Food Standards Agency
Science Council – 24/06/2020 **Ref. SC 7-6**

Update on Working Group 5

Paper by Paul Turner, John O'Brien and Alisha Barfield

For further information contact Alisha Barfield on 07388 854689 (Mob)

Email: Alisha.Barfield@food.gov.uk

Contents

Update on Working Group 5 1

1. Summary 1
2. Introduction 2
3. Discussion 3

Annex 1 - Working Group 5 Workplan overview 7

Annex 2 – Science Programme Review Checklist 8

Annex 3 - Priority Setting Exercise Scoping Document 20

Annex 4 - Priority Setting Exercise Survey 28

1. Summary

1.1 This paper outlines progress against the work plan as well as the mitigations due to COVID-19 for Working Group 5 on food hypersensitivity as agreed by the Science Council in December 2019.

1.2 The Science Council is requested to discuss and endorse the current progress and future workplan for Working Group 5 on food hypersensitivity.

This includes:

- Work Package 5.1 and 5.3 – Research programme review and best practice review including case studies.
- Work Package 5.2 -Priority Setting Exercise
- Work Package 5.4 – Literature review of the Top 10 priority areas identified from the PSE.
- Work Package 5.5 – Horizon Scanning.

2. Introduction

2.1 The FSA is reviewing its strategy on food hypersensitivity (food allergy and intolerance) to ensure it has access to the best available science and evidence to support the delivery of appropriate and effective actions so consumers can make safe and informed food choices.

2.2 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.”

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

- Conduct a review of the science and evidence base for addressing food hypersensitivity
- Consider and advise on future research priorities and direction in respect to food hypersensitivity.
- Advise on the role the FSA should play to enhancing scientific knowledge.

2.4 At the Science Council’s open plenary meeting of June 2019, it was agreed to establish a new Working Group 5 to assess food hypersensitivity (FHS) issues in response to the request from the Board. The Working Group presented and agreed the following workplan at the Science Council open meeting in December 2019 (Annex 1):

- Review the FSA’s allergy and intolerance research programme utilising a research question checklist. This will include a review of the 2008 and 2012 research programme reviews. (WP5.1)
- Identification of the Top 10 priority areas in food hypersensitivity using an adaptation of the James Lind Alliance methodology for the priority setting exercise (PSE). (WP5.2)
- Review of the FSA working practices in food hypersensitivity. An end to end audit from evidence generation to utilisation of evidence in policy to broader strategy setting. (WP5.3)

- Literature review of evidence underpinning the Top 10 priority areas in food hypersensitivity as identified from the PSE. (WP5.4)
- Identification of future priorities in the 5-15-year timeframe through a horizon scanning workshop. (WP5.5)

2.5 An update on Working Group 5 will be provided at the FSA Board meeting on 16th September 2020 with a final report due to be presented to the FSA Board in June 2021.

3. Discussion

3.1 Progress on work packages 1, 2 and 3 as per the agreed timeline and has been relevantly free from impacts of COVID19.

3.2 **Research Programme Review (WP5.1)** The Working Group have contracted an independent expert, Dr Alisdair Wotherspoon to complete a desk study on the FSA's allergy and intolerance research programme, also looking at the implementation of previous recommendations from reviews held in 2008 and 2012. A checklist was utilised to support this review. (Annex 2). This review has been completed and the findings shared with the Working Group. These findings have also been discussed with Prof. Ian Kimber (Emeritus Professor of Toxicology at University of Manchester) to provide further legacy knowledge in his role as the External Programme Advisor to the allergy and intolerance research programme. The recommendations and findings of this work package will be presented in the report presented at the FSA's Board meeting in September 2020.

3.3 **Priority Setting Exercise (WP5.2)** The FSA and Working Group 5 have developed a Priority Setting Exercise (PSE) process inspired by the James Lind Alliance Priority Setting Partnerships methodology (Annex 3). The PSE is comprised of a public survey (Annex 4), data analysis and prioritisation workshop. The Council is asked to review progress and endorse the following:

- The "FSA Survey: Improving life for people with Food Hypersensitivity" was launched on 20th February and has been communicated to over 250 individual stakeholders/organisations *via* social media channels such as Twitter, LinkedIn, Facebook. The survey closed, earlier than anticipated due to COVID-19, on 26th March.

