

## Food Hypersensitivity Priority Setting Exercise

### PROTOCOL Feb 2020<sup>1</sup> Version 1.0<sup>2</sup>

## 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 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,

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<sup>1</sup> 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.

<sup>2</sup> 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.

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 etc.

### 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](http://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 be challenges in reaching certain stakeholder groups, which could result in underrepresentation of some affected individuals, e.g. consumers under 18 years. We will therefore 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 (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.

This will be completed in accordance with the FSA communications policy and ethics guidance.

### **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 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 12/12/2019