labelling, including Precautionary Allergen (“may contain”) labels. | 8) What forms of allergen labelling are effective in order for consumers to make informed decisions as to whether a food is “safe” for purchase and consumption? | Labelling to inform both what is present, what might be present (through cross-contact), and what is not present (whether or not a “free-from” claim is made). | How can advanced approaches for food labelling be used to protect UK consumers with FHS?<br><br>How can the FSA enhance the quality of life for consumers with FHS and help them manage the risks that come with it? |

| | | | |
|---|---|---|---|
| | | | How can allergy threshold doses be defined most effectively and applied?<br><br>What are the emerging allergens beyond the current 14 priority allergens? |
| Informing the FSA as to incidents involving food hypersensitivity. | 9) What evidence is there for different reporting systems to deliver useful data to regulators that can impact on reducing the risk of unintended allergen consumption?<br><br>10) What are the barriers that prevent reporting of near misses and other incidents to official bodies? | Reporting systems might include:<br>• Mandatory/voluntary reporting by healthcare professionals.<br>• Direct reporting by FBOs and members of the public<br>• Surveillance of serious incidents e.g. coronial system<br>• Strategies to overcome fear of enforcement such as no-blame approaches. | |
| Impact of co-factors on reaction severity | 11) In consumers with FHS, what are the factors which can increase the risk of a severe reaction?<br><br>12) How should risk posed by co-factors be communicated to those affected by FHS? | Incorporates both general advice to all FHS consumers, and individualised advice with respect to patient-specific co-factors. | How can the FSA enhance the quality of life for consumers with FHS and help them manage the risks that come with it? |

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| Impact of socioeconomic factors (including race/ethnicity) on FHS | 13) What are the socioeconomic factors which impact on risk in consumers with FHS?<br><br>14) How do cultural attitudes impact on the management of FHS? | Includes:<br>• understanding the impact of ethnicity/race as confounders<br>• language impacting on access to effective advice and communication of consumer needs<br>• impact on affordability/ accessibility/availability to safe foods for those with FHS | How can the FSA enhance the quality of life for consumers with FHS and help them manage the risks that come with it? |
| Impact of environmental exposures on risk of developing FHS | 15) What are the factors that drive a loss of immune-tolerance to food allergens?<br>*(The impact of disturbances to the microbiome was discussed, but considered out of scope of the FSA)* | Applies to both childhood- and adult-onset allergy e.g. how common is loss of prior tolerance? | What are the mechanisms that affect the development of and tolerance to FHS? |
| Current knowledge of FHS amongst the general public | 16) What are the current gaps/ inaccuracies in knowledge with respect to FHS amongst the general public? | Focus on general public, but also applies to specific stakeholders e.g. FBOs, healthcare | How can the FSA enhance the quality of life for consumers with FHS and help them manage the risks that come with it?<br>What are the statistics on food hypersensitivity prevalence (in the UK)? |

**Table 5**: Summary of evidence identified for each priority research question

| Research Question | Review of the existing evidence |
|---|---|
| 1) In consumers with FHS, what measures are needed to monitor for reactions due to:<br>• new uses of known allergens?<br>• novel proteins which might induce sensitisation and thus clinical reactivity? | Minimal existing evidence, perhaps because work in this area tends to be reactive (i.e. in response to a new use or novel allergen). The focus here was to review evidence for measures to *monitor* for reactions, rather than assess potential to induce allergic sensitisation and/or reactivity (for which processes have already been established by the FSA's Advisory Committee on Novel Foods and Processes (ACNFP).<br>There are concerns reported in the literature of reactions to protein concentrates (e.g. derived from pea) where consumption levels are far greater than with "normal" consumption.<br>No evidence identified with respect to "post-marketing" surveillance of novel foods. |
| 2) What protocols should the FSA use when assessing the risk to consumers with FHS posed by novel foods/ processes/ packaging? | ACNFP has established protocols for risk assessment of novel foods/processes, as has the European Food Safety Authority. The focus here is on processes which map theoretical risk i.e. sensitisation to actual risk to consumers. Minimal evidence was identified. The literature has examples of *in vitro* work to assess cross-reactivity to novel proteins in patients with relevant food allergies, which could form part of relevant FSA protocols (in a similar way to which concerns over the risk of lupin in peanut-allergic individuals was established). |
| 3) What data exist as to the likelihood of allergenic proteins in biobased food contact materials (BBFCMs) migrating into foods? | REA did not identify any relevant literature. A previous FSA-commissioned report from 2019[6] concluded that "*materials used for packaging include substances that are known allergens or are extracted from matrices that contain allergens. The effects of processing to produce packaging materials may alter allergenicity in unpredictable ways… Very limited information is available on the allergenicity of BBFCMs as well as the potential for transfer of allergens to food. Current analytical methods and risk assessment processes for establishing contaminant chemical transfer from fossil-based plastics to food are expected to be appropriate for BBFCMs… it might be considered prudent for manufacturers to review the use of potentially allergenic material as components of BBFCMs*." |

[6] https://www.food.gov.uk/sites/default/files/media/document/bio-based-materials-for-use-in-food-contact-applications_0.pdf

| Research Question | Review of the existing evidence |
|---|---|
| 4) How should allergen information be communicated (through the supply chain) to:<br>• improve consumer confidence in terms of possible allergen content?<br>• reduce the incidence of unintended allergen exposure? | Minimal evidence base with a high level of uncertainty. Only 2 reports identified, neither of which had a focus on how to improve traceability of allergens in the food chain (or information about this).<br><br>There is a clear knowledge gap in the specific information desired by different stakeholders in the food supply chain (including the end consumer), and how they would like such information (including the nature of any risk) to be communicated.<br><br>Whether a single digital system can be used to ensure transparency of allergen information from initial supply through to the end consumer needs consideration. |
| 5) What are the health risks to consumers with FHS due to allergen cross-contact during food production? | The REA identified 8 studies. Only one (a modelling exercise estimating the risk posed due peanut-allergic individuals consuming foods containing peanut-contaminated vegetable oils) provided an estimate of health risks. Another 5 described the risks of gluten cross-contact, but not specifically health risks.<br><br>The search strategy used for the REA did not identify the existing literature (at least 10 reports) with respect to unintended allergen presence due to cross-contact in prepacked foods (one of which was funded by FSA[7]) as being relevant to this theme, although some of these reports were identified with respect to allergen labelling. The FSA-funded study led to modelling which defined the specific risks to consumers due to consumption of food products where cross-contamination has been identified.[8] Such an approach provides a strategy which could be implemented to better assess the health risks posed to consumers with FHS during production. |

[7] Hirst B, Reading Scientific Services Ltd. Survey of allergen advisory labelling and allergen content of UK retail pre-packed processed foods. Food Standards Agency (FSA) Project Code: FS241038. http://www.food.gov.uk/science/research/allergy-research/fs241038

[8] Remington et al. Unintended allergens in precautionary labelled and unlabelled products pose significant risks to UK allergic consumers. Allergy. 2015 Jul;70(7):813-9.

| Research Question | Review of the existing evidence |
|---|---|
| 6) How effective are different control options in reducing these health risks? | Six studies were reported by the REA (three of which also discussed the detection of allergen due to cross-contact). Overall, the evidence base was assessed by the WG as low-moderate certainty evidence: the evidence was supportive of food hygiene measures in reducing risk, however data are lacking as to real-world circumstances, and how effective different control options are (in different food businesses) in reducing the risk to consumers with FHS. |
| 7) What are the most effective ways for FBOs to communicate a level of competence (with respect to allergen risk management) to consumers? | Nine studies were identified by the REA, all involving qualitative/mixed-methods analyses, which impacted adversely on the assignment of evidence quality in the REA. The available evidence focussed on how to improve communication from consumers to FBOs, rather than communicating competence from FBO to consumer.<br><br>With respect to the former, the following key areas for improvement were highlighted: supporting consumers with FHS to disclose food requirements; communication from consumer to kitchen in catering outlets; preference towards written information (rather than verbal); basic training to staff within FBOs on food allergy and risk of severe reactions; emphasising it is not for FBO-staff to decide if a food is “safe” for any given consumer. |
| 8) What forms of allergen labelling are effective in order for consumers to make informed decisions as to whether a food is “safe” for purchase/consumption? | The REA evaluated this according to themes, of which 3 were relevant:<br><br>• **Effectiveness of PAL**: multiple surveys have found that consumers with FHS often ignore PAL. Low certainty evidence over wording preferred by consumers with FHS, with some evidence of preference for consistency of wording: the most popular options being “may contain X” or “Not suitable for people with X allergy”.<br>• **Use of symbols to communicate allergens**: low certainty evidence that consumers may have a preference for internationally-standardised symbols (+/- verbal description).<br>• **Use of digital technology to communicate allergen information**: Very low certainty evidence that the use of digital technology (e.g. scanners on mobile devices) might be helpful for consumers, despite numerous apps being available at the current time. |

