

REPORT FROM WORKING GROUP 5 ON FOOD HYPERSENSITIVITY

Paper by Paul A. Nunn and Dr Paul Turner

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1. Summary

1.1 This paper contains a revised Working Group 5 schedule of work and Terms of Reference for consideration by the Science Council.

1.2 The Science Council is asked to agree:

At open session

1. The revised plan of work for Working Group 5 (Annex 1).
2. Revised Terms of Reference for Working Group 5 in line with the revised plan (Annex 2).

At closed session

3. Review a checklist generated from the outputs of Working Group 1 which will be used in the review of the existing FSA Allergy & Intolerance research programme and its execution (Annex 3).

2. Introduction

2.1 The FSA is reviewing its strategy on food hypersensitivity, 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.

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:

- Consider and advise on future research priorities and direction in respect to food hypersensitivity.
 - 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.
- 2.4 At the Science Council open plenary 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 FSA Board.
- 2.5 The Terms of Reference for Working Group 5 were agreed and published on the Science Council website on 4th November 2019. These set out three areas of work, described as work packages, that the new Working Group would cover:
1. Provide oversight and assurance of an internal FSA review into the evidence base for food hypersensitivity and how this informs FSA policy.
 2. Horizon scanning of the food hypersensitivity environment to inform future FSA research and policy direction.
 3. A pilot to evaluate best practice across different areas of FSA research interest, in terms of how science influences policy/decision making.
- 2.6 This work provides an evidence base to help identify future priorities on food hypersensitivity which will influence the direction of FSA research and policy.

3. Discussion (open session)

- 3.1 Since June 2019, there have been changes in how the internal FSA review will be undertaken. Thus, there is a need to review the part of the Terms of Reference with respect to how the Science Council should support this review, and specifically provide oversight and assurance (work package 1).
- 3.2 The Working Group Chair has devised a more straightforward approach, based on the concept of:
1. a review of the FSA's previous and current research programme on Food Allergy & Intolerance (and its execution), using our previous outputs from WG1
 2. a prioritisation workshop to assess the current research priorities for FSA in protecting consumers with food hypersensitivities, which will then

facilitate an exercise to assess the evidence base relating to these priority areas. This will involve engaging external expertise to advise on this work.

3. a horizon scan workshop: as discussed in previous meetings.
- 3.3 These are all summarised in Annex 1, with specific tasks for the Science Council highlighted in red.
- 3.4 The Terms of Reference for Working Group 3 have been revised to reflect the proposed changes to the work plan and is attached in Annex 2.
- 3.5 Note that on 11th December the Working Group Chair and the Secretariat will be meeting with James Lind Alliance to discuss application of their prioritisation methodology. Timescale of delivery to be confirmed following this meeting
- 3.6 **The Council is asked to review these two documents and confirm their agreement with the changes proposed.**

4. Discussion (closed session)

- 4.1 Finally, as part of Working Group 5, a checklist of questions (Annex 3) has been prepared to provide a framework for both (i) an external subcontractor to review the existing FSA Allergy & Intolerance research programme, and (ii) to facilitate interviews with FSA staff to better understand how the existing research programme is executed, and to identify areas of best practice. This checklist has been largely drawn from the recommendations of Working Group 1 on Science Capability and Assurance.
- 4.2 **During the closed session discussion on Working Group 5 at the Science Council meeting on 17th December members are asked to discuss this checklist and agree the questions proposed.**

Annex 1

Working Group 5 Revised Plan of Work

(see included file *SC 6-5i - Annex 1 – Working Group 5 Revised Plan of Work.pdf*)

Annex 2

Draft Updated Terms of Reference for Working Group 5

**FSA SCIENCE COUNCIL WORKING GROUP TO SUPPORT FSA FUTURE EVIDENCE
NEEDS ON FOOD HYPERSENSITIVITY**

Terms of Reference – December 2019

Background

The FSA is reviewing its strategy on food hypersensitivity, 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 has 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 2019¹, the Science Council was asked by the Board to:

- I. *Consider and advise on future research priorities and direction in respect to food hypersensitivity.*
- II. *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.*

The remit of the Science Council is to work with the FSA to:

- Help to ensure that science has impact through advising on how the FSA can deploy the best evidence and advice to identify key issues and to support the FSA’s decision making now, and in the future.
- Help the FSA to identify and access wider, external expertise and evidence relevant to FSA’s objectives.
- Advise the FSA on how it should address issues of strategic importance to the FSA that are not covered by an existing Scientific Advisory Committee, or which relate to general principles.
- Provide advice and challenge on how the FSA identifies, gathers and uses scientific evidence and advice.

