Food Hypersensitivity: Update on Progress and Options for Improving the Provision of Allergy Information

FSA 2023-12-08 - This paper provides an update on progress against the plans for the Food Hypersensitivity (FHS) work and sets out options for improving the provision of allergen information in the non-prepacked food sector.

1. Purpose

1.1 This paper provides an update to the FSA Board on progress against the plans for the Food Hypersensitivity (FHS) work set out at September 2022 Board (FSA 22-09-07 - Food Hypersensitivity Programme: Outline plans for phase two), which were subsequently updated in the December 2022 re-prioritisation paper (FSA 22-12-05 - In Year Prioritisation) and sets out options for improving the provision of allergen information in the non-prepacked food sector (such as restaurants and takeaways).

1.2 The Board is asked to note progress on the FHS plan and invited to provide a view on the recommended approaches to provision of information in the non-prepacked sector, specifically:

- does the Board agree with the proposal to create a presumption for those supplying non-prepacked food, that they will provide **both** written information **and** a conversation?

For written information in particular:

- does the board agree with the recommendation to adopt option (b) in para 4.4 to set a strong direction on how written information will be provided but recognise the need for flexibility to use alternative means where justified?
- does the board wish to provide a steer on where that information should be provided (for example, on menus)?
- does the board agree we should initially introduce the changes through improved guidance, and not recommend legislation to Ministers at this stage?
- does the board agree we should maintain the option of recommending future legislation?
- does the board agree we should pursue further standardisation of how information is presented?

2. Progress

2.1 The three work areas prioritised for the past year were: continuing work on Precautionary Allergen Labelling (PAL), improving the provision of information for consumers in the non-prepacked food sector, and information gathering to support the development of training.

2.2 Action on **Precautionary Allergen Labelling (PAL)** is summarised below. Further detail can be found in Annex A. Since the September 2022 Board we have:

- Developed, consulted, and published (September 2023) an update on the allergen labelling technical guidance which includes setting best practice standards for the application of PAL
- Reviewed the scientific literature on cleaning to prevent allergen cross-contamination (published in June 2023).
- Continued work on allergen thresholds including:
    - commissioning a Committee on Toxicity (COT) assessment of a Joint FAO/WHO Expert Committee report looking at the use of thresholds to inform the use of PAL.
    - reviewed analytical methodologies available in the UK to detect food allergens (published in June 2023).

2.3 The COT subgroup recommends that the accuracy and reliability of derived ED values should be evaluated more rigorously if they are going to continue to form the basis for determination of reference vales for food allergens (ED is the eliciting dose predicted to provoke reactions the allergic population, i.e. for a value of ED05 95% of the allergic population would not have a reaction). We are considering what further work is required to address COTs recommendation, we will also need to assess other factors such as impact on consumer choice and deliverability before coming to a future board in late 2024 with a separate paper on thresholds.

2.4 **Provision of Information** - we have commissioned and completed new research as requested by the Board in September 2022 set out in Annex B. The research to date shows:

- Better interaction between consumers and food businesses, both written and verbal, is needed to make eating out safer and easier.
- There needs to be flexibility in the allergen information requirements to complement and encourage the provision of more accurate information.
- There are factors outside of the immediate control of food businesses, particularly SMEs, that impact on the allergen information provided such as last-minute changes to ingredients due to supply chain problems.
- Local Authorities have an important role to play through dissemination of advice and enforcement.

2.5 In addition to the work agreed at September 2022 Board, in June 2023 revised Food Law Codes of Practice (FLCoPs) were published in England and Northern Ireland, introducing a new model for delivering food standards controls. These are the checks carried out by local authorities (district councils in Northern Ireland) to make sure food produced and sold by food businesses is safe and what it says it is. A specific 'Allergen Information' risk factor, which considers compliance with allergen information requirements has been added to the food standards risk assessment. The proposed new model is currently being piloted in Wales.

2.6 The inclusion of a specific risk factor focusing on compliance with allergen information requirements will ensure they are given greater emphasis in the overall risk assessment of the food business, and there will be an incentive for the business to resolve any issues so they don't impact on the resulting date of the next official control (i.e. where appropriate subjecting the business to more frequent official controls until they are resolved). This also importantly opens up options to deliver the proposals set out below.