- The survey asked for responses questions under the following five thematic areas:
    i. Eating out
    ii. Pre-packed food,
    iii. Handling and understanding food,
    iv. Changes in how we interact with food
    v. Improving what we know about food allergy and food hypersensitivity.
- The survey was directed to stakeholders in the general public, food businesses, patient groups /charities, healthcare workers, academics, local authorities and professional bodies.
- At the January 2020 FSA Board meeting, the following themes were emphasised as core objectives for the developing FSA strategy for food hypersensitivity: safety, trust and choice. The PSE survey was highlighted at the meeting as a key component for the development of an evidence base and understanding for the strategy. It was further noted that this survey was particularly valuable because of its wider stakeholder consultation. The PSE was also mentioned at the March 2020 FSA Board as one of the activities being undertaken as part of the FHS programme.
- Ipsos MORI were commissioned by the working group to analyse the ~300 responses received from the survey. The first round of analysis has been undertaken and presented to the working group as well as other FSA stakeholders in allergy and social science. The working group has identified which of these questions would be in/out of scope for the FSA. Ipsos MORI will be finalising a list of 20-25 questions that will be taken forward into a 2-day PSE workshop.
- The PSE workshop was due to take place on 1st and 2nd July during which a range of interested FHS stakeholders were to be asked to prioritise this into a top 10 of research questions for the FSA to address. The working group considered using alternative methods such as online collaborative tools to

convene discussions. However, it was agreed that due to the complexity of the exercise, the richness of discussion may be lost and breakout sessions hard to manage through online discussions. Until the current Government guidance allows for such a meeting to take place, the PSE has been postponed.

