

FOOD HYPERSENSITIVITY PROGRAMME: UPDATE

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1. Summary

- 1.1 This paper provides an update on the FSA Food Hypersensitivity (FHS) Programme.
- 1.2 The Board is asked to consider this update and progress on the FHS programme workstreams (see annex 1).

2. Introduction

- 2.1 At the December meeting the Board was updated on progress on the 2019-25 FHS Strategy. In recognition of the high priority of this policy area, it was agreed that that the Board would be provided with a report on progress every six months.
- 2.2 The FHS Programme will help deliver the objectives of the strategy and the programme aligns with the eight strategic objectives of the strategy which are grouped under the themes of Safety, Trust and Choice.
- 2.3 There have been a number of staff movements from the team and recruitment is underway. We have reviewed internal delivery timescales in light of this and revised timings for the Enhanced Learning and Digital Discovery workstreams which will now be started later in the year. Nevertheless, we consider that the programme remains on track to deliver to agreed business plan milestones for FY21/22.
- 2.4 Current programme activity is focused on:
 - improving our understanding of FHS;
 - working with stakeholders and supporting businesses;
 - supporting FHS Consumers; and
 - engaging Internationally.

3. Improving our understanding of FHS

- 3.2 A key objective of the programme is improving our understanding of the causes and impacts of allergen incidents and adverse reactions.
- 3.3 Several FHS programme studies (including the Food Allergy and Intolerance Research programme) have run during FY20-21 and FY21-22. Areas covered include FHS prevalence, Precautionary Allergen Labelling (PAL) and

Prepacked for Direct Sale (PPDS) foods, as well as providing analysis of key data trends in incidence and hospitalisations (see annex 2).

- 3.4 The outputs of this work, and work such as the Science Council WG5 FHS report (covered in a separate paper), will be used to inform programme deliverables (see annex 1) and direct future programme priorities.
- 3.5 Work has progressed on estimating the societal impact of FHS. Data have been acquired from field surveys, including measures of quality of life for FHS consumers, estimating the financial burden and non-financial costs (willingness-to-pay) of FHS. This work remains a priority and the data will be used to populate a Cost of Illness model related to food allergies, food intolerance and coeliac disease (see annex 3).

4. Supporting FHS Consumers

- 4.1 The primary focus of the programme is to ensure that we keep FHS consumers safe and informed.
- 4.2 Work taking place in FY21/22 includes:
 - As part of the Food Allergic Reaction Reporting Mechanism (FARRM) we have carried out research to better understand consumer motivations when self-reporting allergic reactions. We have used the outputs of this work to inform the next stage of the FARRM development which will include proof-of-concept testing due to be completed by December 2021.
 - For the Food Allergy Safety Scheme (FASS), we commissioned research to look at the effectiveness of existing consumer information schemes and what exists both nationally and internationally.
 - We have commissioned social science research to better understand consumer needs and preferences for PAL. The findings of this work will be used to support the consultation.
- 4.3 We launched our 'Speak Up For Allergies' campaign in February 2021 which targeted 18 to 21 year olds and encouraged them to always speak to a food business directly when ordering food. Initial results indicate a strong reach to young people, other consumers, and businesses. Further consumer focussed messaging will be included later this year as part of the PPDS campaign.

5. Working with stakeholders and supporting businesses

- 5.1 We have put working collaboratively with stakeholders at the heart of our approach to the FHS Programme.

5.2 We have successfully delivered a range of engagement activities, for example:

- In March 2021, we hosted a virtual FHS symposium for approximately 115 delegates. The event included workshops on the possibility of a Food Allergy Safety Scheme and PAL. We used these workshops to test stakeholder views on delivery options for the two activities.
- To support the forthcoming Prepacked for Direct Sales regulations (PPDS), we have engaged with businesses through presentations and panels at industry events and meetings. We have also worked with representative bodies to ensure members have the information they need, for example, working with them on material such as frequently asked questions.
- Recent research found the majority of businesses likely to be affected by the PPDS changes were aware of them and were optimistic about compliance. The catering sector was least aware, with restaurants and cafes showing lower levels of preparedness, so we will ensure messaging and engagement is targeted to address this gap.