At the Science Council Meeting on 27th June 2019², the Council agreed that it is within their remit to support FSA activity on food hypersensitivity and proposed that they should form a new ‘Working Group on Food Hypersensitivity’ (WG5), chaired by Dr Paul Turner. Dr Turner has existing involvement in the FSA’s work on food hypersensitivity (his interests and how they will be managed are set out in the Annex to these ToR).

Approach

¹ <https://www.food.gov.uk/about-us/fsa-board-meeting-may-2019>

² <https://science-council.food.gov.uk/science-council-meetings>

The Working Group will oversee a programme of work to evaluate the Research Programme commissioned by FSA in food hypersensitivity – historically, the current programme and in the future – as outlined below.

1) Provide oversight and assurance of an internal FSA review into the previous and existing FSA research programme for food hypersensitivity (WG5.1)

- i. As part of its activities in 2017/18, the Science Council recommended the FSA “develop a framework to be used for assurance of FSA’s access and use of science”. This is in development by the Science, Evidence and Research Directorate (SERD).
- ii. The Science Council is able to support SERD in providing scientific oversight and assurance of a review into the existing FSA research programme for food hypersensitivity and how this has informed FSA policy.

2) Research prioritisation and existing evidence

- i. The Science Council will support FSA in undertaking a Research Prioritisation exercise involving all relevant stakeholders to identify current priorities for research to support FSA in providing safe food for all consumers, including consumers with food hypersensitivity. (**WG5.2**)
- ii. This will identify the current and short-term research priorities for FSA, for which FSA will then undertake a comprehensive and systematic review of the literature to evaluate the current evidence base relating to these priority areas. (**WG5.4**)
- iii. The Science Council is able to support SERD in providing scientific oversight and assurance of this process.

3) A pilot to evaluate best practice across different areas of FSA research interest, in terms of how science influences policy/decision making (WG5.3)

- i. This would seek to evaluate areas of best practice across different FSA teams in terms of how scientific peer-review is accessed and used, and subsequently informs both policy and future research. We will look to develop recommendations to assist the lateral transfer of best practice across the FSA, without getting directly involved in operational activities.
- ii. In the first instance, this would include structured interviews and case study presentation from FSA staff working in the Allergy & Intolerance area, which can then feed into the internal review mentioned above. However, depending on progress, this could then be expanded to include different FSA teams that undertake significant research programmes (e.g. Microbiological and Chemical Risk Assessment Teams) to evaluate existing processes.
- iii. Specific lines of enquiry are likely to include:
 - a) How does FSA use external evidence, including peer-review and external experts?
 - b) How does FSA survey the research landscape within a specific area (with focus on non-FSA commissioned activities) and identify other potential partners / the need to commission its own research?

- c) How can internal communications within FSA about research programmes be optimised for maximum impact and efficiency?

