

## ALLERGEN INFORMATION FOR CONSUMERS ON PRE-PACKED FOR DIRECT SALE (PPDS) FOODS

### 1 Purpose of the paper

- 1.1 This paper seeks the Board's views on the outcome of the recent UK-wide consultation on options for strengthening the regulatory framework for the provision of allergen information for foods that are pre-packed for direct sale (PPDS). The consultation was undertaken jointly by Food Standards Scotland (FSS), the Department for Environment, Food and Rural Affairs (Defra), and the Food Standards Agency (FSA), following a Coroner's inquest into the death of Natasha Ednan-Laperouse who died after eating a baguette that contained sesame seeds as an ingredient. In the context of wider public health concerns this has raised the issue of whether the current regulatory framework for the provision of allergen information for PPDS foods remains sufficient to give consumers the information they need to make safe food choices.
- 1.2 This paper considers a number of policy options for Scotland, informed and refined by stakeholder responses to this consultation, as a basis for FSS's advice to Scottish Ministers, and any further stakeholder engagement and consultation.
- 1.3 The Board is asked to:
- **Note** the non-regulatory and regulatory policy options that were proposed in the UK-wide consultation, outlined at paragraph 4.1.
  - **Note** the consumer and stakeholder responses to each of these four options, summarised at paragraph 5.3.
  - **Consider** the assessment of consumer benefits, risks and business impacts associated with each of these policy options, set out in section 6.
  - **Agree** that, whilst Option 3 would be an important and potentially more achievable step in the right direction to improve the provision of allergen information to consumers for PPDS foods, the overwhelming consumer support is for Option 4.
  - **Note** that for Option 4 to provide the certainty needed to deliver the confidence that consumers seek in allergen labelling, businesses that supply PPDS foods will need to be able to provide accurate full ingredient labelling on a consistent basis, and it is recognised that to do so will be more challenging for some businesses than others. In short, whilst Option 4 is the approach that the majority of consumers support, it is not without risk and challenges, and is likely to have impacts on the businesses involved. Whilst Option 3 may be more achievable as mandatory labelling would be limited to the 14 allergens listed in the FIC Regulation, this would still present challenges for some businesses, and consumer confidence will be dependent on consistent, accurate information being provided.

- **Agree** that FSS provides advice to Scottish Ministers that recommends moving towards delivery of Option 4 in Scotland, but that further work should be undertaken to assess the benefits, impacts and risks of introducing mandatory full ingredient listing for PPDS foods.

## 2 Strategic Aims

- 2.1 This work supports FSS Strategic Outcomes 1 and 2 – Food is Safe and Food is Authentic. It is important that consumers have confidence that food information is accurate and clear, and that food information and labelling about allergenic ingredients in products allow them to make safe food choices.

## 3 Background

- 3.1 A key driver for Government intervention with respect to allergen information on PPDS foods was the publication in October 2018 of the Coroner's report into the death of Natasha Ednan-Laperouse. The inquest concluded that the teenager died due to an anaphylactic reaction to sesame contained in a baguette which did not carry specific allergen information on the packaging or near the product on the shelf. One of the concerns raised by the Coroner in London was that the business, using local kitchens, was not required to undertake full labelling through an exemption in food labelling regulations for food sold PPDS. Following receipt of the Coroner's report, the Defra Secretary of State sought cross-government agreement to review the information needed on food sold on a PPDS basis, and Scottish Ministers agreed that this review should be undertaken across the UK.
- 3.2 Businesses supplying non-prepacked food whether PPDS, sold loose, or in catering situations must have allergen information available. There is not a clear definition of PPDS in the EU Food Information to Consumers (FIC) Regulation. Given this lack of a clear definition Defra, FSA and FSS have previously agreed guidance on how to interpret this term and views were sought on this interpretation in the UK-wide consultation. While some agreed with the approach, others felt that clarification of the scope is needed (see Annex A). The FIC Regulation is clear that PPDS food is treated like non-prepacked food such as foods sold loose, and therefore they are not required to carry a label. However, information on the mandatory 14 substances and products known to cause food allergy and intolerance listed in EU law, including sesame, must be available for food sold this way. Under national law across the UK, food businesses have flexibility in how this information may be supplied to consumers, which includes signposting consumers to where information may be found e.g. oral advice from staff, notices and product sheets.
- 3.3 The work FSS is undertaking in relation to the provision of allergen information for PPDS foods forms part of broader range of activities in this area. For example, FSS launched its new allergen alert service in March and take up

amongst consumers and businesses is very positive, generating increases of 208% and 786% for e-mail and text subscribers respectively by early April. FSS has also been working with stakeholders, including Local Authorities, to identify the reasons for the increase in allergen alerts in Scotland and approaches to reduce their occurrence, such as the Menucal system which helps businesses identify allergens in their recipes. In addition, FSS is considering ways to improve the reporting system to ensure we are routinely notified of all food related allergy incidents in Scotland.