2.7 **Training** - our work has focused on developing a better understanding of the needs of target audiences, proposed content, and different delivery options. The on-line FSA training had 473000 registered users in September and, through our work with online aggregators on the Aggregators Food Safety Charter project, we have secured agreement that the larger aggregators will share our current allergen e-training to all their partners/food businesses who are affiliated with them.

2.8 The nature of any future training requirements will be dependent on the approach taken to Provision of Information. Further development of the training package will not take place until this work is sufficiently advanced to enable the outputs to be incorporated as training content. This would ensure the content of any new training reflects latest best-practice/legal requirements.

3. Proposals for Provision of Information in the non-prepacked sector

3.1 The rules regarding the provision of allergen information are set out in the Food Information to Consumers (FIC) Regulation No. 1169/2011: for non-prepacked food (such food served in restaurants and cafes) the information on the presence of any of the 14 allergens must be made available to consumers. This information can be provided either in a written format (for example allergen information on a menu) or orally. If a FBO chooses not to provide written information there must be signposting to direct the consumer to where this information can be found, such as asking a member of staff.

3.2 People with a food hypersensitivity need to be able to make informed decisions on where and what to eat. Our evidence indicates that there is room for improvement in the current information flows, and written information is a key part of that.

3.3 Written information can provide a high level of detail but is relatively static (it takes time to change a menu). Over-reliance by consumers and businesses could result in dynamic risks such as cross contamination or substitutions not being fully communicated and understood. Research shows this can be pertinent for SMEs where changes of ingredients can be frequent. This increases the potential for mistakes when information is not updated correctly.

3.4 Conversations between the business and its customers are much more dynamic and can capture changes in the moment, including specific needs and potential solutions. However, they put a lot of responsibility onto servers to remember to pass on information, and to ensure that the information they provide is accurate and up to date.

3.5 Providing information in writing gives people with a food hypersensitivity more autonomy over their food choices. Putting a greater emphasis on written information also moves the responsibility for the accuracy of this information from servers to the business itself.

3.6 However, there are practical challenges in keeping information up to date with a risk that inaccuracies creep in unnoticed. Written allergen information informs consumers about which dishes they should definitely avoid based on **intended** ingredients but will not inform them if the other dishes have ingredient substitutions or might have **unintended** contaminants. These limitations have important implications for safety.

3.7 The major risk associated with providing more written information is that the limitations are not understood by businesses or consumers, and both become over-reliant on the written information. If people with a food hypersensitivity make selections based on this information alone and do not feel the need to seek a conversation that informs the business of their dietary requirements, additional risks can be missed. Equally if, by providing written information, businesses and their staff feel they have fulfilled their responsibilities, they may not recognise the importance of changes that could leave potentially dangerous information unknown to both the business and the person with food hypersensitivity.

3.8 A conversation in the moment is the best way to mitigate this risk, to understand any dynamic risks not related to the specific ingredients, such as cross contamination, whether a particular dish is suitable, and ultimately to check the accuracy of the written information. A conversation also allows for the possibility of some mitigations such as leaving out ingredients

which could expand the range of options open to people with food hypersensitivities. Even with both written information and a conversation there will always be a residual risk the consumer has to weigh up.

3.9 Our proposal is to create a presumption that there should be **both** written information **and** a conversation. This provides two lines of defence that can be mutually reinforcing.

- To preserve the dynamic element, we want to encourage meaningful conversations that are appropriate to the situation and will provide advice and guidance to support its effectiveness based on our research with customers and businesses.
- We need to balance increased emphasis on written information for consumers against the risks of inaccuracy and overreliance. To achieve this, we have identified different levels of prescription we could apply. These are described, and the benefits and risks set out, in the following section.

Does the board agree with the proposal to create a presumption for those supplying non-prepacked food, that they will provide both written information and a conversation?

4. Level of prescription for written information

4.1 The Board are asked to consider the level of prescription in how written information is provided, and whether any such prescription should be mandated. The focus is on the written information as this inherently affects the content, likelihood, and quality of subsequent conversations.

