

FOOD HYPERSENSITIVITY PROGRAMME: UPDATE

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1. Summary

1.1. This paper updates the Board on the progress of the FSA's Food Hypersensitivity Strategy.

1.2. The Board is asked to:

- **endorse** the proposed approach to progressing the work on a food allergy safety scheme;
- **agree** the proposed approach to progressing the work on Precautionary Allergen Labelling;
- **note** progress on other key work areas (set out in Annex 1).
 - Pre-packed for Direct Sale foods.
 - Communications campaigns.
 - Food allergy and intolerance e-training.
 - Food allergic reaction reporting mechanism.
 - Programme Stakeholder Engagement.
 - Research and evidence.

2. Introduction

2.1. The FSA's work on food hypersensitivity is a strategic priority for the FSA. In May 2019, the FSA Board committed to making food hypersensitivity one of its top priorities and has now established the Food Hypersensitivity (FHS) Programme to support its ambition and vision:

'We want the UK to be the best place in the world to be a food hypersensitive consumer.'

'We want to improve the quality of life for people living with food hypersensitivity and support them to make safe, informed food choices to effectively manage risk.'

2.2. Since the Board endorsed the Programme in January 2020, we have set up the FHS programme structure and governance and the FHS Policy Team has had additional resources from September 2020 (See Annex 2 for programme milestones). The Programme's work has a 'three country' approach to policy and implementation, with the FHS team working closely with colleagues in Wales and Northern Ireland. The membership of the FHS programme board includes representatives from Wales, Northern Ireland and also Food Standards Scotland.

2.3. This has enabled us to progress key areas of work including: an evidence review of existing consumer information schemes to support the development of a food allergy safety scheme; continued support to businesses and local authorities in preparation for the Prepacked for Direct Sale labelling legislation that comes into effect in October 2021; an update of the online food allergy and intolerance e-training; and the development of the Food Allergic Reaction Reporting Mechanism, including completion of the “discovery” phase. Further detail on these is below (for the food allergy safety scheme) and in Annex 1.

Spending Review 2020

2.4. We recently submitted a bid for programme funding to HM Treasury as part of the Spending Review 2020 (SR20) process which set out the planned activities, vision and benefits to be achieved over the programme’s lifetime. However, as the Spending Review is now to be a one-year settlement we will need to review programme activities once we know the final funding allocation.

2.5. A specific bid was made for our work on the development of a food allergy safety scheme and this element of the programme work is highly dependent on the SR20 outcome. The bid would fund additional resource to concentrate on development and delivery of any future scheme. Without that funding the programme would need to re-prioritise key elements and review workstreams.

3. Food allergy safety scheme

3.1. At the January 2020 meeting we committed to an update to the Board on our work to develop ‘at a glance’ information on allergen management along the lines of the existing Food Hygiene Rating Scheme (FHRS) or another similar scheme.

3.2. We are in the early stages of the development of this work and are navigating some complexities in determining the right approach. We are considering, through the use of scoping work, what information consumers need on allergens, how they would use that information, and the best way of delivering the information in a form that can be easily used and understood. Options for a scheme to provide that information ‘at a glance’ could include the possibility of amending the scope of the FHRS.

3.3. Our initial scoping work has produced some helpful indicators to consider as we develop these options. We commissioned an evidence review looking into the effectiveness of existing consumer information schemes and what exists both nationally and internationally. Our aim was to investigate how a food allergy safety scheme might be developed and how it would be of most use to the consumer.