| Research Question | Review of the existing evidence |
|---|---|
| 9) What evidence is there for different reporting systems to deliver useful data to regulators that can impact on reducing the risk of unintended allergen consumption? | Very low certainty evidence for reporting. A number of reports relating to anaphylaxis registers exist (Norway, German-speaking countries, France), and it is noted that mandatory reporting of anaphylaxis is now required in hospitals in Victoria state, Australia, although there are no data on the impact of this currently available. An assessment of the relative utility of voluntary (public) vs voluntary (healthcare professional) vs mandatory reporting might be useful to guide future policy. |
| 10) What are the barriers that prevent reporting of near misses and other incidents to official bodies? | A single report relating to the Norwegian register suggested that systematic reporting of cases is required, but did not address the barriers to reporting. |
| 11) In consumers with FHS, what are the factors which can increase the risk of a severe reaction? | There is limited, mostly low-certainty evidence, highlighting “co-factors” which can increase the risk of more severe reactions e.g. exercise, concomitant infection, alcohol, use of non-steroid anti-inflammatory medication, and “tiredness”. For some allergic conditions (e.g. pollen food syndrome, eosinophilic oesophagitis), symptoms can increase during the relevant pollen season. There is a fundamental lack of knowledge over factors contributing to life-threatening anaphylaxis. |
| 12) How should risk posed by co-factors be communicated to those affected by FHS? | There were no identified reports on how to educate consumers with FHS as to how to mitigate against the potential impact of co-factors on reaction severity. |
| 13) What are the socioeconomic factors which impact on risk in consumers with FHS? | A number of studies were identified assessing the impact of racial or socioeconomic factors on both the incidence and severity of FHS. It is difficult to untangle the relationship between Black Asian and Minority Ethnic (BAME) background and socioeconomic factors, and understand the risk of confounding due to language difficulties and access to healthcare. Despite the lower certainty of evidence, overall there is consistency in the literature with respect to: higher prevalence of FHS (including to multiple foods) in BAME groups (including UK data); lower rates of compliance with dietary advice (with language comprehension and, for gluten-free foods, affordability key factors). More work is needed to understand this in the UK setting. |

| Research Question | Review of the existing evidence |
|---|---|
| 14) How do cultural attitudes impact on the management of FHS? | As for 13) above. |
| 15) What are the factors that drive a loss of immune-tolerance to food allergens? | This is a complex area which has been investigated in the previous FSA-funded work. There is an extensive epidemiological literature assessing different environmental factors, which is not always consistent. Nonetheless, these data have led to intervention studies (including Randomised Controlled Trials) which have impacted on public policy. However, such studies are very expensive to undertake and probably outside the remit of the FSA as a sole funder.<br><br>Factors which drive a loss of tolerance, particularly in individuals with adult-onset food allergy, is a key evidence gap but the FSA has already undertaken stakeholder consultation in 2014/15 which highlighted the practical difficulties of research in this area. The Patterns and Prevalence of Adult Food Allergy (PAFA) study (currently ongoing) may provide some insight into potential opportunities for the FSA to consider in the future. |
| 16) What are the current gaps/inaccuracies in knowledge with respect to FHS amongst the general public? | The REA found a number of low-certainty studies (typically surveys) which reported poor levels of knowledge amongst specified stakeholder groups, however the REA did not assess knowledge amongst the general public. There are reports of surveys undertaken in the USA assessing this (e.g. Gupta et al, 2009) which identified gaps in knowledge with respect to the distinction between food allergy and food intolerance and management of FHS. There were more data when focussing on specific stakeholder groups. Amongst FBOs, five studies were identified, four undertaken in the UK and one in Ireland. Key gaps identified were an awareness over which foods can trigger reactions and the risks of allergen contamination due to handling of food. In many studies, poor knowledge was more evident amongst staff working in takeaway outlets. |

# 6. LONGER-TERM RESEARCH PRIORITIES IN FOOD HYPERSENSITIVITY

Horizon Scanning is the process of looking for early warning signs of (a need for) change in the policy and strategy environment. The aims of this stage of the review was to:

1. identify emerging trends and developments which might impact on future FSA policy or strategy relating to the needs of consumers FHS over the next 5-15 years.
2. Explore how these drivers might interact, and how this might affect the FSA's work in the area of FHS
3. Understand better how the FSA may need to respond to these, both now and in the future.

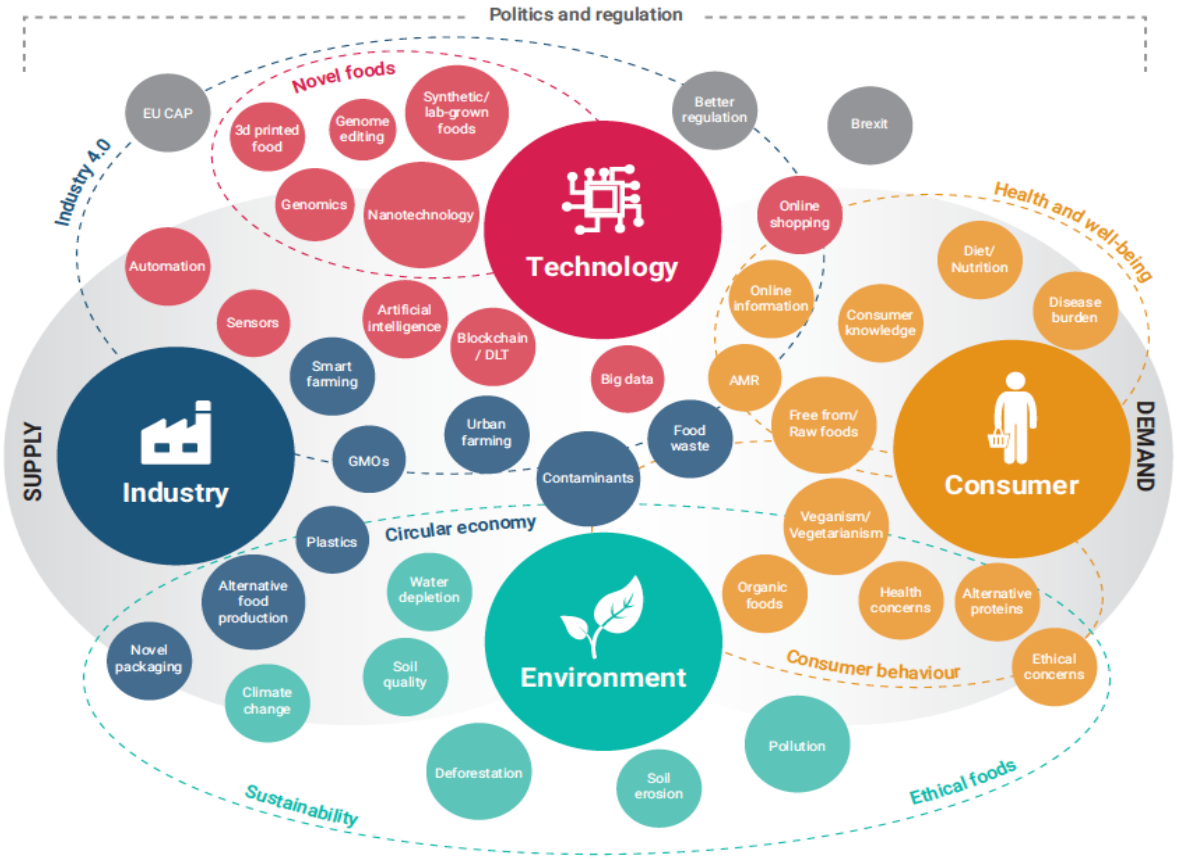
**Methodology**

Over 60 experts from food industry, academia, consumer groups, regulatory bodies (including, but not limited to FSA), other UK government bodies and the healthcare sector attended a 2-day virtual workshop. To facilitate discussions, six themes were identified from a pre-workshop questionnaire completed by participants, outlined in Table 6. Using the RAND map of global food systems interconnectivity and interdependency (commissioned previously for the FSA, Figure 3), attendees were asked to consider how the trends identified might impact on the FSA's ability to provide safe food to consumers with FHS over the next 5-15 years. Participants were reminded that the purpose of this Horizon Scan was *not* on the identification and risk management of new (novel) allergens (which should be identified through existing FSA structures), but rather, areas where new industry/consumer trends might result in different patterns of consumption or different uses of foods.

