FINAL REPORT FROM SCIENCE COUNCIL WORKING GROUP ON FOOD HYPERSENSITIVITY AND FSA RESPONSE

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1. Summary

- 1.1 The Board is asked to:
 - Consider the Working Group's report; and
 - Agree the proposed FSA response to the recommendations

2. Introduction

- 2.1 This paper:
 - Presents the final report and recommendations from the FSA Science Council's Working Group on Food Hypersensitivity (Annex 1); and
 - Sets out the FSA's analysis of the Working Group's recommendations with our proposed response to these.

3. Evidence and Discussion

- 3.1 The Science Council Working Group (WG) on food hypersensitivity (FHS) was established to answer the question set by the FSA Board in May 2019 asking that the Science Council:
 - Consider and advise on future research priorities and direction in respect to FHS.
 - Conduct a review of the science and evidence base for addressing FHS, and the part the FSA and others should play in enhancing knowledge.
- 3.2 The WG's report (at Annex 2) sets out the three phases of the review:
 - 1. Phase I: A review into the previous and current Research programme, including an assessment of best practice in undertaking such a programme. This was done via structured interviews with FSA staff.
 - 2. Phase II: A Priority Setting Exercise (PSE) with wide stakeholder input, to identify research priorities for the FSA over the next 5 years in the area of FHS, and a review of the existing literature associated with these identified priorities. The PSE was done via a stakeholder survey followed by a prioritisation workshop.
 - 3. Phase III: Identification of future priorities in a 5 to 15-year timeframe, through a horizon scanning workshop.

- 3.3 An interim report covering the outcomes of Phase I was presented to the FSA Board at its meeting in September 2020.
- 3.4 This report and the interim report set out the review recommendations in detail, but these have been summarised in Annex 1.

4. The FSA's Analysis and Response to the Working Group's Recommendations

- 4.1 The FSA welcomes recommendations and research priorities laid out in the Science Council's report, recognising how they help us in our ambition to make the UK the best place in the world to be a food hypersensitive consumer.
- 4.2 We recognise the findings of the report show close alignment with the existing work of the FSA FHS Programme.
- 4.3 We also identify that several of the specific recommendations in the report such as "Improving surveillance of FHS reactions occurring in the community" and for the FSA to "engage with FBOs and other relevant stakeholders ...to communicate allergen risk throughout the food supply chain" map across to current programme activity; for example, the precautionary allergen labelling workstream.
- 4.4 In addition, the FSA also recognises that the outputs of the WG5 work show a strong alignment with three themes of the FHS Programme:
- 4.5 **Safety:** Improving our understanding of FHS and the associated risks.
- 4.6 **Trust:** Increasing business and consumer trust and confidence.
- 4.7 **Choice**: Ensuring that people with FHS are not unnecessarily excluded from participation in our food culture.
- 4.8 The FSA wishes to highlight the synergies of existing work with the overall recommendations from WG 5:
 - A new 'programme approach' has been implemented for the management of FSA scientific activities, including analytics, which partly addresses WG5 recommendations on management and governance. A research programme has been set up for each of the Areas of Research Interest (ARIs), including FHS. The programmes are coordinated by steering groups with representatives from Science, Evidence and Research Directorate (SERD), policy, and other internal stakeholders. Science programme coordinators have been recruited to manage the programmes ensuring they are adequately resourced. The steering group allows for the improved internal coordination of research and policy activities including providing a forum for the discussion of evidence gaps including both "policy pull" and "science push". The FHS steering group held its first

meeting in November 2020 and was used to prioritise future FHS research for the current financial year (21/22).

- The FSA agrees with the importance of maximising the use of routinely collected data. SIMS (Signal and Incident Management System), a new IT platform introduced in November 2020, enables users to receive signals (external source information) and manage notified incidents. Individual incident information is recorded on the System using defined categorisations (e.g., hazard category, product type, business and local authority involved), enabling statistical analysis of aggregated incident data. A Discovery (a deep dive investigative process with active input from stakeholders, focusing on how to address a problem) was recently undertaken to investigate the use of root cause analysis (RCA) as a mechanism for working with industry to prevent incidents.
- With respect to improving the visibility of our external research calls at the FSA; the FSA's Finance and Science teams are already working on improving web presence, generating simple guidelines for potential bidders and other approaches.
- The FSA has also been successful in terms of engaging with external R&D programmes and co-funding. Alongside UKRI partners, we are a UK co-funder of a Healthy Diet for a Healthy Life Joint Programme Initiative "Addressing adverse and beneficial effects of food ingredients and food processing on hypersensitivities to food". This is an exciting collaborative funding model with European partners as promotes research coordination and alignment whilst funding remains on a national level. Including the FSA's maximum £250,000 contribution, the UK has committed up to £1.25m to support aligned UK research, with up to £7m being made available across Europe. Applications are currently being reviewed on competitive scientific merit by a central Scientific Evaluation Committee, with public announcement of funding expected in October 2021.
- 4.9 The FSA notes the importance that the WG5 report places on uptake and impact:
 - A project has been initiated within SERD to investigate approaches to evaluate research impact (including analytics). The use of external reviews is one of the approaches being considered as part of this project.
 - The FHS Programme benefits realisation strategy will ensure that the programme focuses on activity that has the highest impact.
- 4.10 The FSA welcomes the investigation of research priorities for the next 5 years from the Research Priority Setting Exercise. The FHS research programme and steering group will consider these priorities as one input to inform future discussions of evidence gaps and potential research projects. Specific projects

have already been developed or are underway to address some of these priorities:

- The inclusion of a Food Hypersensitivity module into the FSA's flagship survey Food and You 2 (priority 4).
- The surveillance of FHS reactions occurring in the community (priority 1) is partly addressed by research projects which are using NHS data to monitor trends in the occurrence of severe, food induced allergic reactions and on patterns and prevalence of adult food allergy. Potential gaps can be considered to inform future projects. From a policy perspective we are continuing to develop our plans for a food allergic reporting platform which will address this priority.
- Improving traceability of allergens was partly covered by an existing project to understand challenges and identify behavioural incentives to help Food Business Operators (FBO) improve food safety culture and allergen management at the manufacturing level.
- Research is planned for the next financial year to investigate the utility of precautionary allergen labelling (PAL). This project will focus on both the motivations behind FBOs applying PAL, and consumer needs and preferences.
- 4.11 In addition to the alignment and learning directly related to the FSA's FHS work, there have been additional cross-cutting learning too. We have recognised that during the delivery of the PSE, the SC WG utilised some innovative and useful methodologies (e.g. James Lind Alliance methodology) and we will continue to explore the utilisation of these in other areas of our work. For example, Priority Setting in future activities not necessarily limited to FHS where defining priorities and developing a consensus within a wider stakeholder group is needed to inform thinking when developing or reviewing science and policy strategies.
- 4.12 With respect to drawing on PSE methodology for future science and policy prioritisation (and engaging with communities of interest), this is an approach that the FSA can add to our toolkit to inform our thinking. Our Strategic Insights Team are already using similar methodologies such as Delphi in planning future work priorities and horizon scanning.
- 4.13 Next Steps: in response to the Science Council recommendations, an implementation plan is being progressed and the FSA will provide an update in due course.

5. Conclusions

- 5.1 The Board is asked to:
 - consider the Working Group's report; and
 - agree the proposed FSA response to the recommendations.

ANNEX 1

Summary of review recommendations

Part I: Review of historic and current practice

Strategy and Direction

- The FSA Board should provide a clear steer on the FSA role on commissioning broader research on FHS.
- The way in which science is brought to the FHS programme board needs a more structured approach to provide "science push" while the Programme Board creates "policy pull".

Management and Governance

- The FSA should reinstate regular stakeholder and external reviews to build relationships and create collaboration opportunities.
- 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 for the non-commercial sector with respect to contracted research vs that funded through UKRI.
- Steps should be taken to minimise the impact of GDPR and associated legislation on research activities.
- Reduce reliance on 'lynchpin' individuals.

Research Outputs

- Additional resources should be allocated to maximise use of routinely collected data across the FSA (e.g. post-incident analyses).
- Avoid the situation where operational and analysis roles may be combined resulting in limited capacity for data analysis.

Uptake and Impact

- 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.

Review and Learning Mechanisms

• 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.

Part II: Near term priorities (next 5 years)

The Science Council recommends the FSA consider as potential research priorities for the FSA over the next 5 years:

- Improving surveillance of FHS reactions occurring in the community, to inform both current policy but also allow the detection of new allergen sources which pose a hazard to consumers with FHS.
- The assessment of allergenicity arising from novel foods and processes may require in vitro evaluation, dependent on blood samples (sera) from patients with FHS. The FSA should consider supporting the establishment of a serum biobank (for example, of participants enrolled in FSA-funded research) which could be used for this purpose.
- The FSA should engage with FBOs and other relevant stakeholders to develop a framework which can be used to communicate allergen risk throughout the food supply chain, and potentially be used for allergen disclosure to the end consumer through digital technology.
- Undertake research to better understand the impact of socioeconomic factors on risks to consumers with FHS, in conjunction with other relevant government departments, given that these factors may also impact on access to health advice which in turn impacts on consumer choice and behaviours to reduce risk.
- The current level of knowledge amongst the general public of FHS is largely unknown. This could be undertaken through existing FSA projects (e.g. Food and You) and may inform public education strategies.

Part III: On the Horizon (5-15 years ahead)

The Science Council recommends the following priorities are considered by the FSA in terms of future-proofing regulatory capability over the next 5-15 years:

- Facilitate the development of data standards with respect to digital data used for allergen traceability, including on how such data might be accessed by consumers with FHS to make safe food choices.
- Investigate the process by which FSA may need to inform or regulate 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.
- Continue to engage with multiple stakeholders involved in FHS to be able to proactively address emerging drivers of change which might affect consumers with FHS.

ANNEX 2

Final Report from the Science Council Working Group 5 on Food Hypersensitivity This Report is provided separately.