5.3 For the remainder of FY2021/22 we plan a range of engagement activities including:

- In June we will be holding the first FHS external expert panel meeting. The panel includes representatives from allergy charities, industry, local authorities, and research organisations. The role of the panel is to test emerging policy options and assist us in understanding stakeholder needs. This will support the development of the programme and help to ensure our policies and projects are fit for purpose.
- Support for businesses in the run up to the implementation of the PPDS legislative changes in October. We will provide sector specific content for those sectors that will be particularly affected or where there are lower levels of awareness.
- A Precaution Allergy Labelling (PAL) consultation towards end of FY21/22. The consultation will enable us to gain stakeholder views on issues such as: the format and wording of PAL statements; regulation and compliance, standards for allergen risk-analysis and traceability in the supply chain; and effective advice and communication mechanisms.

6. International Work

6.1 International work to date has focussed on Codex. Through the Codex Committee on Food Labelling and the International Life Sciences Institute Allergens Task Force, we are influencing the development of international standards and best practice, including the harmonisation of allergen thresholds,

guidance for the application of PAL, Quantitative Risk Assessment Guidance, and a report on upper thresholds for PAL use.

7. Conclusion

- 7.1 We continue to work across the FSA, and with stakeholders to develop and deliver the work of the FHS Programme and will update the Board on progress again at future meetings.
- 7.2 The board is asked to note this update and progress on the FHS programme workstreams (see annex 1).

ANNEX

Annex 1: FHS programme workstreams

Annex 2: FHS research and evidence

Annex 3: Estimating the societal impact of FHS

Annex 1: FHS Programme Workstreams

Precautionary Allergen Labelling (PAL)

PAL, or advisory allergen labelling, refers to voluntary food labels, such as “may contain”, used by industry to help manage and communicate the risk of reaction by FHS consumers to allergens that are unintentionally present within a food product.

Key areas which have been progressed since the December board meeting are:

- The development of PAL guidance for SMEs and a new section on PAL for the Local Authority Food Law Code of Practice Guidance. Publication in England and Northern Ireland is planned for 2021, prior to PPDS legislation coming into force in October. There will be a consultation on the updated Practice Guidance for Wales in early 2022. The advice provided in these documents will support food businesses in applying PAL and help enforcement authorities support them.
- We have started planning for the PAL consultation which is due to take place Q3/Q4 FY21/22.
- We held a PAL workshop at the Allergy Symposium, at which attendees discussed the key issues with the application of PAL and potential ways these could be addressed. Key points raised were the importance of taking a sector-based approach and the need to better understand consumer views in terms of the wide range of wording used by business when applying PAL.
- These initial stakeholder views, along with commissioned consumer and food business studies, will help to shape the PAL consultation.

Food Allergic Reaction Reporting Mechanism (FARRM)

The objective of FARRM is to provide feedback information to the FSA on the extent and nature of allergic reactions, particularly when buying food outside the home. This information would give us a better understanding of the nature of reactions and inform policy development in the area of food allergy and intolerance.

We have recently carried out some research to better understand consumer motivations when self-reporting allergic reactions. The work also considered the type of data which should be collected. The study found:

- That consumers are keen to report their allergic reactions to raise awareness of FHS and help others.
- There was limited desire for an enforcement element to the reporting tool as respondents reported that they generally prefer to speak to the food business directly when there is a problem.

We now plan to carry out proof of concept testing of the platform which will include finalising data capture fields to ensure that they provide the required information, consumer testing and exploring potential links to other projects within the FHS programme. This work is due to start in July and be completed by Dec.

Food allergy safety scheme (FASS)

We provided an update to the board in December 2020

Our scoping work to date is:

- Social science research looking into the effectiveness of existing consumer information schemes both nationally and internationally. We provided a summary of this research in our update to the board in December 2020.
- Results of interviews with FHS consumers to gather views on whether a scheme is necessary, how consumers would use a scheme, what information is important and whether alternatives to a scheme could be considered. The key findings from this work are:
 - The concept of FASS was received positively, and participants felt it would increase their confidence, particularly when eating somewhere new.
 - They also thought they would feel more confident that an establishment understood their needs and would accommodate them sensitively.
 - Participants thought that looking at any scheme would only be part of their information gathering process, and they would still carry out their own checks to be safe.
 - An app or an online based scheme was seen as a good idea as it would be convenient to check before dining out. Those interviewed had concerns about how an app or website could compete with existing platforms and whether the information could be updated in a timely way as menus change.

At the Allergy Symposium we held a workshop to gather stakeholder views on such a scheme. Themes similar to those raised in the consumer research emerged from this.

To build on this scoping work we now plan to gather more information on the existing provision by current hypersensitive accreditation schemes in the UK, as well as examining whether or how such a scheme could join up with the existing FHRS and what the limitations or opportunities are.