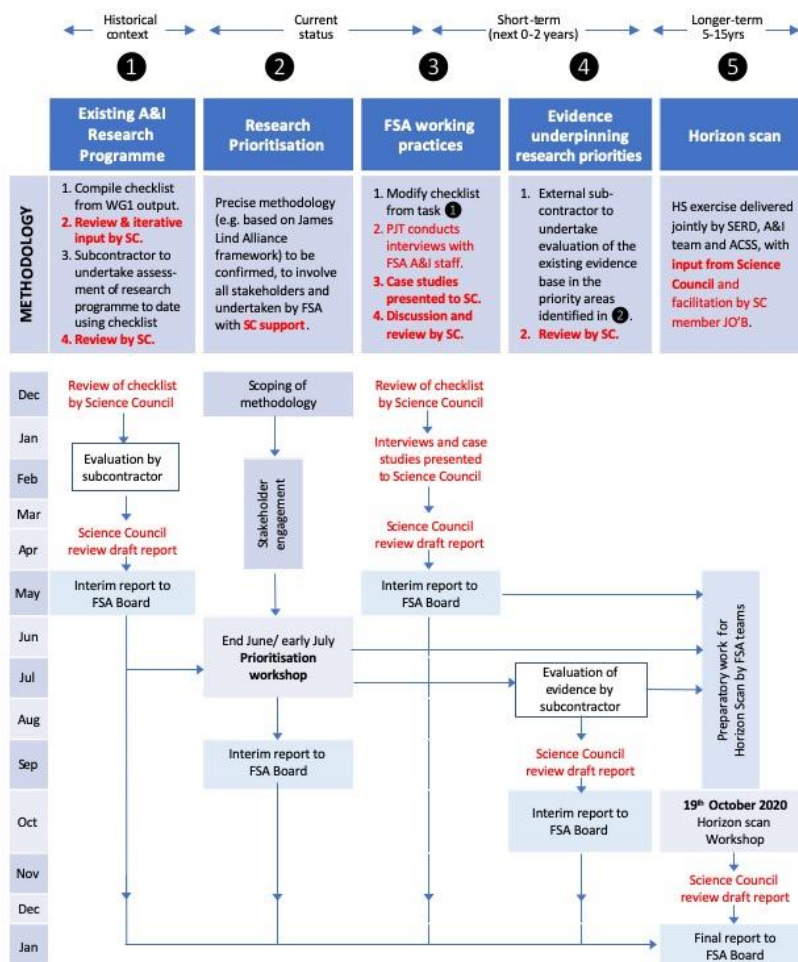
4) *Horizon scanning of the food hypersensitivity environment to inform future FSA research and policy direction (WG5.5)*

- i. The Science Council Working Group on Horizon Scanning (WG3) reported its recommendations on what the FSA should do to improve its horizon scanning and its understanding of global food systems risks (and opportunities)³. The FSA is at this time responding these recommendations⁴.
- ii. It is proposed that Working Group 5 can oversee a horizon scanning exercise delivered by SERD, supported by the FSA's Allergy & Intolerance Team and the FSA's independent Advisory Committee for Social Science (ACSS), with the aim to deliver a report on the food hypersensitivity environment and potential novel emerging risks and opportunities, to inform FSA's strategy and resilience.
- iii. Emphasis will not be on the identification of new allergens (which should be identified through existing FSA structures), but on areas where new industry/consumer trends might result in different patterns of consumption or different uses e.g. changing influence of high protein supplements or food banks.

These tasks and how they interact and inform each other are summarised below, along with the proposed timeframe.

³ <https://science-council.food.gov.uk/sites/default/files/fsascwg3finalreport.pdf>

⁴ <https://www.food.gov.uk/sites/default/files/media/document/fsa-19-06-07-final-report-from-science-council-working-group-on-food-system-risks-and-horizon-scanning.pdf>



Membership

1) Steering Group	2) Secretariat	3) FSA Input
4) The WG5 steering group will be led by Paul Turner, with contributions from other members of the Science Council.	5) Paul Nunn	6) Guy Poppy
	7) Chun-Han Chan	8) Michelle Patel
	9) FSA food hypersensitivity Science contact	10) Ross Yarham

FSA Inputs

Procurement and finance input to commissioning of the any preparatory work needed to provide support materials for the planned workshops. The Science Council will co-opt external experts as needed to assist with the delivery of this project. Funding can be drawn from the Strategic Evidence Fund for this preparatory work

Other inputs as required by the WG, but likely to include:

- Draw on leads/contacts in other government departments (including Go-Science and Defra network) and additional expertise from the FSA register of specialists.
- As a first and ongoing task - considering what other inputs the Working Group needs in terms of expertise/insight/commentary as well as of written material.

SAC Inputs

We envisage working with the Advisory Committee on Social Science (ACSS) to consider the social aspect of future horizons in food hypersensitivity (WG5.5).

Outputs

Science Council will review the interim reports generated by FSA/Subcontractor in each task, before compiling a final report to the FSA Board summarising the project and its recommendations in time for January 2021. This will include: Council advice on FSA best practice to improve its overall capability to maximise its use of science in delivering policy.