| Topic | Considerations: |
|---|---|
| **"Data" and Digital** | • Technological innovation incl. machine learning and Artificial Intelligence<br>• Data assurance: Blockchain / Distributed Ledger Technology<br>• Tensions with respect to access to commercial data<br>• Advances in how data is communicated to food businesses/consumers<br>• Use of data generated at point of consumption |
| **Food innovation** | • Food production/processing/transportation<br>• Food packaging/labelling/information<br>• Impact of gene editing and other technologies which might "inactivate" allergens, allowing consumers to eat allergenic foods<br>• Novel foods and processes<br>• New methods in shared production lines<br>• Food storage<br>• Impact of climate change on relative prevalence of specific allergens |
| **Needs and behaviours**<br>- FBOs<br>- Consumers | • Changing diets<br>• Consumer drive towards a more "sustainable" food system / "circular economy"<br>• Socioeconomic drivers<br>  ○ Ethnicity / BAME backgrounds<br>  ○ Food banks etc<br>• Changes in food service/hospitality/ delivery of food to consumers<br>• Changes in supply e.g. to more Small and Medium Enterprises (SMEs), "under the radar" routes which bypass regulation/ enforcement<br>• Changes in how food information is communicated<br>• Consumer distrust/misinformation/food fraud/food scares<br>• Impact of pandemics/other external factors<br>• More litigious culture<br>• Consumer empowerment vs government intervention |
| **Future regulation/ ways of working for regulators** | • International standards/regulations and agreement/discordance between national and international regulators<br>• Cross-government collaboration<br>• Changes in risk assessment processes |

| Topic | Considerations: |
|---|---|
| | • Safety assurance<br>• Food fraud<br>• Enforcement<br>• Use of thresholds in allergen risk management, away from a hazard risk approach (binary, where risk is present or absent)<br>• Use of monitoring and surveillance to understand and pre-empt risks |
| **Developments in scientific knowledge** | • Improved understanding of why some people develop FHS<br>• Prevention of FHS<br>• New methods to “inactivate” allergens<br>• Use of predictive/diagnostic techniques to identify:<br>  ○ New foods which could cause risk<br>  ○ Consumers at greater/lower risk who might then alter their behaviours accordingly<br>• How best to educate consumers as to scientific developments?<br>• Impact of misinformation / misuse of technology<br>• Impact of developments on regulation / legislation |
| **Food analysis** | • Developments and innovation in analytical science (e.g. Mass Spectrometry)<br>• Sensitivity/specificity of assays<br>• Sampling and impact of conventional and novel processing on analysis<br>• Point-of-consumption analytics<br>• Use of modelling to inform analytics |

**Table 6**: Themes identified for horizon scanning




*Source: RAND Europe analysis*

**Figure 3: RAND Global Food Systems Map**

The outputs from the Horizon Scan activity were then synthesised into 8 thematic risk/opportunity statements for review at a separate risk rating workshop. This used the RAG (red-amber-green) approach (Figure 4) to judge both the impact and likelihood of potential risks or opportunities associated with outcomes. The RAG assessments were carried out by a small group of experts (6 in total) from industry, academia, clinical science, and FSA officials. Outcomes may lead to a risk or an opportunity, and this can often depend on who is affected (consumers, food business operators etc). Risks and opportunities were considered through the lens of impacts/likelihood in relation to consumers affected by FHS and to food systems, and any divergence of opinions discussed and documented.

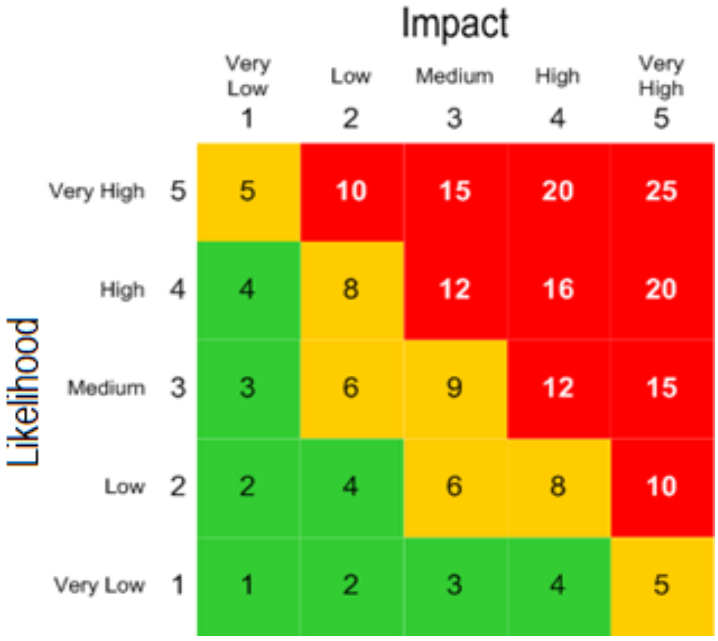



**Figure 4: Impact and Likelihood Matrix for the assessment of priorities**

The matrix has a 1-5 score (representing very low to very high) along the x axis (impact) and the y-axis (likelihood). Participants in the workshop identified the square they considered best represented these two axes for each risk/opportunity being discussed. The number in each box is the multiple of the two axes and was used to provide an individual participant's rating for that risk/opportunity.

**Summary of Findings**

A very broad spectrum of views emerged from the Horizon Scan workshop, with a mix of possible drivers, risks and opportunities which could impact on the direction and scale of future developments. These are summarised in Annex F. These outputs were condensed by the project team into 8 thematic risk/opportunity statements for consideration in the subsequent RAG workshop:

- Climate change – direct and indirect consequences
- Discordance between analytical capability and risk assessment
- Future disruptors to food supply chains
- Food fraud due to development of lucrative markets in tools/products

- (Mis)use of social media
- AI/digital developments driving misinformation/miscommunication
- New tech/products outpacing regulation
- New tech and tools facilitating safe consumer choice

Based on the broad tenor of the material that informed each of these, 7 are framed more as risk statements and 1 as opportunity. However, it was recognised that opportunities could also be presented in the risk cases and vice versa – this is reflected in the comments on the statements. The outputs of the RAG workshop are summarised in Table 7. In general, there was a good level of clustering of scores for each statement, though the RAG participants commented that the breadth of the themes, particularly with respect to climate change, did not lend itself well to scoring as a single entity, and further breakdown of the underlying drivers and issues would have allowed a more granular consideration, probably leading to a range of scores across the grid.

| Theme | Rating | Comments |
|---|---|---|
| **Technology/ tools facilitating choice** | Mean 18.5<br>Median 20 | Very high likelihood that new technology and tools will come on stream; if these relate to consumer-based products, then there is likely to be a high impact, particularly if driven by “influencers”. There is potential to increase power to the consumer (e.g. point-of-consumption allergen detection) but this risks safety/trust if the developments are not fit for purpose: who would have the remit of ensuring the reliability and appropriate use of such tools? Is there a risk of technology increasing inequalities in provision of safe food? |
| **(Mis)use of social media** | Mean 17.5<br>Median 16 | High likelihood given current trends but impact may be variable. It is likely that social media will become more pervasive as a source of information for consumers with FHS (both positive and negative impacts), however consumers are also becoming more digitally aware. Social media |

| | | |
|---|---|---|
| | | also presents opportunities to build a trustworthy base of information for consumers with FHS. |
| **Future disruptors to supply chain** | Mean 14<br>Median 14 | Concern (evidenced by COVID-19 pandemic) that significant external disruptors impact on choice due to risk of "panic buying". Future changes in retail and food service provision (including food sourcing, access to food e.g. increased use of remote ordering) presents unforeseen risks to consumers with FHS. This could be mitigated against through increased use of digital processes to ensure provision of information and facilitating communication within FBOs, and between FBOs and consumers. |
| **Discordance between analytical capability and risk assessment** | Mean 12<br>Median 11 | Risk assessment requires the correct "inputs" e.g. ability to accurately detect an allergen, risk assessment of the likelihood of harm given a potential exposure etc. As analytical advances are made, there is a risk of discordance between analytical capability and risk assessment/management.<br>Rating assignment was split between participants who:<br>- felt analytical advances would support improvements in risk assessment (mitigating against adverse impact)<br>- expressed a concern that current limitations of allergen analytics may not result in an improvement to the degree needed to appropriately support allergen detection, driving a more risk-averse approach to allergen labelling which will impact on consumers with FHS. |
| **Climate change** | Mean 11<br>Median 10.5 | Incorporates multiple, complex and interdependent factors, many of which are not necessarily direct drivers of changes in the food system, but indirect e.g. climate change resulting in different patterns of allergic sensitisation in the UK; impact on migration to the UK. Current RAG rating relies on the ability of existing risk assessment paradigms being applicable in a timely manner, and their ability to deal with |

| | | |
|---|---|---|
| | | potentially more complex innovations in food supply.<br><br>This theme would benefit from a more granular consideration and analysis. |
| **Food fraud** | Mean 10.5<br><br>Median 10 | Providing food for consumers with FHS is a lucrative market which brings both opportunities and benefits to consumers but also risk of food fraud. This may be exacerbated with move towards dark kitchens. From experience, fraud is difficult to predict and has a high impact when it occurs. |
| **Digital misinformation** | Mean 9.5<br><br>Median 8.5 | Rapid developments in data science will generate an exponential increase in the amount and complexity of data available, potentially increasing risk of misinterpretation and/or misinformation. However, algorithms can also help interpret data responsibly. There is also likely to be some degree of self-policing, with reviews driving consumers towards more highly rated sources of information. |
| **New technology /products outpacing regulation** | Mean 9<br><br>Median 9 | High likelihood of new technologies, but this will have both positive and negative impacts, with the former limiting the latter to some degree. To date, adoption of digital technology to inform risk by FHS consumers has been limited. Regulation is likely to improve, although there will always be an element of reactivity by regulators. This might act as a barrier to innovation slowing desirable impacts of consumers with FHS. Agility of response to rapid innovations therefore important, with a need to consider both “hard” as well as “soft” regulatory tools. There is a risk that non-traditional operators may enter this space, who have a poorer understanding of risk posed by FHS to consumers. |