3.4 A review of best practice (WP5.3)

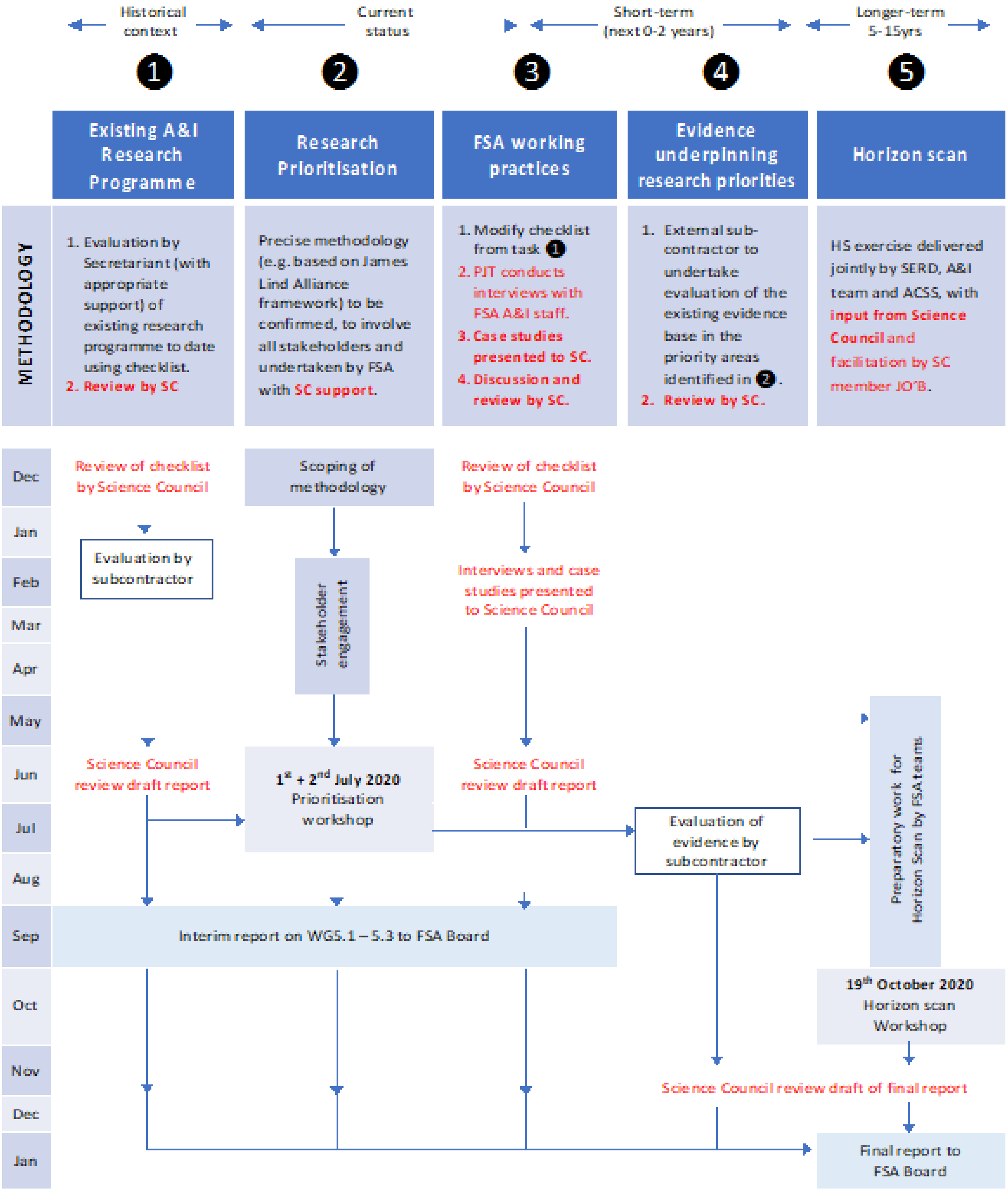
- Several interviews with current and previous FSA staff were held throughout February and March within allergy science and policy.
- A workshop was due to take place on 19-20th March to review these findings but this was moved to an online meeting instead, at which Dr. Alisdair Wotherspoon, Prof. Ian Kimber and Julie Hill provided input.
- In tandem three best practice case studies on existing and historical FSA projects relating to food hypersensitivity have been produced and are under review. These will be presented to the Council at a later meeting in July.
- A final report combining the findings of the WG5.1 and WG5.3 pieces of research will be presented to the Council prior to the FSA September 2020 Board meeting.

3.5 The **actions that have been taken to mitigate the impact of COVID-19** on the working group are as follows:

- WG5.1& WG5.3 – No significant changes as most of the work has been delivered to the original timetable.
- WG5.2 – The Priority Setting Exercise due to take place on 1st/2nd July has been postponed until the FSA is able to host face to face meetings.
- WG5.4 –Until the PSE is able to take place, a literature review of the top 10 research questions has been postponed.
- WG5.5 – A cross-stakeholder horizon scanning workshop set for 19th October to coincide with an international food allergy conference (15-17 October, Manchester is currently under review due to COVID19.

- Overall – Delivery of the paper to September 2020 FSA board on WG5.1 and WG5.3 is still due to be presented. The final WG5 paper will be presented at June 2021 Board instead of March 2021.

Annex 1 - Working Group 5 Workplan overview



	Historical context ❶ Existing A&I Research Programme	Current status ❷ Research Prioritisation	Short-term (next 0-2 years) ❸ FSA working practices	❹ Evidence underpinning research priorities	Longer-term 5-15yrs ❺ Horizon scan
METHODOLOGY	1. Evaluation by Secretariant (with appropriate support) of existing research programme to date using checklist. 2. Review by SC	Precise methodology (e.g. based on James Lind Alliance framework) to be confirmed, to involve all stakeholders and undertaken by FSA with SC support.	1. Modify checklist from task ❶ 2. PJT conducts interviews with FSA A&I staff. 3. Case studies presented to SC. 4. Discussion and review by SC.	1. External sub-contractor to undertake evaluation of the existing evidence base in the priority areas identified in ❷. 2. Review by SC.	HS exercise delivered jointly by SERD, A&I team and ACSS, with input from Science Council and facilitation by SC member JO'B.