- 3.4 There are around 2 million people in the UK with a food allergy and the most recent FSS consumer attitudes tracker survey shows that 15% of people in Scotland are living in households where at least one person is allergic to certain foods or ingredients. Additional background on food hypersensitivity and the relevant legislation on food information is in Annex A.

## 4 Discussion

- 4.1 The UK-wide consultation focused on the provision of allergen information for PPDS foods. The four policy options on which stakeholder views were sought are as follows:

- Option 1 – Promote best practice
- Option 2 – Mandate the use of ‘ask the staff’ labels on all PPDS foods.
- Option 3 – Mandate the name of the food and 14 allergens listed in the FIC Regulation on labels of all PPDS.
- Option 4 – Mandate the name of the food and full ingredient listing on labels of all PPDS foods

- 4.2 While mitigating the risk of potential cross-contamination is an important aspect of consumer protection with respect to allergens, the consultation was specifically focused on the provision of allergen information in relation to intentional ingredients in PPDS foods, and circumstances where there are opportunities for consumers to speak to the food business about allergens before making a purchasing decision. Therefore, the scope of the consultation did not include:

- Precautionary allergen labelling such as ‘May contain’ statements to indicate the unintentional presence of food allergens due to cross contamination.
- Allergen information for non-prepacked food ordered via distance selling.
- Food that is not packed (such as meals served in a restaurant), or that is packed on the sales premises at the consumer’s request (such as a sandwich made to order, cheese or meat sold loose from a delicatessen or bread and pies sold at bakeries).

- 4.3 The overarching objective of the four consultation options is to improve the provision of information to consumers about food allergens present in PPDS foods. Each option considers various measures that could be implemented to improve the information made available to consumers, and alleviate consumer concerns related to allergen information provision on PPDS foods.
- 4.4 There is no doubt that more needs to be done to alleviate consumer concerns, but given the size and scale of the out of home sector and the range of outlets, from national chains to small family owned SMEs, none of the options of themselves remove the necessity for individuals to continue to manage their own allergies, not least because the 14 allergens listed in the FIC Regulation are not the only allergies consumers have to food and food ingredients. We therefore need to focus on delivering outcomes that provide consumers with information that enables them to make informed decisions, and reduces the risk to consumers.
- 4.5 The four policy options represent a sliding scale moving from a non-regulatory measure to increasingly prescriptive regulatory measures. Option 1 is aimed at raising consumer confidence without regulatory intervention, through encouraging changes to business practices around allergens and campaigns to raise awareness for allergic consumers. Options 2 to 4 consider using regulatory measures, underpinned by legal obligations on food businesses, in order to achieve the same objective of improving the provision of information to consumers.
- 4.6 Food information is a devolved area and modifying existing national flexibilities and introducing any new mandatory measures for Scotland would require amendments to secondary legislation i.e. the Food Information (Scotland) Regulations 2014. A detailed Business and Regulatory Impact Assessment (BRIA) would also be necessary to support any legislative proposals. It should be noted that as PPDS food is supplied to consumers at the point of packing, any divergence of approach across the UK would only impact local markets, and a tailored approach to consumer protection for Scotland, if warranted, regarding the means by which allergen information should be provided for these foods is unlikely to raise wider UK market concerns. This is of course subject to the views of Scottish Ministers and the Scottish Parliament.
- 4.7 All food businesses are already obliged by law to have allergen information available which consumers are entitled to receive. All the options that were consulted on aim to improve how consumers are informed about allergens in food sold PPDS, with three of the options placing a greater emphasis on written information. We would encourage businesses to consider the needs of all their consumers, for example, those with impaired vision or multiple allergies who may need extra time to assess if food is suitable for them.

## **5 Consultation Feedback**

- 5.1 Public consultation took place across the UK between 25 January and 29 March 2019, generating 223 responses from Scotland. Around 65% of those responses came from individuals, 21% from businesses and the remainder

from Non-Governmental Organisations (NGO) and Public Sector Bodies (PSB). Overall, 52% preferred full ingredients labelling (Option 4), 20% opted for a combination of the options and 13% preferred information on the 14 allergens on foods sold PPDS (Option 3).

5.2 FSS undertook additional stakeholder engagement with consumers and the environmental health profession in Scotland. The outcome of this also demonstrated that full ingredients labelling (Option 4) and allergen labelling (Option 3) were the most popular options. All sectors also showed support for a combination of options.