4.2 There are three elements to defining the level of prescription of written information:

- How the information is provided (where, what format)
- Enabling compliance (ensuring it happens)
- Consistency of presentation (how it looks, abbreviations used)

How allergen information is provided

4.3 There are a number of ways written information could be provided and therefore a choice on how prescriptive we want to be about which are used. There is a balance to be struck between consistency for consumers, and the consistency and practicality for the business, with the key variable being accuracy. If it is difficult for the business to keep the information up to date then there is the risk it could become inaccurate, or the business will be driven towards the use of blanket ‘may contain' type statements. Neither of which benefits people with food hypersensitivities.

4.4 We have identified three options to address this balance with decreasing levels of prescription and therefore increasing flexibility for the business:

a) Clearly define how non-prepacked food businesses are expected to provide written allergen information for example, must be on menus.

b) (**Recommended) Set strong direction on** how to provide the required written information (for example, allergen information for individual food items should be provided on menus where possible) but recognise the need for flexibility to use alternative written means where justified (e.g., an allergen matrix displayed at point of sale).

c) Expect all non-prepacked food businesses to provide written allergen information in some form without specifying the format or location.

4.5 Our research shows consumers express a preference for written information, and that menu labelling is an important method for accessing allergen information, whereas there are mixed reactions from FBOs. Chains and larger businesses are more likely to consider it feasible.

4.6 For SMEs, the approach to allergen information provision is often shaped by factors such as a service model, business size, service environment and the types of food served. Menus and practices are more dynamic in this sector which raises a key risk for consumers that over prescription can potentially lead to inaccurate information, either through non-compliance or overuse of precautionary statements.

4.7 This makes it difficult to adopt a single solution or approach to allergen information and management, and to apply this effectively across the whole sector.

4.8 Our recommended option is therefore to set a strong direction so written information is provided in a consistent manner, primarily on menus, but allowing the flexibility for alternative formats to be used where justified. This will maximise consistency while enabling businesses to use an approach which is best suited to individual circumstances where it provides more accurate information for customers and safety.

4.9 One of the difficulties with this approach may be how we ensure compliance. By its nature offering some flexibility makes it harder to define in law should that approach be desired (see discussion below).

Enabling compliance

4.10 The second element where we have choices on the level of prescription is in how we support and/or drive businesses to meet the expectation of providing written information. In order to ensure businesses, meet that expectation we can either:

- **(Recommended)** Strengthen guidance to reflect the prescribed approach and use existing food standard inspections to drive engagement and improvement while maintaining the option of further legislation in the longer term, or
- Recommend to Ministers that we modify legislation to make it a legal requirement for suppliers of non-repacked food to meet that expectation in the prescribed manner.

4.11 The first of these would see the creation of new ‘best practice guidance’ underpinned with the existing legislation as the minimum requirement. Importantly the revised FLCoP in England and Northern Ireland now includes ‘Allergen Information’ as a specific compliance risk factor in the Food Standards Risk Assessment. The Code also requires that the relevant competent authority “have regard to… …any appropriate guidance.” As such the new guidance can help underpin assessment by local authorities of how a business is meeting allergen information requirements. The benefits of this approach are:

- It brings guidance on written allergen information and conversations into an existing framework for official control delivery that is designed to drive improvement.
- Guidance can be more easily revised and updated (for example to incorporate findings from evaluation) than would be the case for legislation.

4.12 It is within the FSA’s remit so would be relatively quick, although it will take time to embed the revised FLCoP itself. Now is the opportune moment to develop the guidance and training to underpin the new allergen section as the FLCoP rolls out.

- The limitations of this approach are around the lack of a specific legal requirement.
- It may not give provision of allergen information sufficient profile amongst other requirements.
- It may not give local authorities the necessary tools to drive improvements quickly.

- It would not be associated with specific direct penalties for non-compliance.

4.13 Introducing a specific legal requirement would mean enforcement authorities would have the ability to take action if information was not provided in the prescribed manner and issue whatever penalties the legislation included. Enforcement would be subject to the local authority's enforcement policy and most likely be wrapped into the inspections under the FLCoPs so the opportunities to identify non-compliance would not differ much in terms of frequency.