**Table 7: Outputs from RAG rating workshop**

## 7. CONCLUSIONS AND RECOMMENDATIONS

Having completed the first part of a review into the FSA's research programme in FHS (see Interim Report, summarised in the Introduction), the focus for this report is to inform the FSA's future research direction and strategy. Research priorities are often developed without wide and coordinated stakeholder contributions. To the FSA's credit, the direction of the FSA's FAIR programme was very much informed by stakeholders through the regular review meetings which were last held in 2012. Since then, with the notable exception of a stakeholder workshop to discuss research into adult food allergy in 2014, this wide input has not occurred. The aim of this review was therefore to undertake an extensive and robust consultation to help define future research priority areas for the FSA.

**1. Short-term research priorities over the next 5 years**

The Science Council was reassured that seven of the 10 priority questions identified through the PSE were closely aligned to the Areas of Research Interest (ARIs) identified for FHS by the FSA (see Annex D), with only 3 (see Table 3) as supplementary to the ARIs. While the overall evidence base for these questions was limited, there were 5 areas particularly lacking in evidence, and which the Science Council recommends are considered as potential research priorities for the FSA over the next 5 years:

1) **Improving surveillance of FHS reactions occurring in the community**, to inform both current policy but also allow the detection of new allergen risks (either arising from novel allergens/processes, or changes in the consumption patterns of existing allergens) which pose a hazard to consumers with FHS. The Science Council notes that the FSA is funding the establishment of a UK-wide Anaphylaxis Registry to report allergic reactions, and developing a Food Allergic Reaction Reporting Mechanism (FARRM) to better capture food incidents.

   With respect to the risks posed by new allergens, the Science Council suggests that establishing a serum biobank (for example, using blood samples from participants currently enrolled in FSA-funded research) would facilitate any future need to evaluate allergenicity arising from novel foods and processes.

2) The **assessment and communication of allergen risk throughout the food chain** is challenging. New tools (including data sharing) and solutions should be evaluated to provide consumers with better information with which to make safe food choices. The REA reported a consumer preference towards *written* allergen information. The FSA should consider incorporating this in its guidance[9] to FBOs with respect to best practice.
3) Research to better understand the impact of socioeconomic factors on the risks to consumers with FHS, both with respect to the development of FHS and its management. The FSA should consider **funding research to better identify the impact of socioeconomic factors on consumer behaviour** with respect to FHS. There is clearly a large degree of overlap with "health" (socioeconomic factors may impact on accessibility to diagnosis which in turn informs consumer choice and behaviours to reduce risk). The Science Council advises that the FSA will therefore need to work with other relevant government departments (such as health) in this regard.
4) The current **level of knowledge amongst the general public of FHS** is largely unknown. The FSA should consider whether work to address this could be undertaken alongside existing FSA projects (e.g. Food and You), and how the outputs of such research can inform public education strategies. For example, the FSA could consider working with the Department for Education to target school pupils in secondary education through the national curriculum. Such a strategy is likely to help address the increasing role of FHS in bullying[10], and may also raise the level of public awareness and thus better support consumers with FHS.
5) The Science Council recommends that the FSA should continue to support work to identify the **biological mechanisms that affect the development of FHS or loss of tolerance** that result in food allergy. This is a challenging area, requiring wider stakeholder input and novel approaches to develop cost-effective proposals which will deliver impact.

[9] https://www.food.gov.uk/business-guidance/allergen-checklist-for-food-businesses#allergen-checklist-for-waiters-and-front-of-house-staff
[10] Brown et al. Ann Allergy Asthma Immunol. 2021 Mar;126(3):255-263.e1. doi: 10.1016/j.anai.2020.10.013.

**2. Longer-term research direction over the next 5-15 years**

Predicting future research needs is challenging but the horizon scanning activity undertaken by the Science Council provided insights for future work, based on participants' knowledge and experience of the trajectory of change over recent years (particularly related to the impact of COVID-19 on the food supply system). The RAG workshop identified the following areas of activity for the FSA which the Science Council recommends are considered in terms of "future-proofing" its regulatory capability:

1) Define the **requirements of a digital framework** (and associated data standards) **to communicate allergen risk throughout the food supply chain**, including on how such data might be accessed by consumers with FHS to help them make safe food choices. The FSA should continue to engage with FBOs and other relevant stakeholders to achieve this.
2) Investigate *proactively* the process by which FSA may need to engage with **social media and information platforms** as to the presence of misleading or incorrect information with respect to FHS, and consider approaches to online food fraud which may be more difficult to manage than conventional food outlets.
3) Continue to engage with multiple stakeholders involved in FHS, to **maintain an ability to address emerging drivers of change** which might affect consumers with FHS.

These drivers and trends are subject to, and a consequence of a complex interplay and interdependency of factors – developments are unlikely to be linear, and will occur at differing speeds and be subject to unexpected/unpredictable events and behaviours. In terms of policy/regulation and science/evidence, the **Science Council recommends that the FSA continues to develop a capability and capacity to act (and at pace where needed)**. This is likely to require a combination of approaches, such as legislation and enforcement, as well as "soft" tools (e.g. guidance, codes of practice, educational and advocacy strategies) to ensure that the interests of the FHS community are appropriately addressed in the challenges and opportunities ahead.

### 3. Internal co-ordination of research strategy

The Science Council welcomes the establishment of the Food Hypersensitivity Programme Board, to improve internal coordination of research and policy activities in the area of FHS. As highlighted in the Interim Report, the Science Council recommends that **the process by which science and data are brought to the Programme Board should be made more resilient**, with a more structured approach to provide "science push" while the Programme Board creates "policy pull".

In addition to explicit research outputs, there are several additional FSA activities (e.g. Food & You, routinely-collected data pertaining to food incidents/root-cause analysis) that may not be considered or classified as "research". The value of such data may not be fully recognised, and **a small investment might enable more rapid analysis of incidents data, deliver improvements in incident prevention, and facilitate real-time analysis** as changes to food supply chains occur in the future. The Science Council considers a more joined-up coordinated approach to data collection and analysis in FHS is an opportunity. In this respect, the Science Council welcomes the development of the Food Allergic Reaction Reporting Mechanism (FARRM) by the FSA.

### 4. Funding

Attempts to co-fund projects with other funders have had limited success. The Science Council notes a recent call for research "Addressing adverse and beneficial effects of food ingredients and food processing on hypersensitivities to food" under the EU Horizon 2020 programme[11] (partly funded by UKRI and the FSA), and hopes that similar opportunities for co-funding will occur in the future. In 2007, the House of Lords Science and Technology Committee identified a clear gap in funding for translational research into FHS in the UK. This situation has persisted, although the FSA has historically helped to address this through the FAIR programme.

**The management of FHS at a public health level involves multiple government departments,** including the FSA, Department for Environment, Food & Rural Affairs, Department of Health and Social Care, Department for Education, public health agencies, among others. The advent of cross-governmental Areas of Research

[11] https://www.healthydietforhealthylife.eu/index.php/call-activities/calls/106-calls-site-restyling/calls-era-hdhl-site-restyling/636-era-hdhl-2021

Interest (ARIs) provides a fresh opportunity for greater cooperation and research integration. **The FSA is well-positioned to lead this, and the Science Council encourages the FSA to do so,** increasing its FSA's visibility across government agencies in the process.

**5. Stakeholder engagement and review**

Finally, a recurring theme throughout this review has been the significant positive impacts of regular FSA-organised stakeholder meetings, which were held until 2012. **The Science Council recommends that the FSA reinstate regular stakeholder and quinquennial external reviews, to ensure ongoing evolution and external monitoring of the FHS research environment.** This would also facilitate:

- more structured (and regular) horizon scanning
- wider dissemination of research programme outputs and impact
- development of more strategic relationships with other funders and stakeholders to maximise potential for collaborative working/funding and sourcing of high-quality proposals, particularly in new/complex areas
- assurance to FSA with respect to the quality of the programme, its future direction and that the necessary oversight is in place.