5.3 Key themes from the consultation responses in Scotland are:

- Individuals felt overwhelmingly that full ingredients information is necessary to help those consumers with allergies and intolerances to foods which are not included in the list of 14 substances and products in EU law.<sup>1</sup>
- Individuals also felt that food business staff may not always seem to have a proper understanding of food allergens, and want more staff training and allergen labelling to improve the clarity and consistency of information.
- Businesses consider dialogue between businesses and consumers as very important, and an area in which they could improve.
- Businesses expressed significant concerns over the risks and practicality of mandating full ingredients listing under Option 4, given the complexity of supply chains, frequency of recipe changes, and potential to unintentionally mislead consumers.
- NGOs overall favoured a combination of options with equal support for allergen labelling and full ingredients information.
- PSBs preferred allergen labelling followed closely by a combination of options. They felt that full labelling would be too onerous and subject to errors, especially for smaller businesses dealing with frequently changing recipes, suppliers or ingredients.

5.4 A summary of Scottish consultation responses is provided in Annex B. The overall themes and trends in the responses to the consultation in Scotland were broadly similar to those in the rest of the UK, although different proportions of the responses were received from consumers and businesses, with 65% of Scottish responses being from consumers compared to 87% in the rest of the UK, and 21% of Scottish responses being from businesses, compared to 7% in the rest of the UK.

---

<sup>1</sup> The list of 14 substances and products known to cause food allergies or intolerances in the EU Food Information to Consumers Regulation is based on public health importance (most potent and prevalent food allergens in the EU). However, the list is not exclusive and many people can be allergic to foods not on this list.

## 6 Policy Options Appraisal

6.1 As the Board is aware, it is the responsibility of businesses to produce and sell safe food. The decision on whether or not a food is suitable for them rests with the consumer. The current approach for PPDS food relies on consumers making food businesses aware of their dietary needs, and businesses in turn being able to inform consumers by providing accurate allergen information when asked.

6.2 The review and consultation identified the need to address the following risks and issues:

- Consumers not always being clear with food businesses about their allergies and/or intolerances.
- Some consumers may be reluctant to ask for allergen information.
- Some consumers may assume that the lack of information on wrapped products means that there are no allergens present.
- Businesses failing to make allergen information available due to:
  - lack of awareness of their legal obligations
  - lack of adequately trained and informed staff
  - lack of robust systems to check ingredients and track allergens going into recipes and products

6.3 The following analysis gives an overview of each option in the consultation along with an assessment of the advantages and disadvantages, and how the risks in paragraph set out above would be addressed. There are two considerations that are relevant in the assessment of the options: the first is related to the degree of certainty each option gives to consumers, which potentially leads to increase in confidence, and the second is whether an option reduces the risk.

6.4 An initial assessment of the cost impacts for businesses and enforcers is provided in Annex C. A more detailed impact assessment will be needed in developing any proposals for legislation.

### **Option 1** – *Non-regulatory - Promote best practice.*

6.5 This option would entail additional activity by Government departments to promote best practice within the current legislative arrangements. The aim would be to encourage businesses and consumers to review their knowledge, skill and actions to help develop a safer environment for consumers. This could include, for example:

- Best practice guidance for businesses and enforcement authorities.
- Stakeholder conferences with businesses hosted by FSS and other leads across the UK (i.e. Defra and FSA) to discuss best practice and encourage business change without amending legislation.

- Awareness campaigns to highlight the risks and issues around allergens and food hypersensitivity to food businesses and other target audiences.
- 6.6 The advantages of this approach are that it could be introduced with greater pace compared with regulatory change, given the relative ease of adapting existing guidance and best practice advice so that it remains fit for purpose. It would also provide flexibility for businesses in the way they are required to provide allergen information to consumers, at a relatively low cost. However, a non-regulatory approach does not guarantee that businesses will review their own arrangements and consistently provide accurate allergen information to consumers, and consumers may not have increased confidence in allergy information on PPDS foods.
- 6.7 Businesses were generally supportive of this option and were keen to promote dialogue with consumers. There was also business support for combining best practice guidance with the other options, notably Option 2. Few of the responses from individuals favoured best practice advice in isolation from other regulatory approaches. Similarly, NGOs and PSBs were supportive of this approach in combination with the other proposed options.
- 6.8 While Option 1 would help raise awareness and understanding of the need to provide allergen information amongst food businesses, it is unlikely on its own to guarantee an improvement in the provision of allergen information over the current arrangements.
- 6.9 The potential for a huge variance in business approach would not be in consumers' interests and would not improve certainty on the safety to consumers of the product they wished to buy. Given the voluntary nature of this option, the level of uncertainty for consumers would remain high and provides limited confidence that it would reduce the risk to consumers.