3.4. This review looked at:

- existing UK and international examples of ‘on the doors’ and ‘at a glance’ schemes;
- possible alternatives to ‘on the doors’ schemes (specifically existing digital apps, databases or catalogues for the allergy community);
- the effectiveness of ‘on the door’ and ‘at a glance’ schemes; and

- consumers views of ‘on the doors’ and ‘at a glance’ schemes.
A summary of the research is set out in Annex 3.
- 3.5. We have also commissioned new qualitative research to gain the views of hypersensitive consumers on a potential food allergy safety scheme, including whether a scheme is necessary, how they would use the scheme, what information is important and whether there are better alternatives e.g. an allergy app or website. We expect the outputs of this qualitative research will be available during December and will update the Board on these at a later meeting.
- 3.6. Whilst it is early days and we will clearly gather further information and evidence, based on what we have considered so far, we feel it would be useful at this stage to develop some overarching principles that would help guide our consideration as we progress the work.
- 3.7. Key points to be considered are whether we establish a new FSA-led scheme or whether the FSA should support third party schemes, for example through the setting of standards.
- 3.8. We seek the Board’s endorsement of the following approach:
- Any viable scheme should involve both a physical and a virtual element, to ensure all age groups can access it.
 - A scheme should not replace a business’ offer of allergy information to hypersensitive consumers and knowledge of staff on menus and allergens.
 - We should explore how we could use existing schemes, including how the FSA could set standards for third parties delivering their own schemes.
 - We should ensure any scheme directly addresses consumer wishes and needs, based on qualitative research.
 - We should attempt to maximise ease and accessibility of any scheme for hypersensitive consumers as well as all sizes of business, particularly SMEs.

4. Precautionary Allergen Labelling

- 4.1. Precautionary Allergen Labelling (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 food hypersensitive consumers to allergens that are unintentionally present within a food product.
- 4.2. Our current position on PAL is that it should only be applied if, after thorough risk assessment and review of manufacturing processes, there is a likely presence of an allergen in a food product. Nevertheless, industry has been reporting problems in its application - particularly around the consumer desire for more accurate allergen labelling. Industry is also seeking better guidance on consistent practices in applying PAL.
- 4.3. The use of PAL has increased since 2012; the 2020 follow-up study on the food industry’s provision of allergen information for non-prepacked foods found that more

than half (55%¹) of FBOs said they used precautionary advice warnings on these foods, such as ‘may contain’ labelling. In 2012, just three in ten (29%) of Food Business Operators (FBOs) used ‘may contain’ labelling specifically. Follow-up interviews² found that the key drivers for using precautionary labelling were to ensure customer safety, but also to protect the business (i.e. the perception was that it would reduce business liability). Usage may also be linked to uncertainty around risk management and the regulatory landscape.

- 4.4. The issue is complex, particularly given the wide range of potential sources of cross-contamination through the food production process. PAL application without carrying out a thorough risk assessment reduces consumer choice and restricts the FBO market as the food, though labelled, may not provide any actual risk to consumers. Blanket bans or waivers can undermine the credibility of PAL and increase the risk of consumers ignoring the precautionary advice on the label.
- 4.5. FSA has been actively involved in PAL for a number of years and its work on allergen management is recognised internationally, for example the 2006 FSA guidance was used as the basis for FoodDrinkEurope’s 2013 “Guidance on Food Allergen Management for Food Manufacturers.” FSA also has a history of carrying out research on the issues surrounding PAL use, for example investigating the methods used to detect allergens in food ingredients, increasing our understanding of the risks associated with setting thresholds for individual allergen presence in foods, and working with industry and consumers on how to come to a consensus on the acceptability of risk.
- 4.6. While it is ultimately the responsibility of industry to ensure it is using PAL judiciously, we recognise the need to better understand the current causes and impacts of the increased usage of PAL and also FSA’s role in addressing them. We have spoken to industry, and consumers and propose work in the following areas:
 - Improve understanding of the current risk management practices employed by FBOs, the extent to which FBOs are using blanket waivers, and current usage of thresholds, for example through the Australian Voluntary Incidental Trace Allergen (VITAL) Program – an industry funded, risk-based PAL system introduced in 2007.
 - Continue to work with the international Codex Committees to facilitate the international harmonisation of thresholds and assess whether current testing methods are robust enough for industry to consistently detect regulated allergens at those threshold levels for a range of foodstuffs.
 - Work with industry to review current FSA guidance and explore the potential to develop industry set standards to ensure greater consistency in PAL application.