In addition, the Science Council reviewed the utility and effectiveness of the methods used in generating the outputs of this report, including participant feedback (Annex F) from the Priority Setting Exercise. The Science Council found the PSE, utilising adapted James Lind Alliance (JLA) methodology, was effective, inclusive, transparent and efficient in terms of resource requirements. Despite initial concerns over delivering this activity by a virtual format, the use of experienced, independent facilitators allowed the inclusion of geographically-diverse experts, including participants from the devolved nations and abroad. This helped achieve a greater confidence in the relevance of the prioritisation achieved. The Council therefore recommends that the FSA consider utilising such a process in future activities – not necessarily limited to FHS – where prioritisation and consensus within a wider stakeholder group is needed to inform both science and policy.

## LIST OF ANNEXES

1. **ANNEX A – Declaration of Interests**
2. **ANNEX B – Public stakeholder survey for Research Prioritisation Exercise**
3. **ANNEX C – Indicative uncertainties**
4. **ANNEX D – ARIs with respect to FHS**
5. **ANNEX E – Outputs from Horizon Scan Workshop**
6. **ANNEX F – Feedback from Stakeholder Representatives attending Research Prioritisation Exercise**

## ANNEX A: DECLARATION OF INTERESTS

### Chair's Declared Interests

As a Reader and Clinician Scientist in Paediatric Allergy & Immunology at Imperial College London, the Chair of the Science Council Working Group on Food Hypersensitivity (Dr Paul Turner) has a record of research and advisory interaction with the FSA in relation to food hypersensitivity.

In line with the FSA's approach to managing the interests of its external scientific advisers, Dr Turner has provided further details of his current and past (up to 5 years previous) research and advisory interactions with the FSA. A full record of Dr Turner's most recently published Register of Interests is available at: https://science-council.food.gov.uk/sites/default/files/sc510registerofinterests.pdf.

Dr Turner's declared interests were not considered prohibitive to his involvement in this Review by the Executive.

| | |
|---|---|
| **1** | **FSA Contract FS101222: Using NHS data to monitor trends in severe, food-induced allergic reactions**. This was an open tender call relating to the use of NHS data for monitoring trends in allergic reactions to which Imperial College London placed a successful bid. Dr Turner is the project lead, directly contributing an estimated 6.5% of total staff effort. The project commenced in 2019 and is due to complete 2022. The remit includes the establishment of a national Anaphylaxis Register in the UK. |
| **2** | **2012-2017 (TRACE Peanut Study)** (FS241037). Dr Turner was part of the study team. Dr Turner was not funded directly by the project but through a Fellowship from the UK Medical Research Council to undertake work on TRACE study participants to better understand mechanisms of anaphylaxis. Dr Turner was involved in the supervision of a PhD student at the London site. His role included protocol input, trial management and clinical supervision of day-to-day work in undertaking food challenges with patients. |
| **3** | **2015-2017 External Advisor to the Committee on Toxicity**. Dr Turner provided advice to COT with respect to the systematic review into food hypersensitivity commissioned by the FSA at that time. |
| **4** | **2014-2015 Appraiser/peer reviewer**. Previous agreement with Dr Turner to provide services as an appraiser/peer reviewer for Apr 2014 to Sept 2015. This amounted to one meeting with Darren Holland of the FSA and significant e-mail correspondence. |

# ANNEX B: PUBLIC STAKEHOLDER SURVEY FOR RESEARCH PRIORITISATION EXERCISE

### FSA Survey: Improving life for people with Food Hypersensitivity

The FSA is an independent Government department working to protect public health and consumers' wider interests in food. We make sure that food is safe and what it says it is.

We want the UK to become the best place in the world for people living with food hypersensitivities.

Do you have big questions that we could answer through research, to make things better for people with food hypersensitivity? Tell us your thoughts and help us to make a difference.

### Why is the Food Standards Agency (FSA) carrying out this survey?

Around 2% of adults and 8% of children in the UK have a food hypersensitivity. This includes:

- food allergies (which involve the immune system, and can cause severe allergic reactions (anaphylaxis)
- coeliac disease
- food intolerances (e.g. lactose intolerance) which do not involve the immune system).

We are carrying out this survey to get a better understanding about the key questions and issues the FSA needs to address through research, in order to better provide safe food for people with food hypersensitivities.

### Who is the survey for?

- You can complete the survey if you are aged 18 years or over and you are:
- a member of the public with an interest in food hypersensitivity

- affected by food hypersensitivity yourself, or care for someone else with a food hypersensitivity
- a food business operator, representative or member of staff who has an interest in food hypersensitivity
- a charity representative or worker with an interest in food hypersensitivity
- a healthcare worker or researcher with an interest in food hypersensitivity
- a local authority or professional body with an interest in food hypersensitivity

This survey is funded by the Food Standards Agency. The survey is voluntary, and you are free to exit at any point - you don't need to answer all the questions.

**What will the survey involve?**

This survey asks about your experiences and how you think the FSA can help people affected by food hypersensitivity to make safe food choices. Note that the FSA is not responsible for the diagnosis or management of food hypersensitivity.

We will use your responses to help the FSA define and prioritise its research activities in the area of food hypersensitivity. It will take approximately 10 minutes to complete.  If you have any problems completing this survey, please email fsadigital@food.gov.uk. We will not ask you for any personal data;

The only personal details that we will be collecting are: your age range; whether you live in the UK; and your general demographic i.e. consumer, business, charity etc. This is so we can ensure we hear from a broad range of people. You will not be identifiable from this information. Please do not include any other personal details in your answers.

For further information on how FSA handles the information you have shared with us, please see our privacy policy on our website https://www.food.gov.uk/about-us/privacy-policy

## Questions

### Theme: Eating Out

Eating out describes the consumption of food away from home, especially at a restaurant, café or take away establishment.

Thinking about the experience of eating out, what unanswered questions and/or issues should the FSA try to answer in order to help people with food hypersensitivity?

### Theme: Buying Prepacked Food

Prepacked food describes food that has been prepared in advance of sale e.g. ready meals, packaged sandwiches etc.

Thinking about the experience of buying prepacked food from shops, what unanswered questions and/or issues should the FSA try to answer in order to help people with food hypersensitivity?

### Theme: Handling and Understanding Food

Handling and understanding food means being able to make informed choices about buying safe food, which involves: food preparation, labelling, food/ingredients supply, preventing cross-contamination, effective cleaning, testing and monitoring to ensure food safety.

Thinking about the experience of handling and understanding food, what unanswered questions and/or issues should the FSA try to answer in order to help people with food hypersensitivity?

**Theme: Changes in how we interact with food**

This relates to changes in how and where we obtain food today e.g. new foods and novel allergens, food banks, food business practices, new and reusable packaging, online purchasing through the internet etc.

Thinking about changes in the food we eat and where we get it from, what unanswered questions and/or issues should the FSA try to answer in order to help people with food hypersensitivity?

**Theme: Improving what we know about food allergy and food hypersensitivity**

What unanswered questions and/or issues about food hypersensitivity should the FSA try to answer, in order to help ensure that food is safe for people with food hypersensitivity?

For example, your questions could be about the numbers of people in the UK affected by food hypersensitivity; or why some people develop food hypersensitivity but then outgrow their allergy or sensitivity.

## Demographic Questions

**Do any of the following apply to you?**

- I am a member of the general public with an interest in food hypersensitivity
- I have a food hypersensitivity myself
- I care for someone with a food hypersensitivity and /or I am completing this survey on behalf of someone else affected by food hypersensitivity e.g. my child
- I am a food business operator, representative or work for a food business
- I work or volunteer for a charity who helps provide for people with food hypersensitivities
- I work for a local authority or professional body with an interest in food hypersensitivity

- I am a healthcare professional (e.g. doctor, nurse, dietitian etc)
- I am a researcher with an interest in food hypersensitivity
- Other (free text)
- Prefer not to say

Do you currently live in the UK?

- Yes
- No

What age are you?