***Option 2 – Regulatory – Mandate ‘ask the staff’ labels on PPDS foods with supporting information for consumers in writing.***

- 6.10 This option would require PPDS foods to include a label/sticker on the packaging advising consumers to “ask the staff” about allergens. When asked, staff would have to provide supporting information in writing upon request, before the food was purchased. This information would comprise of either a list of any of the 14 allergens contained within the specific product, or a full ingredient list with allergens emphasised.
- 6.11 Most businesses were supportive of this option compared with other stakeholder groups, although combining this with other options such as best practice guidance also received considerable business support. Overall, this option attracted the least support from individuals, NGOs and PSBs.
- 6.12 Option 2 would encourage businesses to strengthen existing traceability, records, and product tracking systems to support the provision of allergen information to consumers, particularly to manage product ingredient

substitution. Using a sticker on PPDS foods would not eradicate the need for businesses to clearly indicate to consumers how allergen information is to be made available for other non-prepacked foods, such as foods sold loose. This approach would present the least costs for businesses of the three regulatory options.

- 6.13 While this approach may generally encourage consumers to engage with business staff on allergens, it may not address a reluctance by some consumer groups to ask food businesses for allergen information, e.g. teenagers were specifically highlighted in the consultation as not wanting to be seen to 'make a fuss'. It is also unlikely to reduce any potential confusion between PPDS and prepacked foods, where consumers may believe the absence of information on PPDS foods means there are no allergens present. The level of uncertainty is likely to be less than Option 1, but still has limited assurance in terms of reducing the risk to consumers, not least because the emphasis is on consumers to be pro-active, rather than businesses.

***Option 3 – Regulatory – Mandate the name of the food and allergen labelling on PPDS food.***

- 6.14 This option would require the packaging to carry a label containing the name of the food and a declaration of any of the mandatory 14 allergens specified in the FIC Regulation when used as an ingredient. Flexibility could be provided to businesses on the manner in which this mandatory information should be provided, such as the use of pre-printed labels or a tick box approach, and in terms of format and presentation. Alternatively, a more prescriptive approach could be adopted to help drive consistency for both consumers and businesses. However, this would need to be explored as part of any further targeted consultation on any proposed mandatory approach.
- 6.15 This was the second most favoured of the four consultation options amongst stakeholders. Half of the businesses supported this option, and individuals preferred this to options 1 or 2. This option was preferred by PSBs with NGOs showing some support but with a preference for a combination of options.
- 6.16 Under this option consumers would be provided with upfront written allergen information on PPDS food packaging, with the aim of improving confidence amongst food allergic and intolerant consumers. It is also more likely than Options 1 and 2 to reduce any potential consumer confusion between PPDS and prepacked foods, and would address the reluctance amongst some consumers groups to ask for allergen information. However, this option does not cater for those consumers with allergies and intolerances to substances and products that are not listed in the 14 defined in the FIC Regulation, so is not a complete solution.
- 6.17 While there would be costs for businesses in terms of product relabelling under this option, it is considered to be practical and achievable approach. Businesses would be required to assess all ingredients in PPDS foods to ensure allergen information on product labelling is accurate, and that ingredient substitutions do not affect the allergen status of foods on display. This would



require businesses to track and record allergen information effectively, which they are currently required to do, and so mitigates the cost issues.

- 6.18 While this option may carry a risk of an increased number of allergen mislabelling incidents if not carried out with care, this risk may be less than under Option 4, as businesses would only be concerned with the 14 FIC allergens, and not all ingredients present. There is also a risk of unintended consequences under Option 3 (and Option 4) in that it could drive businesses towards selling more loose foods and fewer PPDS foods, to avoid any additional allergen labelling requirements. This could increase potential cross-contamination and food hygiene risks, and these are issues that would require further detailed consideration as part of any future stakeholder consultation. From a consumer perspective, this option provides a higher degree of certainty in respect of the 14 FIC allergens, but also has some risks because of the limitations outlined above.

***Option 4 – Regulatory - Mandate the name of the food and full ingredient list labelling, with allergens emphasised, on PPDS food.***

- 6.19 This option would require PPDS foods to include the name of the food and an ingredients list with the allergens emphasised on the packaging, with the potential to fully align with allergen labelling requirements for prepacked foods. This would include the 14 mandatory allergens listed in the FIC Regulation, or any derived substance or product causing allergies or intolerances used in the manufacture or preparation of a food, and which are still present in the finished product, even if in an altered form. These allergens would need to be emphasised to stand out from the other ingredients in the list.
- 6.20 Option 4 was overwhelmingly supported by consumers, and was the most favoured consultation option overall, due to the high number of responses from individuals. Business stakeholders offered mixed views on this option, with notable support from some larger businesses with greater technical capacity and the ability to implement full ingredient listing. However, smaller businesses were particularly concerned about the practical challenges and risks of any move towards mandatory full ingredients labelling for PPDS foods. There was an equal level of support from NGOs and PSBs for this option.
- 6.21 Full ingredient listing would provide consumers with detailed allergen information for PPDS foods, and a greater alignment between the information on labels for PPDS and prepacked foods. The greater consistency this would provide for consumers between PPDS and prepacked foods would remove any confusion about ingredients contained in wrapped foods regardless of how they are sold, thereby improving consumer choice and confidence amongst food allergic and intolerant individuals.
- 6.22 As with Option 3, this would require businesses to assess all ingredients in PPDS foods to ensure that allergen and ingredient information on product labelling is accurate. This would require businesses to have robust traceability systems to track and record allergen and ingredient information in order to label products accurately, and reflect any ingredient substitutions or recipe changes. As noted above, this is expected to bring practical challenges for smaller