¹ Base: 2,303 food business operators, telephone survey, England, Wales, NI and Scotland.

² Base: 21 interviews (of which 12 food business operators used PAL).

5. Conclusion

- 5.1. We will continue to develop and deliver the work of the Food Hypersensitivity Programme and will update the Board on progress again at future meetings.
- 5.2. The Board is invited to discuss the content outlined in this paper and to:
- **endorse** the proposed approach to progressing the work on a food allergy safety scheme
 - **agree** the proposed approach to progressing the work on Precautionary Allergen Labelling
 - **note** progress on other key work areas (set out in Annex 1)
 - Pre-packed for Direct Sale foods
 - Communications campaigns
 - Food allergy and intolerance e-training
 - Food allergic reaction reporting mechanism
 - Programme Stakeholder Engagement
 - Research and evidence

Annex 1: Progress on key areas in the Food Hypersensitivity Programme

1. Prepacked for Direct Sale (PPDS) food

- 1.1 New allergen labelling requirements for prepacked for direct sale food (PPDS) will come into effect on 1 October 2021, following the introduction of the legislation in England, Wales and Northern Ireland.
- 1.2 We are phasing communications ahead of the implementation date to ensure businesses, local authorities and consumers are well prepared. We launched a campaign targeting businesses to mark 'one-year-to-go' from 1 October 2020 which included:
 - Revised online information about PPDS aimed at businesses, explaining the changes, what food will be affected and what they need to do.
 - FSA Explains video – a short video explaining the new PPDS rules.
 - Social media activity highlighting the new information.
 - Trade media coverage and an FSA blog post in New Food Magazine.
 - Specific communication to reach industry stakeholders in Wales (content in the Welsh Government Food and Drink newsletter and on the Food Centre Wales website) and Northern Ireland (article on NI Business Info website).
 - Targeted communication to 200 partners to help communicate the message via existing networks including businesses and other food providers (e.g. care homes and schools).
- 1.3 This launch has already generated a fourfold increase in website visits for the PPDS information, good trade media coverage and above average engagement with the partners we have communicated with.
- 1.4 The next key phase of communications activities will be from January 2021, to emphasise to businesses that the PPDS changes are coming later that year. In 2021, closer to the implementation date, we will also target messages to consumers.
- 1.5 We are looking to provide a toolkit to local authorities that will help them target messages to businesses in their areas. We will also ensure local authorities are clear on the enforcement approach they need to take, for example, providing targeted information through the FSA's Smarter Communications platform.
- 1.6 We will carry out monitoring of how the PPDS changes are being implemented by businesses from the implementation date and consider if any follow up activities should be undertaken for businesses, local authorities and consumers.

2. Communications campaigns

- 2.1 The FSA had been planning key allergen campaigns aimed at businesses and young people when the COVID-19 pandemic hit. The business campaign was put on hold, because of the escalation of the response to COVID-19, while we took the opportunity

to reassess the young people's campaign, taking into account the changing context and circumstances.

- 2.2 We have now carried out qualitative research to see how a young people's campaign could be delivered. The current context of COVID-19 means there is more of a focus on takeaway food and new pressures when it comes to ordering food (e.g. businesses changing delivery models and menus).
- 2.3 The research findings provided good detail on young people's experiences of ordering food, and how different messages and approaches resonated with them.
- 2.4 We are using this insight to inform a campaign approach focussed on the 18 to 21 age group, with the aim to deliver this in the last quarter of the financial year. This group see themselves as confident in managing their allergies, however, this confidence can turn into complacency, where they do not always ask about allergens when ordering in or eating out. Given the audience, this campaign will be delivered in the digital space, using social media, influencers and strategic media partnership channels.
- 2.5 We recently met with key allergy charities and consumer groups to seek their views and gain buy-in on this approach and the response was very positive.
- 2.6 We also continue to review the broader landscape to ascertain when may be appropriate to revisit the business campaign focused solely on allergen management. In the meantime, messages around allergen management have been incorporated within the FSAs award-winning campaign 'Here to Help' that launched in August 2020 and is ongoing.