Annex 2 – Science Programme Review Checklist

Science Programme Review Checklist

The Science Council Working Group 5 (WG5) on food hypersensitivity has been tasked with two core objectives:

(1) Consider and advise on future research priorities and direction in respect to food hypersensitivity.
(2) Conduct a review of the science and evidence base for addressing food hypersensitivity, and the part the FSA and others should play in enhancing knowledge.

To address each objective, WG5 have outlined a number of work packages that seek to gather a historical context/review, review the current research programme and *modus operandi* within the FSA, and identify emerging priorities in the 5-to-15-year timeframe.[1]

Relating specifically to objective (2) the Science Council will work with the FSA to:

- Evaluate the impact of science on FSA policy in the area of food hypersensitivity
- Advise as to the key issues in this area, to support the FSA's decision-making in the future
- Provide advice and challenge on how the FSA identifies, gathers and uses scientific evidence and advice in the area of food hypersensitivity

The FSA has defined science governance as *'the methods by which we assure and demonstrate that scientific evidence and analysis are sought, obtained, interpreted, used and communicated appropriately and effectively by the FSA'.* The FSA's approach to science assurance was set out in its response[2], the Science Checklist[3], to the recommendations from Science Council Working Group 1 on science capability and Assurance, agreed by the FSA Board in December 2018.[4]

Inspired by The Methods Lab approach[5] and the FSA Science Checklist, WG5 has developed a modified framework by which the FSA research programme surrounding food hypersensitivity will be reviewed for best practice surrounding the commissioning, management and utilisation of the research programme.

---

[1] https://science-council.food.gov.uk/science-council-subgroups/science-council-working-group-on-food-hypersensitivity (Accessed 14/01/2020)

[2] https://www.food.gov.uk/sites/default/files/media/document/fsa-18-12-09-sc-wg1-capability-assurance-final_0.pdf (Accessed 14/01/2020)

[3] https://foodgov.sharepoint.com/sites/SCIChiefScientificAdviserTeam/Shared%20Documents/DWP%20Development/Updated%20Science%20Checklist%20Feb%202016%20-%20final.docx (Accessed 14/01/2020 - Internal)

[4] https://science-council.food.gov.uk/science-council-subgroups/science-council-working-group-on-science-capability-and-assurance (Accessed 14/01/2020)

[5] Pasanen, T., and Shaxson, L. (2016) 'How to design a monitoring and evaluation framework for a policy research project'. A Methods Lab publication. London: Overseas Development Institute.

The checklist presented below should be utilised to support desk studies, 1-to-1 interviews and group consultations on the FSA’s internal organisation of a research programme. It will initially support a review of the FSA food allergy and intolerance research programme as a component of WG5.

The questions are intended to gather understanding of the decision-making process in commissioning, project management and dissemination of outputs etc within the research programme. Section 2 (management and governance) is a two-tiered approach with the aim to differentiate between higher-level programme, and individual project level management analyses. Not all of the points in the checklist will be relevant for all research projects, proposals and papers, however, every endeavor should be made to address the questions in the checklist.

Science Programme Checklist

1. Strategy and direction:

1.1. How were individual research gaps identified, to inform the aims and objectives of the Research Programme? 1.2. What measures were taken to ensure this process was transparent?	What inputs were obtained? e.g. comprehensive and structured literature review? Review of “grey” literature? Stakeholder engagement? External advisers? Other sources e.g. surveillance or enforcement, or unpublished data from government, industry? Were all key scientific uncertainties, including gaps in the analyses and strength of the evidence, highlighted and expressed clearly? What processes were followed to assess this? e.g. GRADE Evidence to Decision frameworks or equivalent. Relevant documentation: Programme reviews, Reports, other key documents Subsequent workshops and meetings with stakeholders Discussions on steering group or management meetings
1.3. Stakeholder engagement	Who was engaged, and were they the right stakeholders? How was this reviewed on a regular basis, to capture new inputs (e.g. from early-career researchers; non-academic inputs)? e.g. Stakeholder analysis/social network analysis, stakeholder mapping What elements of the programme did stakeholders contribute to? e.g. identifying research gaps, methodology, communication of tender calls