4.14 The benefits of this approach are:

- It would give a clarity to businesses and local authorities on what they are expected to do and allow local authorities to take action.
- It would allow the potential for specific penalties to be introduced.
- It would send a signal to businesses on the importance of allergy management and set clear standards against which consumers with a hypersensitivity can assess the ability of a food business to cater for them.

4.15 The limitations of this approach are mostly related to the nature and process of legislation and the risk of perverse outcomes:

- It makes it harder to retain the flexibilities outlined in option (b) above for the provision of information. It also makes it harder to evolve the approach based on experience as legislation provides a fixed requirement.
- Introducing legislation requiring written information and a conversation could amplify the overreliance risks outlined above and give rise to higher risks of non-compliance and inaccurate information if the penalties are not sufficient. There is also a risk that good practice is disincentivised through businesses focusing on compliance rather than embedding an allergen management culture in the wider business.
- We would only be able to recommend legislative change and penalties to Ministers, they would determine whether to pursue it. The process of legislating takes time, requires strong evidence of need and impacts, and we may not get penalties and enforcement any stronger than the existing approach.

4.16 Any legislative change will almost certainly also need to be included in the new assessment of 'Allergen Information' in the FLCoP and so delivery will be very similar between the two options. Therefore, unless we are able to secure more substantial penalties for non-compliance, the marginal benefit of additional legislation will be minimal. Many of the limitations around awareness can be addressed through effective communications and training.

Costs and benefits

4.21 Irrespective of the approach taken there would be implementation costs for local authorities and businesses. Any additional costs imposed on local authorities (whether legislation, guidance, or ministerial announcements) would have to be funded by the FSA.

4.22 Based on our experience of implementing the Pre-Packed Direct Sales requirements (Natasha's Law) we estimate the costs for any legislative route to be:

- Local Authorities: £1.8m for one-off familiarisation costs and £1.6m annual burdens payment
- For businesses: £17.70m for one-off transitional costs, £223.67m familiarisation costs, and annual labelling costs of £13.45m

4.23 To address the limitations around flexibility, and to reduce implementation costs one option might be to consider a two-tiered approach, as is the case for the 2021 Calorie Labelling Regulations which applies to business with 250 or more employees; for business

types/size/models which might struggle to comply, legislation could include less prescriptive requirements supported by guidance with greater improvement focus. However, this could lead to reduced choice and increased risk for consumers who may interpret no, or different, allergy information as allergens not being present. Similarly, businesses not covered by the more prescriptive requirements may assume they do not need to act, missing those who often need to improve most.

4.24 Tragically each year a number of incidents result in fatalities. Many more incidents result in illness with consequential costs to individuals, the NHS, and the economy. There are clear potential benefits to reducing incidents and therefore these consequential costs. It is hard to measure these benefits: the action people with a food hypersensitivity take to avoid incidents is choosing a different meal or choosing not to eat in a particular place based on the information available to them. These actions may be instantaneous decisions that are quickly forgotten, and therefore difficult to quantify. It could be expected that the various approaches outlined will increase the number of successful decisions and therefore reduce incidents.

4.25 There would an economic benefit to (and driver for) improved provision of allergen information for businesses through the potential for increased numbers of people with a food hypersensitivity choosing to eat at their premises; some businesses we have spoken to have highlighted the fact that, for larger groups, it is usually the person with an allergy who decides where to eat.

4.26 The ultimate benefit will be for people with a food hypersensitivity who will be better equipped to make informed choices, from a wider choice of food businesses, and with greater confidence that the food they eat is safe and is what it says it is.

Does the Board agree with our recommendation to focus on strengthening guidance and use existing food standards inspections to drive improvements at this stage, but in setting a direction for improvement retain the option to legislate at a later date?

Consistency of presentation

4.27 Our research indicates that consumers want a consistent approach to allergen information, such as using the same symbols, numbers, abbreviations, or colours for different allergens. We also recognise the need to allow businesses to maintain a degree of flexibility and individualism. Further research is required on what the optimal format or style may be including clarity and accessibility for different people.