Annex 1: Science Council Working Group on Food Hypersensitivity Chair’s Declared Interests

As a Clinical Senior Lecturer and Clinician Scientist in Paediatric Allergy & Immunology at Imperial College London, the Chair of the proposed 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 advisers⁵, 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 are not considered prohibitive to his Working Group involvement by the Executive, and will continue to be managed in an open and transparent fashion, throughout the course of the Working Group’s activity, with mitigating adjustments made as deemed necessary.

1	Research bid - Using NHS data to monitor trends in severe, food-induced allergic reactions (FS101222). Open tender call on using 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 FSA and Imperial College London are currently finalising particulars and contracts, and the project will likely start Sept/Oct 2019, aiming to complete Dec 2021.
2	2012-2017 MRC fellowship (TRACE) (FS241037). Part of the study team working on the TRACE study. Dr Turner was not funded directly by the project but via an MRC Fellowship to use samples collected from 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.

⁵ [https://www.food.gov.uk/sites/default/files/media/document/fsa-19-03-10-annex-fsas-approach-to-managing-interests-of-external-scientific-advisers .pdf](https://www.food.gov.uk/sites/default/files/media/document/fsa-19-03-10-annex-fsas-approach-to-managing-interests-of-external-scientific-advisers.pdf)

Checklist for Interviews carried out for the pilot study to identify FSA best practice in using science in policy and decision making

FSA SCIENCE COUNCIL: RESEARCH CHECKLIST FOR WG5

Identifying: i) research gaps
ii) potential methodology to address research need
iii) internal and external peer-review?
1. How was the research gap identified, and was it clearly defined?
2. Has a comprehensive and systematic literature survey been undertaken? Did this include 'grey literature'? Was this process transparent?
3. What stakeholder engagement and external review has there been? How were these individuals/groups identified? Non-academic input sought?
4. Have other sources of evidence such as surveillance or enforcement, or unpublished data from government, industry or other sources been considered? Please provide details where appropriate.
5. What steps have been taken to ensure that these data are reliable? How have the areas of uncertainty including gaps in evidence or analysis been handled?
6. How was this process (of identifying the research gap) communicated, both internally and externally?
How does FSA commission research?
7. Is there a clear rationale for the research commissioned? <ul style="list-style-type: none">• What are the desired outcomes?• How do these link to FSA objectives?• Who should be involved both internally and externally?
8. Are all key scientific uncertainties including gaps in evidence or analysis highlighted and expressed clearly?
9. Has the FSA used iterative approaches (e.g. sandpits, validated frameworks) when commissioning work in new research areas?
10. Is there engagement with early-career researchers?
11. How has the FSA ensured wide / impactful dissemination of research calls?

12. Selection of tenders: Has the appropriate methodology been used? How is this assessed?
Project management and completion
13. Has there been input from specialist research roles within FSA, or externally (by means of peer-review) including a) defining projects, b) managing projects and c) data interpretation?
14. What is the strength of the commissioned evidence? Are the conclusions consistent with the published quantitative and/or qualitative evidence?
15. Is the scientific evidence base transparent to stakeholders? Is it clear how this has been peer-reviewed? Are data available for sharing?
16. Is further research required? <ul style="list-style-type: none">• Is it clear how the conclusion(s) are reached, based on the evidence considered? In particular, is the extent to which judgement has been used clear?• Are there any alternative interpretations of the same evidence?• If the research is brand new or groundbreakingly, does it need corroboration by further studies duplicating the results?• Are all key scientific uncertainties including gaps in evidence or analysis highlighted and expressed clearly? What processes have been followed to assess this? E.g. GRADE Evidence to Decision...
17. How have the results been disseminated?
18. What impact has the research had on practice and policy? What would trigger a review of any decisions made?
19. Is the data subsequently shared and used by non-FSA stakeholders? If so, how?
Other considerations:
20. Can the available evidence be applied to UK? Is there a need to consider different data sets for different regions of the UK or for different groups of the population?
21. When monitoring / surveillance, how does FSA use field data over time to improve quality?