	How and when were the identified stakeholders engaged in the decision-making process? Were iterative approaches (e.g. sandpits, validated frameworks) considered when commissioning work in new research areas? Please give details
1.4. Was there a strategic document which laid out the strategy and direction of the programme?	What did the document define with regard to research need, objectives, desired outcomes and policy change recorded to set / agreed? When was this reviewed? Was there a trigger for any review? How was it reviewed? Who reviewed this? How did this align the research programme to the FSA's strategic objectives / priorities?
With respect to specific projects: 1.5. What processes were followed by drafting research specifications and evaluating tender bids?	What guidance was followed for drafting research specifications and/or evaluating the research bids submitted?
1.6. How did the tender call evolve from the original research gap(s) identified?	How were these research questions/tender specifications informed by internal and external review?
1.7. Was there a clear rationale for the research commissioned, in terms of planned impact on FSA policy?	Did the commissioned research directly address the identified research gap in the most cost-effective way?

2. Management and governance

	Programme	Projects
2.1. Was the agreed programme realistic in terms of set-up, timing, staffing and resources?	Were there internal FSA capacity issues, and how were these addressed? Issues with staff turnover? To what extent were outputs from the overall programme completed on time and to budget? How were risks of delivery identified (and managed)? What was the effectiveness of countermeasures put in place? (To what extent did risks not materialise?)	From the perspective of contract managers working with the project delivery contractor: To what extent were deliverables completed on time and to budget? Were there capacity issues within contractors' teams, and how were these addressed? (Capacity relates to finance, human resources, expertise etc.) Problems with staff turnover? How were risks identified and managed? What was the effectiveness of countermeasures put in place, and were these described upfront at tender?

		To what extent did risks not materialise?
2.2. How was the relationship fostered between the FSA and interested stakeholders?	How were stakeholders engaged? How was insight and information shared to shape the programme? Were their clear descriptions for different non-contractor roles within the programme?	How were tender partners engaging and sharing information among themselves? Was there clarity over the roles of non-contractors in individual projects? e.g. independent Data Monitoring Committee (IDMC), Trial Steering Committee (TSC) Did the scope and depth of collaboration with and between tender partners increase since the programme inception? If not, why?
2.3. How were decisions made, with what criteria, and how were they documented?	Were any decisions made consistent, inclusive and transparent? What processes were in place for documenting and learning from experiences and adjusting to changing context?	Were any decisions made consistent, inclusive and transparent? What governance systems were in place, and were they as effective as they could be?

	Frequency and nature of internal review and challenge of the programme objectives against FSA objectives and priorities? What assurance and governance was completed during the decision making process and the resultant research outputs?	What processes were in place for documenting and learning from experiences and adjusting to changing context? How often were project reviews undertaken by FSA, and what format did these take? What assurance and governance was completed during the decision making process and the resultant research outputs?
2.4. Did the project compliment the aims of the wider research programme and FSA strategy?	How were funded projects prioritised against other proposed projects that were not funded? How was the research portfolio regularly review against FSA objectives?	Did the project compliment the aims of the wider research programme and FSA strategy?

3. Outputs

3.1. What review of the data was undertaken?	Internal FSA review by specialists, External peer review Was the scientific evidence base transparent to stakeholders? Is the extent to which judgement has been used clear? Are the conclusions consistent with the published evidence? How were areas of uncertainty handled? Are there any alternative interpretations of the same evidence?
3.2. What outputs were generated? 3.3. How does this compare to what was planned?	Was the output type appropriate? e.g. Project reports, conference presentations, publications, blogs, infographics, films etc. What peer-reviewed journal articles (or similar) were published or directly generated by the research project in open access formats? Are data available for sharing? Other outputs: capacity building etc.
3.4. Are the outputs relevant to the context in which the research was originally commissioned?	Do the outputs identify what the real issue is that end users face?