- 18-24
- 25-34
- 35-44
- 45-54
- 55-64
- 65-74
- 75+

## ANNEX C: INDICATIVE UNCERTAINTIES IDENTIFIED BY IPSOS MORI ANALYSIS

| Initial indicative question | Questions for prioritisation | Rationale |
|---|---|---|
| What is the type and prevalence of food hypersensitivity? | none | Existing FSA-commissioned research is examining this:<br>• PAFA study (adults)<br>• Anaphylaxis (all ages) |
| How and why do people develop food hypersensitivity? | What are the environmental exposures which increase the risk of developing food hypersensitivity?<br>How do socio-economic factors impact on individuals with food hypersensitivity?<br>What co-factors (other than exercise and sleep deprivation) increase the risk of a severe allergic reaction? | Survey responses included whether individuals from some SE backgrounds are at greater risk of severe FHS reactions |
| Is it necessary to review the regulatory allergen list? | none | Existing FSA-commissioned research is examining this (anaphylaxis register) |

| | | |
|---|---|---|
| What is the role of FODMAPS in triggering IBS? | none | Not in FSA remit |
| What do the general public understand about food hypersensitivity? | What is the current level of existing knowledge of food hypersensitivity in the general public (including consumers and food business operators), and how can this be improved? | |
| What information do consumers with food hypersensitivity need, to make choices about food? | What is the most effective way to alert consumers as to changes in ingredients?<br>What are the best ways to communicate risk and appropriate mitigating actions to consumers and food business operators (including, but not limited to, online food business operators/street vendors / food banks)? | |
| What is the most effective way of communicating information to consumers with food hypersensitivity? | What are the risks posed due to shared production (e.g. cooking) of foods to individuals with food hypersensitivity, and how can these be mitigated?<br>What are the best ways for consumers to be confident that the food they are provided with is safe with regard to food hypersensitivity?<br>How can food business owners improve traceability of allergens in the food supply chain | |

| | | |
|---|---|---|
| What do businesses understand about food hypersensitivity? | What is the current level of existing knowledge of food hypersensitivity in the general public (including consumers and food business operators), and how can this be improved?<br><br>What are the risks posed due to shared production (e.g. cooking) of foods to individuals with food hypersensitivity, and how can these be mitigated?<br><br>What risk is posed to health by "derived" ingredients such as plant oils /fats, starches (other than those foods for which legal exemptions currently exist)?<br><br>How can food business owners improve traceability of allergens in the food supply chain | |
| How effective is monitoring and enforcement? | What is the best way to alert the FSA as to incidents involving food hypersensitivity (and increase awareness of how to do this amongst the general public)? | This is captured through existing incidents data |
| How effective are existing measures/guidelines on reducing cross contamination? | What are the risks posed due to shared production (e.g. cooking) of foods to individuals with food hypersensitivity, and how can these be mitigated?<br><br>What is the risk to latex-sensitive consumers from latex cross-contact (both via packaging and during food handling)? | |

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| How effective is guidance on producing gluten free food? | What are the risks posed due to shared production (e.g. cooking) of foods to individuals with food hypersensitivity, and how can these be mitigated? | Food and Drink Federation and Coeliac UK produced evidence-informed guidance to the food industry in 2019. Coeliac UK has undertaken research on risks of gluten cross-contamination in the kitchen environment. |
| What improvements are required to current labelling on prepacked food? | What are the best ways to communicate risk and appropriate mitigating actions to consumers and food business operators (including, but not limited to, online food business operators/street vendors / food banks)?<br><br>What do consumers want from allergen labelling, including Precautionary Allergen (e.g. “may contain”) Labelling)? | |
| What improvements are required to current labelling of non-prepacked foods sold via food business operators? | What are the best ways to communicate risk and appropriate mitigating actions to consumers and food business operators (including, but not limited to, online food business operators/street vendors / food banks)?<br><br>What do consumers want from allergen labelling, including Precautionary Allergen (e.g. “may contain”) Labelling)? | |

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| What role can digital technology play in providing information to consumers and FBOs? | What is the best way to alert the FSA as to incidents involving food hypersensitivity (and increase awareness of how to do this amongst the general public)?<br><br>How can food business owners improve traceability of allergens in the food supply chain<br><br>What are the best ways to communicate risk and appropriate mitigating actions to consumers and food business operators (including, but not limited to, online food business operators/street vendors / food banks)? | |
| What regulation/guidance is needed for novel packaging? | What risk is posed to people with food hypersensitivity by new/novel foods and/or processes (including packaging and other food contact materials)? | |
| What regulation/guidance is needed for package free and reusable packaging? | | |

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| Is there an advantageous commercial value to food hypersensitivity? | Are there economic benefits to providing for individuals with food hypersensitivity, which can be used to encourage food business operators to go beyond the letter-of-the-law? | |

## ANNEX D: AREAS OF RESEARCH INTEREST WITH RESPECT TO FOOD HYPERSENSITIVITY

1. **How can the FSA protect the UK consumer from the health risks posed by food hypersensitivity (including allergies and intolerance)?**

    1.1. How can advanced approaches for food labelling be used to protect UK consumers with hypersensitivity?

    1.2. How can the FSA enhance the quality of life for consumers with food hypersensitivity and help them manage the risks that come with it?

    1.3. What are the mechanisms that affect the development of and tolerance to food hypersensitivity?

    1.4. What are the statistics on food hypersensitivity prevalence (in the UK)?

    1.5. What are the best allergen hygiene practices and how can their effectiveness to protect the allergy sufferers be validated and communicated?

    1.6. What existing or new analytical methodologies can identify potential new food allergens and their characterisation from novel and GM foods for risk assessment and management and how can they be used?

    1.7. How can allergy threshold doses be defined most effectively and applied?

    1.8. What are the emerging allergens beyond the top 14 covered by current legislation?

    1.9. What is the hypersensitivity risk associated with biologically-based food contact materials?

## ANNEX E: OUTPUTS FROM HORIZON SCAN WORKSHOP

| Theme | Drivers/evidence supporting | Risks/opportunities |
|---|---|---|
| **Analysis** | Rapid advances in miniaturisation for more discriminatory methods – already seeing at e.g. airports with Mass Spectrometry, lateral flow devices. Seeing such developments for macro food components<br><br>Development of in line/real time testing capability<br><br>Mobile phone/ app/AI developments and other intelligent tech developments e.g. smart fridges, Amazon supermarkets<br><br>Enthusiasm for Citizen science approaches<br><br>Drive for open data<br><br>Developments in quantitative risk assessment (QRA)<br><br>FHS sufferers' desire for "normal" relationship with food<br><br>Increased understanding of the (biological/physical) mechanisms/causes of FHS<br><br>Likely to see analytical developments focus on allergens, not just epitopes | Access to tech – equity – both for consumers and small medium enterprises (SMEs)<br><br>Rapid access to data to inform consumer choice<br><br>Regulation not keeping up – who regulates? Who is liable for errors?<br><br>Market is flooded with poor quality devices<br><br>→ risk to consumer health<br><br>→ confusion with regard to regulatory oversight (reputational damage to FSA)<br><br>Siloed information - Impaired information access → blocked opportunities for better risk management<br><br>Trust/mistrust in data/tools<br><br>Misinformation spread<br><br>Consumer→Confusion and loss of trust in food companies and regulation<br><br>FSA→ more time needed in "firefighting" misinformation |

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| | "Allergen free" demands such as gluten free – also driving commercial developments to support | How to distinguish between positive result and actual risk – find more if look harder but may always have been there – is it a risk? Communication issues?<br><br>Lack of clarity on data interpretation→erroneous consumption decisions, confusion |
| **Science** | Increased understanding of mechanisms of FHS development – better tools/models (cell based) for prediction<br><br>Potential for new technologies to eliminate FHS triggers/causes, such as gene editing<br><br>Research on epigenetics accelerating<br>- Increasing understanding of role of skin and gut microbiome<br>- Increased understanding of:<br>- risk factors,<br>- immune system (and possibility to tweak),<br>- desensitisation,<br>- lifestyle<br>- nutrition<br><br>Seeing climate change related pollen exposures leading to modified pattern and prevalence of allergies (reference provided)<br><br>Developments in AI/technology with potential to assist in risk assessment/management (already | The potential for evolving/emerging FHS triggers/causes due to impacts of climate change, sustainability drivers (e.g. driving developments in re-use or materials), migration, (re)emerging risks more generally<br><br>↓ trust in regulation as innovation moves faster that it can adapt.<br><br>OR<br><br>↑Consumer confidence in regulation as measures keep pace and anticipate new innovations<br><br>Lack of drive/investment to develop if FHS seen to be receding or niche areas e.g. pea allergen tests not being developed due to lack of demand<br><br>→Gaps in risk analytical tool to support allergen management<br><br>Ability/desire of all scales of FBOs to engage and understand implications of science and put safe and robust developments into place<br><br>New actors in food chain with limited understanding of food related challenges and how to manage→ ↑allergen risks |

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| | seeing trends, such as use of Fitbits, QR codes etc)<br><br>Development of better diagnostic tools<br><br>FHS sufferers' desire for "normal" relationship with food driving science developments<br><br>Enthusiasm for Citizen science approaches<br><br>Developments in behavioural science, including nudge<br><br>Developments in AI/apps/devices to support<br><br>Post COVID-19 interest in capability of science to deliver | due to inexperience/lack of competence of new market entrants<br><br>Need for appropriate data trust/validation -input of poor quality data → risk due to bad decision-making<br><br>→Loss of consumer trust<br><br>Anti-science impacts progress – particularly if serious problems early on→loss of trust<br><br>Increase in knowledge leads to more commercialised approach to FHS "treatment" – but could create haves and have nots? Market segmentation +Inequality →lack of access to innovation |
| **Regulation** | New models of food supply – e.g. pop ups, dark kitchens, online, etc<br><br>New technologies – in food production, analysis, consumer tools etc<br><br>FHS sufferers' desire for "normal" relationship with food posing regulatory challenges<br><br>Fragmented regulatory landscape<br><br>Concerns over siloed consultations<br><br>Developments of "preventative foods"<br><br>Potential impacts related to e.g. climate change, sustainability etc leading to emerging regulatory challenges | Ensuring data is fit for purpose<br><br>Regulation that is understandable to all it applies<br><br>→consumer trust and protection<br><br>→↑compliance by FBOs<br><br>Different patterns of FHS around world impacting on ability to harmonise →"inequality" in allergen risk management in diverse societies<br><br>Broad range of stakeholder groups to engage/satisfy – difficulties in getting consensus views, shared vision and objectives →failure to set priorities for regulatory action in FHS→↓trust & ↑outrage |