Prepacked for direct sale (PPDS) food

Changes to legislative requirements for allergen labelling for PPDS food have now been introduced in all four UK administrations with an implementation date of 1st October 2021. We are delivering communications aimed at stakeholders in England, Wales, and Northern Ireland ahead of the implementation date to ensure businesses, local authorities and consumers are well prepared.

Our recently published research report 'The food industry's provision of allergen information to consumers' (March 2021) gives us helpful baseline information on PPDS food ahead of implementation of the changes. It shows that some businesses are well placed to adapt to the changes as they label allergens and/or ingredients already. But we are aware that many businesses will need support and the right information to adapt in time.

We launched our 'one-year-to-go' campaign in October 2020 which achieved a good level of media coverage and engagement with stakeholders. Since then we have also:

- Engaged businesses through well received webinar presentations and panels at industry events and meetings this year. We have worked with representative bodies to ensure members have the information they need.

- Delivered targeted digital advertising to direct businesses to the PPDS information on our website. In total, nearly 100,000 people visited our PPDS webpage from April 2020 to March 2021.
- Provided reference information to local authorities through our 'Allergy Q&A' on the Smarter Communications platform which we will regularly revise with updates over the coming months, based on queries we receive from local authorities. We have also produced a 'quick guide' that local authorities can use to engage businesses in their areas.

Additional work this year as follows:

- We will provide sector specific content for sectors which will be particularly affected or where there are lower levels of awareness e.g. catering, schools, and restaurants. This will build on existing information we have provided and will specify examples relevant to each sector.
- We are planning FSA-led webinars for local authorities and businesses and are currently determining the specific format and dates for these. These webinars could be recorded so they are available as a permanent training resource.
- Consumer focussed messaging is planned for later this year, closer to the implementation date.

We will assess how the PPDS changes are being implemented by businesses after the implementation date.

Annex 2: FHS research and evidence

Key highlights from 20-21 activities:

- An FSA funded study using NHS data to monitor trends in severe, food-induced allergic reactions and related fatalities was published in the British Medical Journal. The study identified that although there was an increase in hospital admissions for food-induced anaphylaxis in the UK, the case fatality rate decreased by more than half. The study also showed that cow’s milk was the most common allergen responsible for causing fatal reactions in school-aged children.
- Work continued on the Patterns and Prevalence of Adult Food Allergy (PAFA) research project which aims to provide a step-change in our understanding of food allergy in adulthood by determining its prevalence in the adult population.
- Research exploring business allergen information provision for non-prepacked food found food businesses have improved across several areas in providing allergen information to consumers (since 2012 baseline study).
- Primary data have been acquired from field surveys, including measures of quality of life for FHS consumers, estimating the financial burden and non-financial costs (willingness-to-pay) of FHS. These estimates will be used to populate a Cost of Illness model related to food allergies, food intolerance and coeliac disease.

For FY21/22, several multi-year projects will continue e.g., PAFA. Additionally, three projects that support key priorities of the FHS Programme, totalling £320K, have been approved in principle.

- Social science research covering Precautionary Allergen Labelling (PAL) and Food Allergy Safety Scheme (FASS).
- Business compliance to Prepacked for Direct Sale (PPDS) food; and
- The effect of COVID-19 on hospital admissions for FHS.

Current FHS research and evidence projects:

Project	Description	Start	End
FS430387 Food Hypersensitivity: estimating the financial burden	To calculate the financial burden of food hypersensitivity sufferers to feed data into the Cost of Illness model.	Sept 20	Apr 21
FS403027 Follow-up to baseline study on food industry provision of allergy information, with new PPDS baseline	This study both followed up on the provision by businesses of allergic information to consumers for non-prepacked foods since a change in regulation and provided a new baseline on awareness and activity regarding the provision of allergen information for PPDS food.	Nov 19	Dec 20
FS301087 Development of a Food Recall Prevention Platform	Improving traceability of allergens to understand challenges and identify behavioural incentives to help manufacturers improve food safety culture and allergen management	Dec 19	Nov 21