businesses in particular, who may source their ingredients from a range of different suppliers over whom they may have limited influence.

- 6.23 Similarly, the complexity of supply chains and frequency of ingredient and/or product changes could lead to an increased risk of mislabelling, and consequently potential incidents, if not carried out with care and accuracy. There is also a potential risk, as with Option 3, of unintended consequences, whereby businesses could move to selling more foods loose or made to order, to avoid additional labelling requirements, which could present increased cross-contamination and hygiene risks.
- 6.24 This may be the most costly regulatory option for businesses in terms of changes to product with regard to labelling and business traceability systems, but further detailed assessment would be needed to understand the impacts on different businesses. This option, provided businesses are able to do it accurately, has a higher degree of certainty for consumers than the other options, but as with all the other options it doesn't eradicate the risk. We consider that further research and analysis needs to be undertaken to determine if businesses can do this in ways that will provide this greater certainty to consumers, and thereby provide confidence that risks to consumers can be reduced.
- 6.25 On balance therefore, it is recognised that mandatory allergen labelling under Option 3 would be a significant step change in strengthening consumer protection and confidence in relation to PPDS foods for food hypersensitive individuals. However, the outcome of the consultation, both in Scotland and across the UK more widely, is clear that consumers feel strongly that full ingredient listing under Option 4 would provide the best level of protection for individuals with food hypersensitivity, while reflecting the practical challenges and risks in seeking to achieve such an approach. As such, FSS recognises the need to undertake more detailed analysis of the implications for businesses, and SMEs in particular, of seeking such an approach in Scotland.

## 7 UK Considerations

- 7.1 The FSA Board considered the outcome of the consultation in the rest of the UK at their meeting on 8 May 2019, where they agreed that increased allergen information should be provided on PPDS foods to give consumers greater confidence in the food they eat. The Board agreed to advise Ministers in England, Wales and Northern Ireland that full ingredient labelling should be mandatory for all PPDS foods, while recognising the practical challenges this will entail for businesses.
- 7.2 This reflected the FSA's acknowledgement of the strong views of allergic consumers that full ingredient labelling would deliver a significant improvement and greater consistency, by following the same labelling system that consumers are familiar with, as found on packaged food, and that this should be the ambition where it can be introduced in a way that is safe and workable. The Board also set out key priorities identified as part of an ambition "...to make the UK the best

*place for food hypersensitive consumers, which includes those with food allergy and intolerance.”*

## **8 Enforcement**

- 8.1 Local Authorities in Scotland have responsibility for the enforcement of the food information requirements including the provision of allergen information. The introduction of any of the regulatory options would involve extending the scope of the current offences in the Food Information (Scotland) Regulations 2014, and local authority officers would need to become familiar with any new legal requirements to allow them to enforce them effectively. There may also be increased requests for support and advice from businesses in adapting to new requirements.

## **9 European Union considerations**

- 9.1 The rules on food labelling in the FIC Regulation are harmonised across the EU. The flexibilities that are available to Member States to provide certain exemptions from food labelling requirements generally apply in areas where consumers can easily ask questions of food businesses to inform their purchasing decisions. The lack of a clear definition of PPDS in the FIC Regulation means that we are reliant on a policy interpretation to balance how wide the exemption should be. To provide greater clarity on these regulatory flexibilities it may be possible to consider this definition as part of any review of food labelling if the UK leaves the EU.

## **10 Conclusions**

- 10.1 The provision of accurate and meaningful allergen information on PPDS foods is a complex and challenging issue for food hypersensitive consumers, businesses, and regulators alike. In addressing these challenges in Scotland there will be a need for FSS to work collaboratively with a wide range of stakeholders and across governments to deliver the improvements that are needed to ensure that consumers receive the best level of protection, and are confident about the food they eat, while also recognising the responsibilities of individuals who have food allergies.
- 10.2 Whilst there are a range of views on the way forward, the introduction of mandatory allergen labelling on PPDS foods under Option 3 would be a significant step in improving the level of information provided to consumers in a manner that should be achievable for most businesses. However, Option 4 delivers greater parity between prepacked and PPDS food, and businesses must be able to do this accurately and consistently to provide the greater certainty that consumers seek. Given the safety issues associated with allergens it is entirely justified to fully recognise the very strong views that have been expressed by consumers that full ingredient labelling should be mandatory for all PPDS foods. Nonetheless, delivery of Option 4 (and to a lesser extent Option 3) is not straightforward, and it is therefore proposed that in providing advice to Scottish Ministers, that FSS should highlight the need for more detailed work to assess the feasibility and practicality of moving towards Option 4 in Scotland.