4.28 Our proposal is to work with people with food hypersensitivity and stakeholder groups to further understand what they would like to see and to develop a set of guidelines for a standardised approach to allergen information at key consumer touchpoints (such as the symbols used to convey different allergens). The aim would be to ensure a consistent approach for consumers that is still adaptable to different business models and provides businesses some degree of flexibility to tailor approaches to suit their own individual circumstances.

4.29 This approach would take into account work to standardise front-of-house allergen signage, previously agreed at Board and has the potential to go beyond written allergen information to cover other elements such as precautionary allergen labelling, environmental prompts for staff (e.g. signage in kitchens), and approaches to providing oral information (for example verbal confirmation of an order when it is served, including any allergen requirements).

Does the board agree with the proposal to develop a set of guidelines for a standardised approach to allergen information?

5. Evaluation

5.1 We will evaluate the proposed changes to determine impact and whether further action is required. The nature of the evaluation will depend on the approach taken forward but would incorporate both process and outcome measures for food businesses, local authorities and consumers with food hypersensitivity (it will not be possible to measure the impact on incidence of allergic reactions).

5.2 Potential factors to be assessed include:

- Awareness of changes across consumers, food businesses and local authorities
- Uptake and changes to how businesses provide allergen information, including changes in business behaviour (such as how they provide allergen information).
- The effect of changes on people with a food hypersensitivity (such as feeling more informed on allergens when eating out and spending less time and effort finding a suitable establishment).
- Local authority experience of resources to support changes.
- What critical success factors and lessons learned can be gained from the implementation which could be applied in future

5.3 The proposed evaluation we expect to undertake is set out in Annex C

6. Conclusions

6.1 We welcome the Board's views on the proposals for the provision of allergy information in the non-prepacked sector: to set a strong expectation of both written information and a conversation; and to do so in a way that drives a common approach and standardisation as far as possible; while retaining sufficient flexibility that all businesses are willing, able and supported to comply; without the need for additional legislation at this time.

6.2 Next steps will be subject to the board's decisions and resourcing requirements in line with wider prioritisation.

Annexes

Annex A

Precautionary Allergen Labelling (PAL)

The work focuses on what would be required to implement a system where the application of PAL statements is linked to a standardised risk analysis process, including the exceedance of set threshold levels.

Our research has found that at present consumers mistrust and are confused by PAL statements on prepacked food products, because a range of phrases are used that have no correlation with the risk the product poses. Also, there are no definitive standards for the risk-analysis of allergen cross-contact.

In September, we published an update to the allergen labelling technical guidance for prepacked foods, which included setting best practice standards for the application of PAL.

In 2024, we will be producing a quick guide on allergen cleaning validation, because our research has shown that SMEs in the non-prepacked sector tend to not perform any validation, and as a corollary, do not know the effectiveness of their allergen clean.

In September, the Committee on Toxicity of Chemicals in Food, Consumer Products, and the Environment (COT) opined on the Codex Expert Committee's Allergen Threshold Report. The

COT had concerns about the recommended move from ED01 to a higher allergen threshold of ED05. Their view is that there is insufficient evidence to say public health would not be harmed. They also have concerns around the methodology used to derive eliciting doses.

We will consider the COT views as part of our overall considerations, whilst we continue to influence Codex's development of standards for allergen thresholds in our role as UK Co-Chair of the Allergen Labelling e-working group.

Annex B

Provision of Information

We undertook further research in the past year and gathered evidence to assess the options (including our recommended option) and to consider the benefits and risks from those which we have put forward in this paper.