	Are the outputs structured in a way that enhances the main messages? Can target audiences access the outputs easily and engage with them? To whom have outputs been sent, when and through which channels?

4. Uptake and impact:

4.1. What outputs have been used by stakeholders, and how?	What metrics were collected to analyse the uptake of outputs? E.g: citations, downloads, altmetrics Were data made accessible for FSA and non-FSA stakeholders? Is there evidence of translation into policy: FSA (internal) / national / international?
4.2. To what extent has the research influenced policy?	What impact did the research have on legislation, guidelines, advice, resource allocation etc. in the UK and internationally / plans in pipeline? Any unintended impacts? What was the strength of the commissioned evidence? How was this assessed? Did any areas of uncertainty identified during this process match those identified in the original outputs? To what extent was a need for further research identified? Has the research led to capacity development/acted as a catalyst for further research?

4.3. To what extent has research shifted public agendas?	Did the research result in any of the following being generated? - Media items (traditional press media, radio, tv interviews / items etc) - Discussions on social media - Stories of change - Attitudinal / behavioural change?
4.4. What longer-term results have been achieved?	Is there monitoring in place for longer term trends/surveillance data? What type of changes have been observed in target groups behaviour? How sustainable are observed changes likely to be?

5. Review and learning mechanisms

5.1. How has the success and impact of the research been reviewed? 5.2. What would trigger a review of any decisions made?	Did the Programme deliver as intended? Were the objectives addressed by the projects commissioned and the outcomes delivered? How was success and impact measured? – was this an Internal and/or external review? Who was involved in the review of the research programme? When was a review held? What points were assesses and discussed at the review? How were the findings from the reviews recorded and shared? Did this impact on further resource allocation?
5.3. What mechanisms have been put in place to ensure changes are implemented in the future?	Was a plan put into place to implement recommendations coming out from review and learning mechanisms? Who was involved in this? Was a time line agreed? When was a review of implemented change held?

Annex 3 - Priority Setting Exercise Scoping Document

Food Hypersensitivity and Intolerance Priority Setting Exercise

PROTOCOL 12/12/2019[6] Version 1[7]

1. Purpose of the PSE and background

The purpose of this protocol is to clearly set out the aims, objectives and commitments of the Food Hypersensitivity Priority Setting Exercise (PSE) is inspired by the James Lind Alliance (JLA) method and principles. The Protocol will be published on the Working Group 5 Science Council Webpage. The Project Group will review the Protocol regularly and any updated version will be available on the Food Standards Agency Science Council website.

The JLA is a non-profit making initiative, established in 2004. It brings patients, carers and clinicians together in Priority Setting Partnerships. These PSPs identify and prioritise the evidence uncertainties, 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.

The FSA is a non-ministerial Government department working across England, Wales and Northern Ireland to protect public health and consumers' wider interests in food. We make sure that food is safe and what it says it is. The FSA inspired by the PSP process will complete a Priority Setting Exercise (PSE) on Food Allergy and Intolerance (which together constitute “Food Hypersensitivity”). The PSE is similar to the PSP in that it will identify and prioritise the evidence uncertainties, or ‘unanswered questions’, that they agree are the most important for research in their topic area, however, the stakeholders to gather these uncertainties will expand beyond patients are carers but to industry, consumer groups, regulators *etc.* The method by which the PSE will be completed is similar to that of the PSP; a stakeholder consultation will be completed to gather evidence uncertainties, an analysis and grouping of complimentary uncertainties and finally a prioritisation workshop. This PSE has been initiated by the FSA Science Council who will have an oversight and assurance role throughout.