10.3 The Board is therefore asked to:

- **Note** the non-regulatory and regulatory policy options that were proposed in the UK-wide consultation, outlined at paragraph 4.1.
- **Note** the consumer and stakeholder responses to each of these four options, summarised at paragraph 5.3.
- **Consider** the assessment of consumer benefits, risks and business impacts associated with each of these policy options, set out in section 6.
- **Note** that for Option 4 to provide the certainty needed to deliver the confidence that consumers seek in allergen labelling, businesses that supply PPDS foods will need to be able to provide accurate full ingredient labelling on a consistent basis, and it is recognised that to do so will be more challenging for some businesses than others. In short, whilst Option 4 is the approach that the majority of consumers support, it is not without risk and challenges, and is likely to have impacts on the businesses involved. Whilst Option 3 may be more achievable as mandatory labelling would be limited to the 14 allergens listed in the FIC Regulation, this would still present challenges for some businesses, and consumer confidence will be dependent on consistent, accurate information being provided.
- **Agree** that FSS provides advice to Scottish Ministers that recommends moving towards delivery of Option 4 in Scotland, but that further work should be undertaken to assess the benefits, impacts and risks of introducing mandatory full ingredient listing for PPDS foods.

For Queries contact:

**Stephen Hendry**

Senior Policy Advisor

[Stephen.hendry@fss.scot](mailto:Stephen.hendry@fss.scot)

01224 285153

10 May 2019

## ANNEX A

### Background on food hypersensitivity and food information requirements

- 1.1 Food hypersensitivity is a condition where people adversely react when eating certain foods, and is categorised into food allergy and non-allergic food hypersensitivity (food intolerance). In the UK, it is estimated that 1-2% of adults and 5-8% of children have a food allergy<sup>2</sup>. This equates to around 2 million people living in the UK with a food allergy, but this figure does not include those with food intolerances. In addition, it is estimated that 1% of people have coeliac disease, an auto-immune condition which causes damage to the gut lining when gluten is present in food.
- 1.2 Symptoms of an allergic reaction can range from mild symptoms such as itching around the mouth and rashes, and can progress to more severe symptoms such as vomiting, diarrhoea, wheezing and on occasion anaphylaxis (shock). Around ten people in the UK die from allergic reactions to food every year.
- 1.3 There is currently no cure for food allergies and intolerances. The only way to manage the condition is to avoid food that makes the person ill. Therefore, it is very important that consumers are provided with accurate information about allergenic ingredients in products to allow them to make safe food choices.

### Allergenic Foods

- 1.4 There are 14 substances or products known to cause allergies or intolerances that (unless exempted) are subject to a mandatory consumer information requirement under the Food Information for Consumers (FIC) Regulation (EU) No 1169/2011. These are:
  - Cereals containing gluten, namely: wheat (such as spelt and Khorasan wheat), rye, barley, oats and their hybridised strains and products thereof;
  - Crustaceans and products thereof;
  - Eggs and products thereof;
  - Fish and products thereof;
  - Peanuts and products thereof;
  - Soybeans and products thereof;
  - Milk and products thereof (including lactose);
  - Nuts, namely: almonds, hazelnuts, walnuts, cashews, pecan nuts, Brazil nuts, pistachio nuts, macadamia or Queensland nuts, and products thereof;
  - Celery and products thereof;
  - Mustard and products thereof;
  - Sesame seeds and products thereof;
  - Sulphur dioxide and sulphites >10mg/kg or 10mg/L;
  - Lupin and products thereof;
  - Molluscs and products thereof.

---

<sup>2</sup> Source – Food Standards Agency

- 1.5 The list of 14 substances and products is based on public health importance (i.e. the most potent and prevalent food allergens in the EU). This list is harmonised across the EU and cannot be amended by individual Member States. However, the list is not exclusive and many people can be allergic to foods not on this list.
- 1.6 This mandatory consumer information requirement for these 14 allergens extends to all foods provided to consumers, including food that is not prepacked (e.g. restaurant meals); packed at the consumers' request (e.g. a deli sandwich prepared, wrapped and handed to the customer); or is PPDS (e.g. a sandwich prepacked before the customer chooses it).