3. Food allergy and intolerance e-training

- 3.1 The online food allergy and intolerance e-training was updated on 16th September 2020 to improve the content and overall clarity, refresh the website design and incorporate new requirements for PPDS foods.
- 3.2 The training has been primarily developed by the FSA for local authorities' enforcement officers. However, it will also be of interest to food industry organisations and businesses, consumers and others who would like to learn more about food allergy, the provision of accurate allergen information and how to handle allergens safely.
- 3.3 Communications on the new training took place on 6th October 2020, as part of the 'prepacked for direct sale – one year to go' campaign.
- 3.4 As of 2nd November 2020, there have already been more than 14 000 registered accounts on the training platform, of which 11% come from those working for a local authority, 52% are working for an FBO, while 19% are students or teachers and 1% are consumers. Over the next year we will continue to capture and monitor user data, and we will consider if any content should be refreshed in future, as appropriate. Further communication targeting local authorities is planned to take place once COVID-19 pressures on local authorities have eased.

4. Food Allergic Reaction Reporting Mechanism (FARRM)

- 4.1 Currently the FSA and local authorities have no means of collecting data on allergic reactions, as and when they happen, or the reasons why. Recent Coroner's Inquest reports have recommended a UK Anaphylaxis Register of Deaths and it is acknowledged that there are gaps in knowledge as to the real extent of allergic reactions as only the graver conditions result in hospitalisation. The envisaged FARRM will plug this gap by providing real time information that will enable more focussed policy interventions as well as notification of 'near misses' to local authorities so that they can interact with businesses at an early stage.
- 4.2 In order to understand the requirements for a reporting system, in November 2019, the FSA contracted an external company to embark on a 'discovery phase' to examine whether a reporting service would meet consumer, FSA and local authority needs. It also looked to determine who would use the service, if it was set up, and the impact it would have.
- 4.3 Given the current public health situation further appraisal of the Discovery work is being undertaken to ensure the key objectives of collecting reported data, including the consideration of the role of local authorities.
- 4.4 An Alpha phase will include the testing of potential approaches for consumers to report their allergic reactions to the FSA and user testing with consumer groups. It will also consider how the FARRM would operate within the FSA and the relationship with existing incident management approaches. A key element of FARRM is improving data collection and sharing with local authorities and other government departments and also within the FSA, the Alpha Phase will consider options for enabling this.

5. Programme Stakeholder Engagement

- 5.1 We have put working collaboratively with stakeholders at the heart of our approach to the Food Hypersensitivity Programme. We have developed a Programme Stakeholder Engagement Plan which sets out how we will work with business, consumers and sector innovators to ensure that regulation is proportionate and targeted, and to maximise the use of non-legislative approaches and innovative, industry-led solutions.
- 5.2 This will include the establishment of an external Food Hypersensitivity Programme stakeholder panel consisting of representatives from allergy charities, food industry bodies, local authorities and research organisations. The panel will provide feedback on food hypersensitivity policies as they are developed and give insight into priorities and needs. The panel will use an agile and responsive model to maintain effectiveness and meaningful engagement.
- 5.3 We also plan a series of targeted engagement activity to support programme development. This will include a follow-up to the Allergy Symposium held in February 2019.