The FSA Science Council is an independent expert committee of the Food Standards Agency (FSA), comprising a Chair and up to seven members. It provides high-level, expert strategic insight, challenge and advice to the FSA’s Chief Scientific Adviser (CSA) and to the Board and executive of the FSA on the FSA's use of science to deliver FSA objectives. Its purpose is to help to ensure that the FSA identifies, sources, integrates and uses the best scientific evidence and expertise from all relevant

---

[6] This protocol template should be modified with agreement from the PSE Adviser to reflect the make-up of different PSPs/PSE and the organisations driving them.
[7] The Project Group is responsible for ensuring any updates or amendments to the PSE plan are included in subsequent versions of the Protocol for publication on the Science Council website.

disciplines to inform and evaluate its work. FSA defines science in a broad and inclusive way, including the natural, physical, social and economic, digital and data sciences. The Council is constituted to work at a strategic level working across and bringing together insights from different disciplines. The Council forms a core group which is able to identify and to draw in wider inputs across relevant disciplines and perspectives to address the issues at hand. Its members work across disciplines, think strategically, and understand how science can be used to influence and test policy and to achieve concrete impacts to benefit people.

The PSE on Food Hypersensitivity is a component of the Science Council Working Group 5 and includes a number of complimentary activities on this topic area including a review of historical research performance within the FSA and a horizon scanning activity that will look for priorities in the 5-to-15-year timeframe. Full details on Working Group 5 are available on the FSA Science Council website.

2. Aims, objectives and scope of the PSE

The **aim** of this PSE is to identify and prioritise the current knowledge gaps in providing safe food to individuals with Food Hypersensitivity in the UK from key stakeholder perspectives.

The **objectives** of the PSE are to:

1. work with consumers (both allergic and non-allergic), healthcare professionals, regulators, industry and wider stakeholders, to identify current knowledge gaps for the FSA in providing safe food to individuals with Food Hypersensitivity
2. agree by consensus a prioritised list of these knowledge gaps for the purpose of guiding future FSA research activities
3. share the results of the PSE and process

The **scope** of the Food Hypersensitivity PSE will include:

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

The key thematic areas this PSE will seek to investigate include:

- Relevant research areas e.g. changes in the epidemiology of food hypersensitivity in the UK

- Manufactured foods (e.g. ingredients, ready-made meals from supermarkets and other shops)
- Catered foods (e.g. from restaurants, take-aways)
- Changes in consumer behaviours *(e.g.* use of food banks, reusable containers *etc*.)

Given the remit of the FSA, this PSE will not consider questions about:

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

The Project Group is responsible for discussing what implications the scope of the PSE will have for the evidence-checking stage of the process. Resources and expertise will be put in place to do this evidence checking.

3. The Project Group

The Project Group includes membership of the Science Council, FSA Science Strategy, Capability and Research, FSA Allergy Policy and FSA Allergy Science.

The Food Hypersensitivity PSE will be led and managed by a Project Group involving the following:

Science Council and FSA Science Advisory Committees Representatives:

- Dr Paul Turner (Chair of Science Council WG5)
- Professor John O’Brien (Science Council)
- Professor Julie Barnett (ACSS)
- Dr Hannah Lambie-Mumford (ACSS)

FSA Science, Strategy Capability and Research:

- Dr Adam Cook
- Dr Chun-Han Chan

Project coordinator:

- Ms. Alisha Barfield

External PSE Adviser and Chair of the Project Group:

- Ms Katherine Cowan

The Project Group will agree the resources, including time and expertise contributions, to each stage of the process. The Project Group will seek the input from the following Patient Representative Groups as needed: Allergy UK; Anaphylaxis Campaign; Coeliac UK.

4. Stakeholder Groups

The PSE will involve a broad of stakeholders and stakeholder representatives, including (but not limited to):

- 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

The PSE Project Group will ensure a balance between these difference representatives.

Exclusion criteria
We will not exclude any specific stakeholders from this PSE, however all representatives attending the Prioritisation workshop will be required to provide a full and transparent declaration of potential conflicts of interest, perceived or otherwise.