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| | Desire to have harmonised standards<br><br>Need for improvements to data flows, availability, standards, veracity, currency etc<br><br>Improvements in analysis and QRA<br><br>Imperatives arising from political drivers<br><br>Impacts of disruptor events such as Brexit, pandemics etc | Impacts of ongoing challenges in resources/capability of regulatory actors – new models (blend of public/private sector?)<br><br>Barrier to innovation/RA approach focus in FBOs? →lack of progress in consumer choice and protection<br><br>Set (regulatory) analysis within a RA framework to ensure cost effective testing →greater transparency →proportionate investment in testing strategies → consumer protection and trust →improved FBO compliance<br><br>Will be no one size fits all to meet the regulatory challenges |
| **Innovation** | Already seeing evidence of trends via regular literature references to relevant innovation developments<br><br>New "food" examples already – placenta, lactase, microbes, insect<br><br>New manufacturing/production processes e.g. hydroponics, vertical farming<br><br>Rise of popularity of vegan/other types of diets<br><br>Increasing digital resources to support diet/food decisions based on e.g. lifestyle objectives<br><br>Increase in online etc particularly in response to COVID-19<br><br>Seeing drive from Asian markets to enter European markets | Impacts of novel ingredients, products, presentations etc as FHS triggers →"future ready" regulatory policy→consumer protection and trust in the future<br><br>How well characterised are more complex "mimic" foods →lack of preparation for new FHS risks→↓consumer protection and trust<br><br>Equity of access due to cost<br><br>→↑FHS risk in socioeconomically disadvantaged<br><br>Food fraud driven by lucrative markets<br><br>→presence of undeclared allergens→consumer risk<br><br>Unintended consequences of innovations for FHS e.g. potential for cross-contamination, (re)emerging risks |

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| | Science developments such as easier genomic analysis linked to nutritional profiling; interest in influence of microbiome<br><br>Increased interest in “unusual” foods<br><br>Increased interest in potential for nanoparticles in food, supplements instead of fresh food<br><br>Biobased/Integrated sensing packaging developments<br><br>Products to help FHS sufferers – e.g. lactase to allow dairy consumption<br><br>New tech to “grab” allergens from foods – personalised removal at point of consumption? | Trajectory of standards in new trading relationships post Brexit<br><br>Further disconnect of consumers understanding food system from “techno” driven decisions/buying<br><br>More/less potential for cross contamination depending on type of innovation<br><br>Ability of regulation to keep pace with developments – potential barrier to innovation? |
| **Data/digital** | Seeing increasing (particularly through pandemic) digital awareness, availability and sharing – and tools to support such as distributed ledger<br><br>AI developments driving new possibilities e.g. Amazon supermarkets, lifestyle related apps, new pathways to access to food, predictive algorithms for risk assessment and risk management<br><br>Rise of self-reporting/citizen science<br><br>Developments in mobile/smart technology to analyse/present information e.g. Fitbits, apps, smart devices etc | Assuring data quality, standards, security and sufficiency – fitness for purpose<br><br>Maintaining currency/relevance of data related to end users<br><br>Good connection/flow of data across supply chains<br><br>Data integration/interconnectedness challenges<br><br>“Fake” news in a digital world – trust issues. How to discriminate good from bad? ↑ mistrust/confusion<br><br>Regulatory challenges – models/framework to help manage risks? |

| | | |
|---|---|---|
| | Lessons to learn from COVID-19 related data issues? | New actors in food chain – their ability/competence to understand relevant data and risks]<br><br>Seeing move from FHS related developments towards wellness – seen as less risky legally - ?more complexity for regulator]<br><br>Behavioural sciences need to be more integrated into thinking/developments<br><br>Opportunities for post market surveillance to improve transparency/trust<br><br>Radical transparency supporting all consumer needs, not just FHS?<br><br>Face recognition alerts to FHS customers e.g. entering a restaurant. Also creates “nudges” to FHS customers to exercise caution - privacy issues?<br><br>Eventually don’t focus on the 14 allergens – QR reader that highlights risks or next gen smart label – removes issues of label legibility - opportunity for ↑information quality and access for consumer |
| **Behaviour/ Needs** | AI/technology developments fuelling consumer power/responding to consumer needs<br><br>Young people as drivers of change e.g. teenager books on managing allergies | (Mis) information – need to build trusted sources<br><br>Online filters to support decision making with regard to FHS<br><br>If desensitisation successful (or FHS incidence reduces due to lack of exposure in pandemic) – impact on market drivers to address – ?less interest in addressing issues with negative consequence for consumers] |

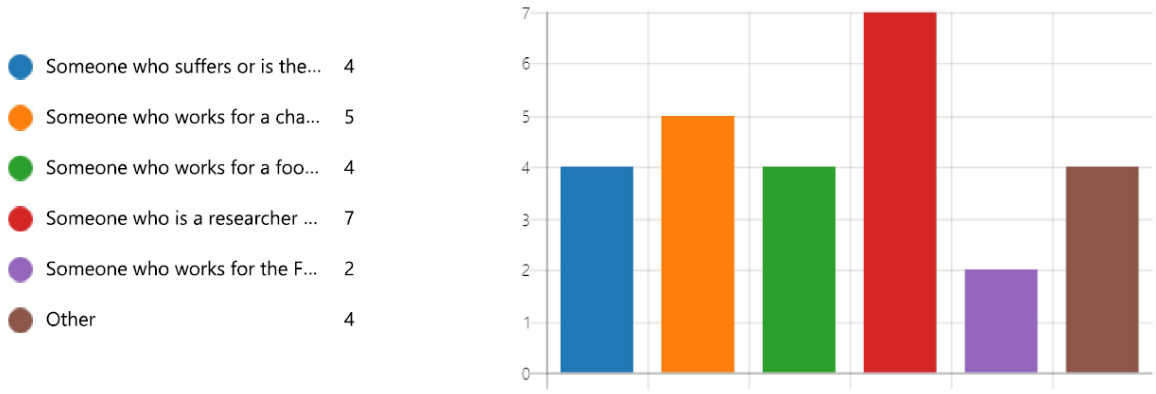
| | | |
|---|---|---|
| | Advances in desensitisation programmes creating consumer demand for products e.g. current trial on peanut in toothpaste<br><br>Drive to put develop products to assist development of tolerance in infants<br><br>New types of products on market e.g. targeting boosting immunity<br><br>More diversity in the marketplace (including pandemic related innovations ) - New ways to access food e.g. online, kits etc, Climate change/sustainability drivers for supply/diet changes, Increasing popularity of vegan and other diets<br><br>Impacts of social media/apps/data on consumer behaviours<br><br>Levels of food literacy/ownership by consumers, especially FHS, to select personal diets | Regulatory challenges, particularly in a rapidly changing/evolving environment – what/how much should be regulated? - a regulatory management risk with risk of ↓trust of consumers and FBOs<br><br>Communication challenges - how to ensure best info in diversifying marketplace - risk of miscommunication but opportunity for regulator?<br><br>Learning from COVID-19 experience – e.g. on behaviours<br><br>New actors in food chain – their ability/competence to understand relevant data and risks - risks but also opportunity if new actors deploy new effective tools to respond to FHS<br><br>Economically driven increase in food risk taking – can risk be managed more effectively using tech<br><br>Health care providers awareness of (changing) FHS risks and how to advise their patients (?could impact on FSA objectives?)<br><br>Decreasing/absent food education is schools – makes messaging more challenging – social media, not science will take lead |

Note that while entries have been categorised under 2 headings of drivers/evidence and risks/opportunities, a number of entries could have easily fitted under either heading.

## ANNEX F: FEEDBACK FROM STAKEHOLDER REPRESENTATIVES ATTENDING PSE

Total Number of Respondents = 19

Q1. Are you ...? (Please select all that apply)




Q2.