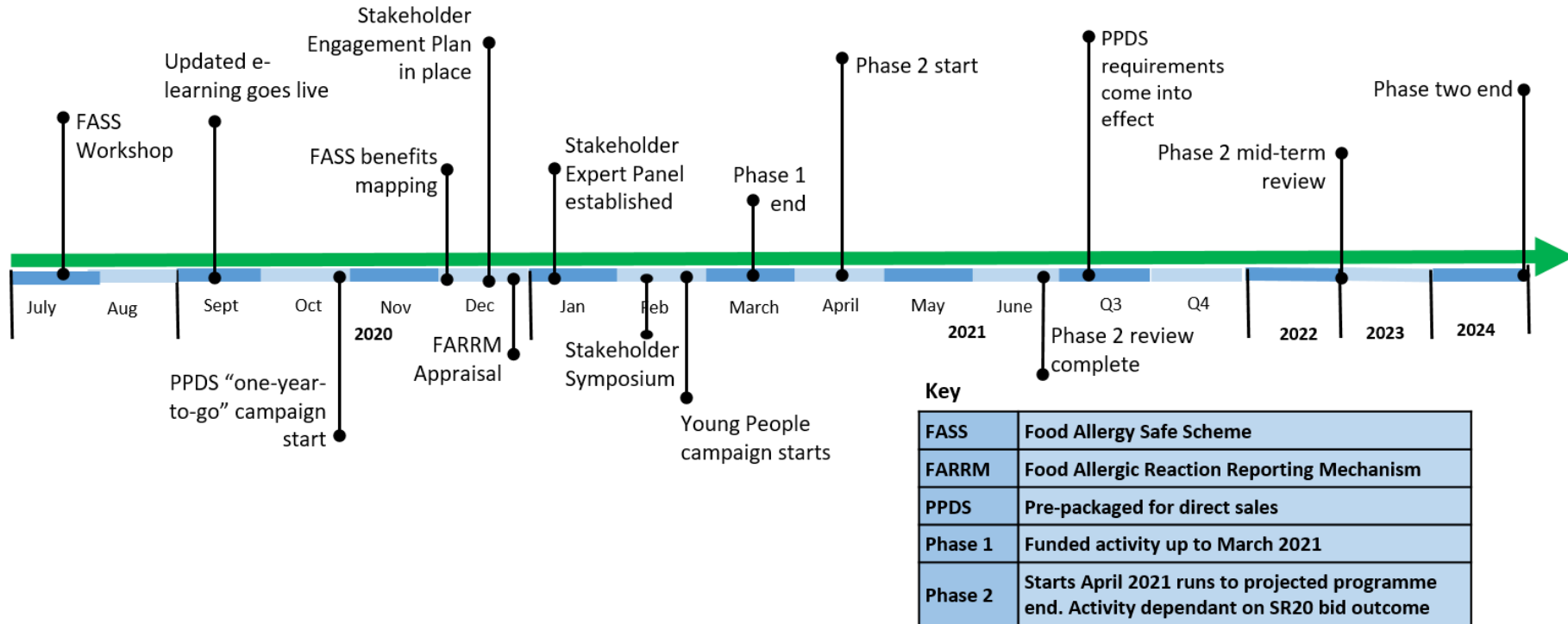
6. Research and evidence on Food Hypersensitivity

- 6.1 Food Hypersensitivity is one of the FSA’s priority Areas of Research Interest. We are building on more than a decade’s ground-breaking work through the Food Allergy and Intolerance (FAIR) programme. Within our current programme of research we are looking at the patterns and prevalence of food allergies in adults, using NHS data to monitor trends in the occurrence of severe allergic reactions, assessing how businesses display and provide allergy information and tracking the quality of life and key behaviours of those with food hypersensitivities.
- 6.2 We are developing our future research and evidence programme based on emerging evidence needs and on the recommendations from Science Council Working Group 5, which the Board saw in an interim report in September 2020. The final report, due in June 2021 will include the results of the Research Priority Setting Exercise that sought a wide range of stakeholder views to help identify current knowledge gaps as well as the conclusions of a horizon scanning workshop to identify potential emerging issues over the next 5 to 15 years.
- 6.3 The current research and evidence projects that form part of the FHS programme are listed in the table below. Many of these projects have been severely impacted by the COVID-19 crisis and are subject to delay. The primary reasons for this are constrained access to clinical practitioners and food hypersensitive consumers. The project leads are working with stakeholders and contractors to try and overcome and mitigate the issues because of COVID-19, but we estimate we will experience delays as outlined below.