The additional research consisted of:

- An assessment into the international provision of allergen information associated with the sale of non-prepacked food. The aim of this review was to summarise the evidence base and evaluate the international provision of allergen information in the non-prepacked food sector.
- A qualitative study of a sample of SMEs in the non-prepacked food sector, to understand in more detail:
    - How SMEs currently provide allergen information to consumers and the reasons for this approach.
    - The challenges SMEs face in managing allergen cross-contact.
    - The challenges SMEs face in providing accurate allergen information to consumers.
    - The challenges and benefits of a range of different options for providing allergen information to consumers.
- A survey with consumers who have food hypersensitivity and who had an incident in the last 5 years, to understand the circumstances associated with reactions and near misses.
- An evaluation of the implementations of the Prepacked for Direct Sale (PPDS) legislation Natasha's Law) and their effect on people with food hypersensitivities, food businesses and Local Authorities. The research objectives were to understand:
    - Awareness of PPDS labelling requirements.
    - Uptake and compliance with PPDS labelling requirements.
    - The effect of PPDS labelling requirements.
    - Local Authority experience of using and developing resources to support compliance.
    - Critical success factors and lessons learned which could be applied in future.
- A study and fact-finding visit to the Republic of Ireland to learn more about how the national legislation works (where they require written allergen information be provided without consumers having to ask for it) in practice and its effectiveness.
- Workshops with internal and external stakeholders including the Food Hypersensitivity Expert Panel and Anaphylaxis UK Business Forum.
- A workshop with Local Authorities discussing current barriers to the provision of allergen information and enforcement and the perceived feasibility of changes to this.

The key findings have been highlighted in the paper and used to develop the options we have put forward.

Annex C

Evaluation

An evaluation of the Provision of Information guidance would incorporate both process and outcome measures for food businesses, local authorities and consumers with food hypersensitivity it will not be possible to measure the impact on incidence of allergic reactions.

We propose a mixed-methods evaluation. For all stakeholders (consumers, food business operators and Local Authorities) pre-intervention baselines we recommend surveys and for post-intervention measures we recommend surveys and interviews. The survey will provide us with quantitative measures, which we can analyse to see if there is a statistically significant difference pre-and-post intervention. The interviews will provide us with an understanding of experiences of the guidance and changes resulting from it. We note that this methodology's limitation is its lack of causality, however if longer-term survey questions were available, we could track trends and see if there are any significant changes since introduction of the intervention.

Following the board's decision we would develop a detailed evaluation plan, based on a Theory of Change. The below describes our broad approach for each stakeholder:

Consumers: We would measure the effects of the guidance on consumer outcomes such as confidence, attitudes and behaviours (such as feeling more informed on allergens when eating out and spending less time and effort finding a suitable establishment). We would use surveys pre and post intervention to identify changes to the identified outcomes and supplement this with interviews to explore people's experiences of provision of information when eating-out (post intervention). We would also compare the qualitative insight to previous qualitative research. Our preferred approach is to use questions already asked in the Food & You 2 survey, supplemented with a few additional questions added to this survey. Based on numbers in wave 6, and assuming similar number of respondents in future waves, typically we would be able to detect around a 10% (absolute) difference (between waves) for those who have clinically diagnosed allergies, around a 7% difference for clinically diagnosed hypersensitivity of any sort and around a 3% difference for any hypersensitivity whether or not diagnosed (these numbers will vary slightly by question). This would all be at a 5% statistical significance. Some questions already have high positive response levels so detecting further improvements may be unlikely. Although it would be possible to use separate surveys to Food & You 2, this is not recommended as it would be both expensive and challenging, due to the difficulties of identifying and recruiting unbiased samples of people with food hypersensitivities.

Food Businesses: we would use surveys to identify the outcomes of the guidance on their business, for example whether they have changed how they communicate allergen information and any consequences on resource, as well as awareness of guidance. For these surveys we will explore the use of the current small and micro FBO tracking survey. This may be supplemented by a broader survey including medium and large food businesses. The current survey should allow us to detect around a 6% (absolute) difference (between waves) in responses to questions on how, and whether, food businesses supply information on allergens. We would use interviews to provide more in-depth understanding of experiences and outcomes, for example – to understand decision-making processes behind choices on how to provide allergen information (such as why they did/did not place on menus) and any challenges they experienced in making changes to their provision of information.

Local Authorities we would use a survey to identify the resourcing implications regarding delivering the guidance (such as time) and any challenges involved in the process. We would use interviews to further understand these outcomes, such as causes of challenges and how/ if they were overcome.

For all groups we would also identify any unintended consequences (known and unknown).