FS101174 Adult Food Allergy Programme of Research	Improvement in our understanding of food allergy in adulthood by determining the prevalence of IgE-mediated food allergy, describing the different trajectories of food allergies and adverse reactions to food that are not mediated by IgE in the adult population.	Apr 18	Dec 22
FS101206 Development of Quality Control Materials for Food Allergen Analysis	Develop quality control and/ or reference materials for food allergen analysis for use by the analytical community to underpin work on allergen management thresholds used to inform enforcement and precautionary allergen labelling decisions.	Feb 18	Mar 21
FS430465 Science Council Working Group 5 FHS and Intolerance	Science Council Working Group 5 - Food Hypersensitivity.	Dec 19	Jun 21
FS101222 Using NHS data to monitor trends in the occurrence of severe, food-induced allergic reactions	Describe trends in the occurrence of FH reactions in the UK and its consequences in terms of healthcare encounters, establish an anaphylaxis registry, and define common patterns in the circumstances of severe life-threatening reactions to food.	Oct 19	Sept 22
FS101209 EFSA Call: Detection & Quantification of Allergens in foods and minimum eliciting doses in food allergic individuals	Develop reference methodologies for the detection and quantification of allergens in foods using quantitative MS-based prototype reference method for the detection of multiple food allergens and generate data on Minimum eliciting doses (MED) and Minimum Observed Eliciting Doses (MOED).	Jan 18	Sept 22
FS430406 Food hypersensitivities: capturing QoL, behavioural measures and WTP	A joint Social Science and Economics project to understand the effects of FHS, in terms of impact in daily lives and willingness-to-pay values of individuals living with FHS-related conditions.	Mar 20	Dec 21

FHS research and evidence projects starting in 21/22:

Project	Description	Start	End
Social science research on PAL and FASS	Additional social science work on PAL and FASS. The PAL element will gain further insight into how and why FBOs are applying PAL. It will explore the motivations driving FBOs in applying PAL, and will improve the FSA evidence base on consumer needs and preferences for PAL. The work on the FASS is exploratory and will test various options with consumers and businesses.	Jul 21	Feb 22
Baseline for evaluation of changes to PPDS	To review the implementation of the new allergen information requirement for PPDS food.	Oct 21	Mar 22
Impact of COVID-19 on allergy hospital admissions	This is a data extract from NHS digital to be used for analysis in support of FHS and foodborne disease.	Dec 21	Mar 22

Annex 3: Estimating the societal impact of FHS

Building on the Cost of Illness (COI) framework developed for foodborne illness, the FSA will adopt an analogous approach and methodology to estimating the societal burden of FHS, disaggregated to include individuals with food allergies, food intolerance, and coeliac disease who follow restricted (or food avoidance) diets.

Development of the COI FHS model is comprised of three distinct strands:

Strand 1: Estimating the Financial Cost to Individual Sufferers with Food Hypersensitivity

- The FSA commissioned contractor RSM to undertake a study into the financial burden of living with a food hypersensitivity (FHS). The study aimed to: quantify the additional financial costs faced by sufferers with FHS in the UK by comparing the price differentials paid for food between households with a FHS sufferer, to a comparison group (households without FHS); and monetising other direct or indirect costs faced by sufferers with FHS in their efforts to remain symptom free (e.g. medical and kitchen supplies to help manage their condition).
- This study is unique in terms of estimating price differentials for food consumption across different types of FHS (food allergy, food intolerance, Coeliac Disease) and then comparing to a non-FHS comparison group. Previous studies have focused on coeliac disease and gluten-free products, so this study is adding new knowledge to the evidence base.

Strand 2: FHS Willingness to Pay Project

- This project addresses the research needs of the FSA to capture and evaluate the burden caused by living with food hypersensitivities, the day-to-day management of these conditions and associated inconveniences. This research is to be completed across two linked workstreams:
 - Workstream 1 aims to develop an annual tracking survey to collect data on management, quality of life and impact on daily lives.
 - Workstream 2 aims to produce monetary valuations on the non-tangible/non-financial element, including pain, grief, and suffering, associated with food hypersensitivity through eliciting Willingness to Pay values.

Strand 3: COI FHS Model

- The COI model identifies and measures the full social cost of FHS based on cases associated with reactions and prevalence, by bringing together strands 1 and 2 (see figure 1) to include both financial (medical and personal costs) and monetary estimates of its non-financial impacts (pain, grief and suffering). This enables outputs from the model to be expressed in monetary terms, thus providing an estimate of the total burden of annual hospitalised UK cases.

Based on current plans we aim to have a fully up-to-date estimate of total societal burden of food hypersensitivity by end December 2021. Work on Strands 1 and 2 are ongoing. We expect Strand 1 to be completed and published by July 2021; and the final report and estimates for Strand 2 to published by October 2021.