	Research and Evidence Project	Project Objectives	Planned Finish	Forecast Finish
1	Science Council Working Group 5	To provide a review of the FSA food hypersensitivity programme, look at past, present and future work. There are 5 key workstreams covering a review of best practice, Priority Setting Exercise and horizon scanning.	31 Mar 21	30 Jun 21
2	Patterns and Prevalence of Adult Food Allergy (PAFA Study)	To determine the prevalence of IgE-mediated food allergy in adults. To describe the different trajectories of food allergy across the life course. To describe adverse reactions to foods that are not mediated by IgE in adults.	30 Dec 21	30 Dec 22
3	Using NHS data to monitor trends in the occurrence of severe, food induced allergic reactions	To determine the trend in the occurrence of food hypersensitivity reactions, and its consequences in term of healthcare encounters. Determine the circumstances surrounding severe, life-threatening reactions to food.	07 Feb 22	01 Sep 22
4	Developing a food recall prevention platform (FOODPro)	To investigate past allergy incidents data and the reasons behind them. To build a database of standardised food ingredient specification templates. To develop an online food recall prevention platform (FOODPro) to address mislabelling food recalls.	01 Dec 21	01 Dec 21
5	Food industry provision of allergen information	To understand the current provision of information on allergenic ingredients by food businesses to consumers for non-prepacked food and how this has changed since the current regulations came into force in 2014. To provide a new baseline on	28 Aug 20	14 Dec 20

	Research and Evidence Project	Project Objectives	Planned Finish	Forecast Finish
		awareness and activity regarding the provision of allergen information for PPDS food.		
6	Capturing quality of life, behavioural measures and Willingness To Pay (WTP).	To collect, and track over time, measures capturing the effects of food hypersensitivity over individuals' daily lives. To monetise intangible aspects of food hypersensitivity through the elicitation of willingness to pay values of individuals suffering from these conditions.	30 Mar 21	30 Nov 21
7	Estimate the Economic Burden of Food Hypersensitivity.	To calculate the financial burden (in terms of basket of goods as well as other direct expenses not associated to health care) of food hypersensitivity sufferers to feed data into the Cost of Illness model.	12 Mar 21	12 Apr 21

Annex 2: Food Hypersensitivity Programme Milestones



Annex 3: Summary of findings of evidence review on consumer information schemes (to inform work on a food allergy safety scheme)

1. A two-stage methodological approach was taken; firstly, a mapping exercise informed by stakeholder interviews, followed by a Rapid Evidence Assessment (REA).
2. The mapping exercise identified 100 schemes (91 if virtual stickers are subsumed):
 - 11 'on the door' hypersensitivity schemes
 - 21 'on the door' schemes – physical
 - 33 'on the door' schemes – virtual (24 if virtual stickers are subsumed)
 - 8 hypersensitivity apps
 - 6 dietary apps
 - 9 hypersensitivity databases
 - 12 dietary databases
3. Evidence regarding state or government implemented hygiene 'on the doors' scoring schemes was identified and incorporated, together with a useful degree of evidence regarding the use and impact of virtual 'on the doors' and 'at a glance' schemes (on databases and apps), specifically in the hotel industry. This evidence was often tied up with the broader literature on consumer generated content, often primarily concerned with use and impact of written reviews on consumer intention.
4. The research identified 72 schemes, 54 'on the doors' and 18 'at a glance' (excluding the 28 hypersensitivity focused schemes). Two delivery models emerged as dominate for these schemes: Physical and Virtual scheme models.
 - Physical scheme models primarily use display mechanisms such as door or window stickers, display certificates, decals or plaques. Often these are supported by online listings in relevant (promotional or accrediting) databases and many have electronic logos (a virtual mechanism) for use online. Physical schemes tend towards independent accreditation models that include hygiene scores
 - Virtual scheme models are online and are often 'virtual high-streets' such as hotel and restaurant booking sites (e.g. Booking.com and TripAdvisor) and food delivery apps. Here virtual stickers are used to display consumer information such as consumer generated rankings and reviews, as well as accreditation and certification
5. Of the 54 'on the door' schemes, 21 are categorised as physical schemes and 33 as virtual schemes. The 'at a glance' schemes comprised of 6 dietary apps and 12 dietary restaurant databases, that is independently managed, publicly accessible, eatery listings with or without consumer generated content. Both the app and database provisions aim to support their target communities in identifying suitable establishments for dining.