5. The methods the PSE will use

This section describes a schedule of proposed steps through which the PSE aims to meet its objectives. The process is iterative and dependent on the active participation and contribution of different groups. The methods used in any step will be agreed through consultation between the Project Group members, guided by the PSE's aims and objectives. More details of the method are in the Guidebook section of the JLA website at www.jla.nihr.ac.uk where examples of the work of other JLA PSPs can be seen.

Step 1: Identification of potential stakeholders

Potential stakeholders and organisations will be identified through a process of peer knowledge and consultation, through the Project Group members' networks. Potential stakeholders will be contacted and informed of the establishment and aims of the Food Hypersensitivity PSE. This will be based upon existing FSA networks and will be expanded into cross cutting stakeholders in social science, the charity sector *etc.*

Upon the identification of the target stakeholders' appropriate steps will be taken to ensure research ethics compliance.

Step 2: Identifying knowledge gaps

The Food Hypersensitivity PSE will carry out a consultation to gather uncertainties from stakeholders and the wider public. The consultation will take place over a period of 6 weeks (February/March 2020, which may be revised by the Project Group if required).

The Project Group recognises that there may challenges in reaching certain stakeholder groups, which could result in underrepresentation of some affected individuals, e.g. consumers under 18 years. We will therefore will use the following methods to reach the target groups:

Consumers who have a food hypersensitivity*:* An online questionnaire will be utilised, and awareness will be raised through patient groups/charities such as Allergy UK, Anaphylaxis Campaign, Coeliac UK *etc.*

- Parents will be prompted to consider whether they wish to complete the survey on behalf of any children/ in their care and be encouraged to involve their children wherever possible.
- Individuals without access to internet or with accessibility limitations: we will approach relevant charities (e.g. Age UK, Shelter, Action for Children, Trussell Trust…)

Industry*:* The same online questionnaire will be utilised and circulated through known FSA contacts which are both direct and through industry groups.

Charities*:* We will also approach charities and religious/cultural to ensure representation from those organisations providing safe food for individuals with food hypersensitivity.

We will also review the existing FSA research programme documentation in the area of food hypersensitivity with respect to previously identified knowledge gaps and research priorities.

Step 3: Formulating summary questions

The consultation process will produce ‘raw’ questions and comments indicating stakeholders’ views. These raw questions will be categorised and refined by an external data analysis company into summary questions which are clear, addressable by research, and understandable to all. Similar or duplicate questions will be combined where appropriate. Any out-of-scope submissions will be compiled separately but will not be included in subsequent PSE activities. The Project Team will have oversight of this process to ensure fairness and transparency.

This will result in a long list of in-scope summary questions. These are not research questions and to try and word them as such may make them too technical for a non-research audience. They will be framed as researchable questions that capture the themes and topics that people have suggested. These summary questions will be narrowed down to a list of approximately 20 by the Project team using clear and accountable criteria and circulated prior to the prioritisation workshop. Any questions not included will be made available to participants, along with the rationale for their non-inclusion.

Step 4: Prioritisation workshop

The aim of the final stage of the PSE is to prioritise through consensus the identified summary questions about Food Hypersensitivity. This will involve input from approximately 25 representatives from the various stakeholder groups. The workshop will consist of two phases.

1. A one-day workshop facilitated by the PSE Advisor and two facilitators. Participants will be asked to determine the top 10 questions for research for the FSA, through discussion. All participants will declare their interests. The Project Group will advise on any adaptations needed to ensure that the process is inclusive and accessible.

2. A second workshop (on a consecutive day) at which the top 10 questions will be unpacked to develop specific research questions and areas of uncertainty which the FSA can then map to existing evidence in a follow-on activity.

6. Dissemination of results

The Project Group will identify audiences with which it wants to engage when disseminating the results of the priority setting process, such as researchers, funders and the patient and clinical communities. They will need to determine how best to communicate the results and who will take responsibility for this. The dissemination of the results of the PSE will be led by Science Strategy Capability and Research Unit.

7. Agreement of the Project Group

The Food Hypersensitivity PSE Project Group agreed the content and direction of this Protocol on 15/01/2020.

Annex 4 - Priority Setting Exercise Survey

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+