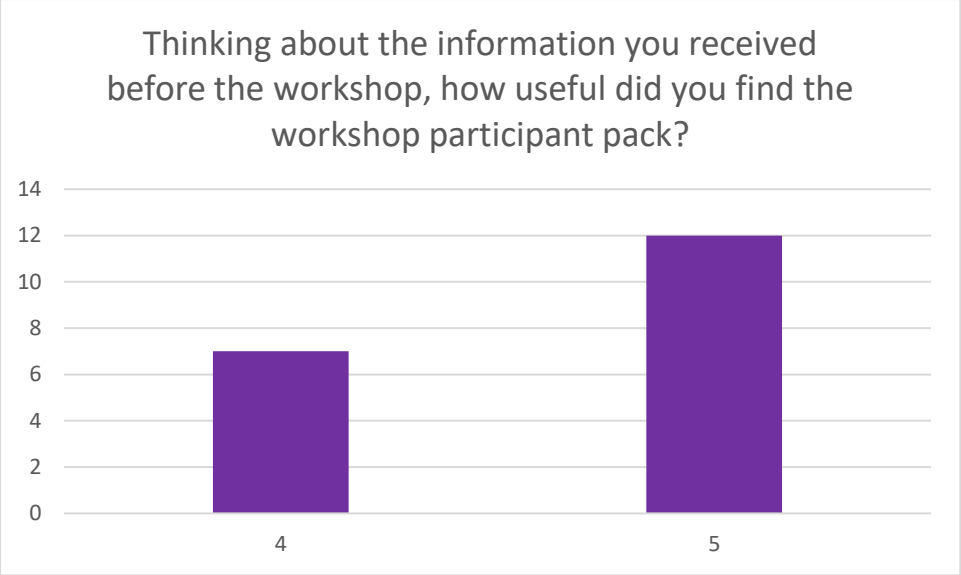
1. I was very happy with this list and with the compromise to have a joint 10th place. Myself and others found it very hard to exclude any of these things from the top 10.
2. It is clear that the questions can be grouped into those that are largely based on communication (broadly how do we communicate the risk) and knowledge building (what is the risk and how do we lower it). The top 5 (with the possible exception of 3) are the former group and the bottom 5 (6) being the latter group. Is this a reflection of the balance of stakeholders present? Does it also suggest that the strategy should be more based on communication than fundamental research? Not an outcome I would like to see.
3. I agree with these.
4. I am broadly content with the above list and would like to expand on certain aspects: 7.B: new/novel foods and/or processes. Detailed research may not be required as there is a process in place to assess novel foods and processes. Novel foods, novel food ingredients and certain novel processes are regulated by Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 which introduces a centralised authorisation procedure with EFSA conducting the scientific risk assessment and also introduces a notification procedure for traditional food from third

countries. The EU law, which has been transcribed into UK law in UK Exit, is implemented by the Novel Foods (England) Regulations 2018 (with devolved equivalents). An applicant to place a novel food or process on the market must provide documentation on the procedure and strategy followed when gathering the dossier data, along with a description of the safety evaluation and toxicological testing strategies, and justify the inclusion or exclusion of specific studies or information. An important aspect that must be covered is the potential allergenicity. The FSA Advisory Committee on Novel Foods and Processes (ACNFP) also makes an assessment. Thus, a procedure is already in place to address potential food hypersensitivity issued associated with novel foods and processes. There are three aspects that should, however, be noted: (1) novel food packaging materials may include allergens or foods such as wheat flour that may pose a risk for people with coeliac condition and this aspect should be drawn to the attention of the Committee on Toxicity, particularly the Joint Expert Group dealing with food contact materials; (2) a separate process may be required to assess emerging allergens not currently included in the Annex II list to the Food Information Regulation 1169/2011 on the provision of food information to consumers; and (3) as more plant based foods appear in the supply chain to replace meat based foods, a process may be required to assess any added impact on food hypersensitivity risk. 10. E: Alerting FSA to incidents. Two aspects require action (and thus may not require research): (1) Deaths and serious near misses must be alerted to FSA with minimum delay; a process similar to that in the RIDDOR - Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013 [check current version] and (2) published FSA guidance is needed supporting consumers to report in an easy and straightforward manner any emerging food hypersensitivity risk in the food chain, i.e. food already on the market.

5. The final list was derived following robust, but very collegiate discussion. very well managed and well facilitated. My top 4 survived the cut which is nice
6. I believe this is a relevant range of research topics covering a variety of aspects which ultimately seek to improve lives of food allergic consumers. The only topic which I wished had made it to the original list is the topic was allergen thresholds and allergen labelling.

7. For O, the most important part of this question is researching how the level of existing knowledge can be improved. Research is not needed into the level of knowledge, we know that that is poor. Knowing how best to improve it is vital, and should be higher up the order of 1-10. As per the feedback in the final discussion session on Tuesday I do not think research is needed into G, it is covered by existing activities and standards. Research is certainly needed into E - particularly for gathering near miss knowledge from catering and home environments - an App to report such things? This is essential otherwise it is fatalities that are reported that might effect change - that is far too late for the person who has died and their family. It is a moral imperative to have reduced the risk of death from food hypersensitivity through alerting the FSA to instances and then for the FSA to act.
8. I think there was a very good level of agreement on this list of priorities, aside from the difficult choice between G and E; including both seems a reasonable compromise.
9. I think this strikes the right balance between short term must have answers and longer term projects that are important for better understanding of the issues surrounding food allergy and ultimately, its prevention.
10. There appears to be quite a lot of overlap between priorities I, D, & F
11. An interesting discussion and good to hear the views of other interested participants.
12. While this was a challenging process, I felt that the final 1-10 (x2) was reached through good discussion and strong consensus.
13. It is important to differentiate between topics attracting frequent attention as FAQs (and may have an education/communication solution) e.g. “I” food labelling (as is much improved nowadays) and issues that may have less “voice” in the public domain but have important unanswered questions on its application which have huge impact (eg “M” cofactors which alone has been researched but how it is then used to make decisions eg threshold labelling or desensitisation treatment protocols) should not be forgotten when prioritising.

Q4. Thinking about the information you received before the workshop, how useful did you find the workshop participant pack?


Thinking about the information you received before the workshop, how useful did you find the workshop participant pack?
14
12
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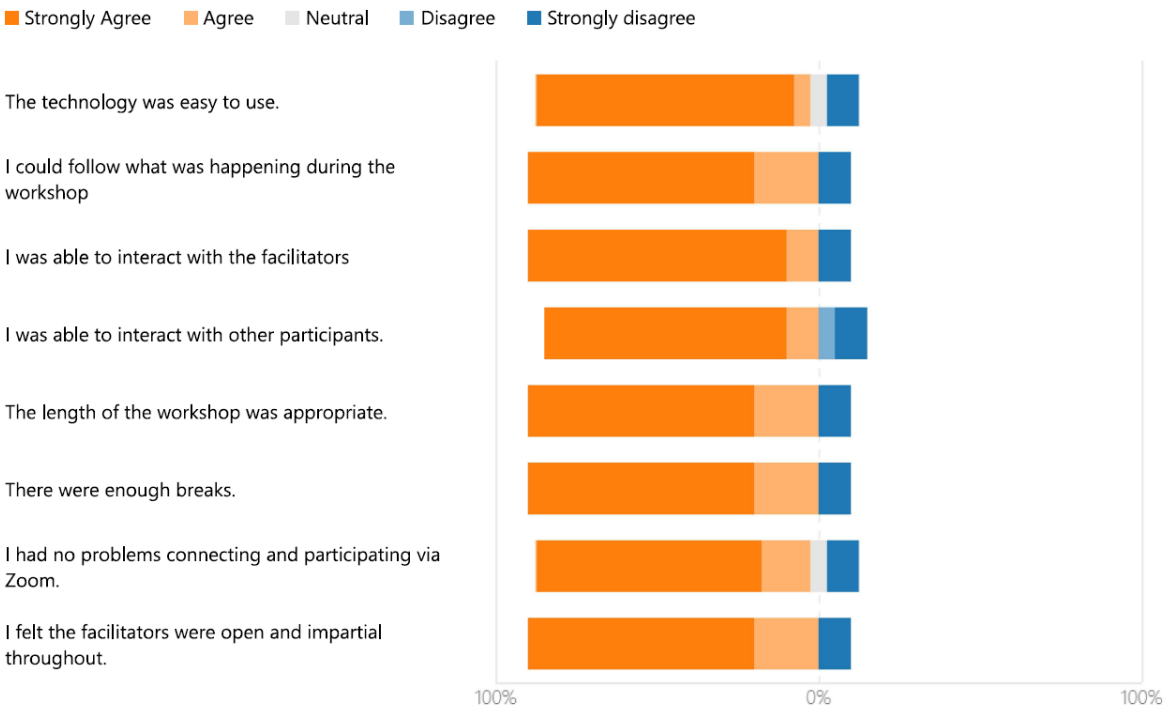
Q5.


Strongly Agree
Agree
Neutral
Disagree
Strongly disagree
The technology was easy to use.
I could follow what was happening during the workshop
I was able to interact with the facilitators
I was able to interact with other participants.
The length of the workshop was appropriate.
There were enough breaks.
I had no problems connecting and participating via Zoom.
I felt the facilitators were open and impartial throughout.
100%
0%
100%