Findings on schemes for hypersensitive consumers

6. The research identified 11 'on the door' hypersensitivity schemes – 9 were to support gluten-free dining and the other 2 schemes support the allergy community. Scheme objectives were generally two-pronged, focusing on industry support and consumer confidence. The delivery model for these schemes have three core elements: physical display mechanism, online database listing and an audit process for validating accreditation.
7. In mapping alternatives to 'on the doors' scheme provision the research identified 18 'at a glance' schemes together with a further 9 hypersensitivity databases and 8 hypersensitivity apps, designed to support the allergy and intolerance community in identifying suitable hypersensitivity or allergy 'friendly' restaurants. The 9 hypersensitivity databases identified include 5 gluten-free schemes supporting Coeliac communities across Europe, 2 for the UK allergy community, 1 Peanut allergy initiative based in the USA and 1 Dairy free scheme for lactose intolerance (USA, Canada, UK & Australia). Whilst the 8 hypersensitivity apps include: 4 for the allergy community specifically, 2 covering allergies and intolerances, 1 just for Coeliac /Gluten-free consumers, and 1 broader app for all dietary requirements.
8. When considering evidence relevant to alternatives to 'on the doors' schemes, it is useful to note consumers' information gathering practices. Consumers now typically turn to search engines and online reviews when making (purchase) decisions for products or services including hospitality. This online activity is particularly acute for hypersensitive communities in seeking dining out experiences. However, online and social media activity tends towards the younger generation with older, more vulnerable, demographics being least likely to check online.
9. For consumers with allergies and intolerances the provision of written allergen information is the 'gold standard'. The literature also suggests that the 'ideal' eating out experience is one in which a range of information resources are available, where written allergen information is complemented by proactive and accommodating staff.

Evidence gaps

10. The research identified substantive evidence gaps, namely:
 - Evaluations of physical and virtual model 'on the doors' and 'at a glance' schemes
 - Consumer use of physical model 'on the doors' schemes
 - Consumer perspectives of physical and virtual model 'on the doors' and 'at a glance' schemes
11. There is an important gap in the literature addressing allergy orientated versions of these schemes or alternative provisions. When considering the alternatives, there is need for evaluative evidence regarding hypersensitivity (and more broadly dietary) databases and apps.

Conclusions

12. The study concluded that the ideal model for a scheme would:

- Be premised on a physical model, and include a virtual element
 - Promote and incorporate consumer/user generated reviews and rankings
 - Have evidence of timeliness
 - Include mandatory display of a scheme sticker/certificate/logo
13. Any apps developed in this area should include:
- An option to personalise it to the user e.g. add allergies and level of severity
 - User-generated rating and reviewing of restaurants
 - Provide a Chatbot to provide information about the restaurants
14. Users of hypersensitivity restaurant apps and databases are most interested in information on:
- Knowledgeability of staff on menu and allergens/allergies
 - Rating of experience (by users/peers)
 - Menu options provided by the restaurant e.g. gluten-free
15. Effective mechanisms for communicating information in a format that is quickly and easily understood are:
- Emoticons
 - Virtual stickers
 - Similar 'at a glance' mechanism
16. Areas to consider on accessibility and participation:
- Apps/virtual schemes are more likely to be used by younger generations, so there are barriers to their use by other age groups
 - Accreditation processes that require financial investments from businesses could exclude small businesses. Schemes with paywalls for consumers could exclude individuals with less economic means