### Prepacked for direct sale

- 1.7 Regulation (EU) No 1169/2011 does not provide a specific definition of PPDS, as it is not intended to be covered by the rules for prepacked foods and fits with other non-prepacked situations mentioned in the Regulation.
- 1.8 However, the interpretation set out in FSA's technical guidance on allergen labelling, published in April 2015, is as follows:

***“Prepacked foods for direct sale:*** *This applies to foods that have been packed on the same premises from which they are being sold. Foods prepacked for direct sale are treated in the same way as non-prepacked foods in EU FIC's labelling provisions. For a product to be considered 'prepacked for direct sale' one or more of the following can apply:*

- *It is expected that the customer is able to speak with the person who made or packed the product to ask about ingredients.*
- *Foods that could fall under this category could include meat pies made on site and sandwiches and sold from the premises in which they are made<sup>3</sup>.*

### Examples of PPDS foods

- 1.9 PPDS foods may be available to consumers in out-of-home and retail environments. In an out-of-home environment such as a sandwich shop, café or burger bar, any food that is prepacked on the premises in anticipation of an order, before being offered for sale, would be considered to be PPDS.
- 1.10 Examples may include foods which the consumer self-selects from a chiller cabinet or has to ask a member of staff for, for example, a sandwich or boxed salad on display behind a counter. Food ordered and collected in person by a consumer in a takeaway, may be PPDS if it was packed before it was offered for sale, for example, a wrapped burger, boxed fried chicken or wedges under a hot lamp.

---

<sup>3</sup> <https://www.food.gov.uk/sites/default/files/media/document/food-allergen-labelling-technical-guidance.pdf>

1.11 In a retail environment such as a supermarket, the following examples would also be considered to be PPDS, provided they are packed on the premises from which they are being sold before they are offered for sale:

- Fresh (uncooked) pizzas from the deli counter;
- Boxed salads;
- Hot foods such as rotisserie chicken or wedges; and
- Foods that are pre-weighed and packed such as cheese or meats from a delicatessen counter or baked goods from an in-store bakery

### **Non-PPDS foods**

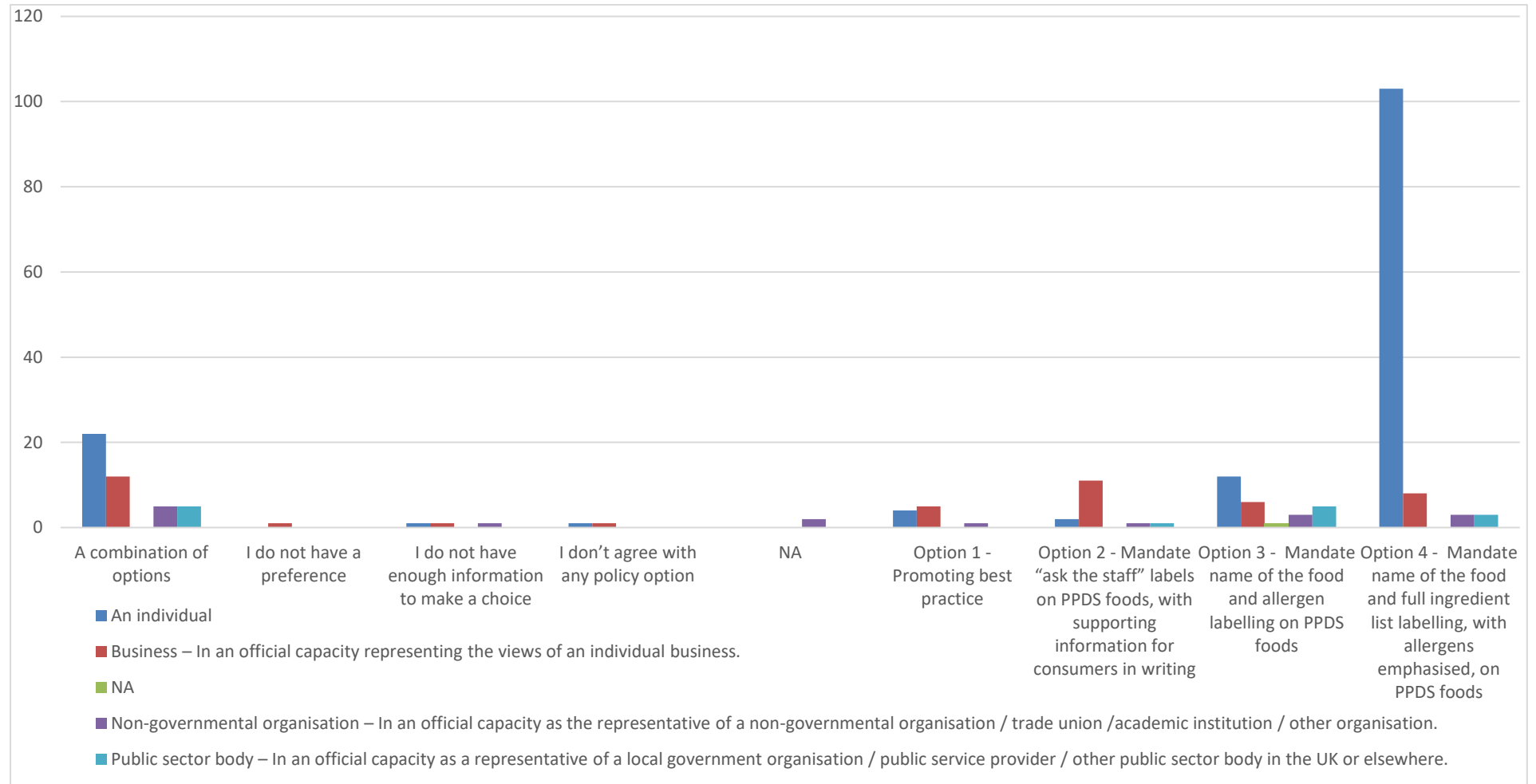
1.12 The following are not PPDS but would be considered to be packed on the sales premises at the consumer's request:

- Foods that are freshly prepared and wrapped after the consumer has placed their order, for example a sandwich or burger that is made and wrapped to order.
- Foods that are pre-prepared but not prepacked, for example a sandwich or slice of pizza made in the morning and displayed behind a counter in anticipation of the lunchtime rush and subsequently wrapped for the consumer on ordering.

1.13 Food not packed, such as loose items sold to the consumer without packaging and meals served in a restaurant or café are neither PPDS nor packed at the consumer's request.

**ANNEX B**

**Summary of Scottish Consultation Reponses**





## Table of Responses

Options	Respondent					Total
	Individuals	Businesses	NA	NGOs	PSBs	
A combination of options	22	12		5	5	44
I do not have a preference		1				1
I do not have enough information to make a choice	1	1		1		3
I don't agree with any policy option	1	1				2
NA				2		2
Option 1 - Promoting best practice	4	5		1		10
Option 2 - Mandate "ask the staff" labels on PPDS foods, with supporting information for consumers in writing	2	11		1	1	15
Option 3 - Mandate name of the food and allergen labelling on PPDS foods	12	6	1	3	5	27
Option 4 - Mandate name of the food and full ingredient list labelling, with allergens emphasised, on PPDS foods	103	8		3	3	117
Total	145	44	1	16	14	221

## Additional Consumer & Stakeholder Engagement

### Allergy and Free From Event, Glasgow 2-3 March

- 1.1 FSS attended the Allergy and Free From Event, at the invitation of Allergy UK, and publicised the consultation by engaging visitors to the stand and food businesses in the hall. This event was designed to appeal to all allergy sufferers, including those with food hypersensitivity, although it was open to the general public too. Visitors were also invited to complete a short survey based on the consultation to gather views on the four options. Over the two days we obtained 117 responses to the survey with 70% of the respondents voting for option 4.
- 1.2 Feedback – comments included Option 4 was preferred by most. Some recognised that the greater the detail on labels the greater the cost on business. Better staff training would help in getting clear information and avoid inconsistent advice from different staff. There were some examples of poor experiences where staff had been uninterested in helping consumers choose suitable food or appeared unaware of the need to have allergen information available. One visitor mentioned they have an allergy to cinnamon and its presence can be difficult to ascertain when ‘spices’ appears on labelling. Of the stallholders approached, their business activities were catering or supplying foods prepacked or loose rather than prepacked for direct sale. While not part of the consultation, ‘may contain’ labelling was seen as unhelpful by consumers. Conversely, some of the stallholders felt anxious at the thought of accidentally causing a reaction in a food allergic consumer and preferred to use ‘may contain’ statements just in case.
- 1.3 At the event 117 visitors participated in an FSS survey on the UK consultation. The results were as follows:
  - Option 1 - 21.5%
  - Option 2 – 18%
  - Option 3 – 29%
  - Option 4 – 70%
- 1.4 Forty-two visitors provided other comments in relation to allergen labelling. These included:
  - Clarity of labelling (bold text, font size)
  - Mix of views regarding highlighting either what is in the food or what it is free from.

- Food labelling needs to be taken more seriously with better training and appreciation of allergies for people to understand it is not just a choice or people being 'awkward'.
- Concern from a consumer that some takeaways are not interested in providing allergen information to customers.
- Some businesses will find increased labelling technically, physically and financially impossible.
- More labelling will result in more cost for the consumer but full labelling is now imperative in today's climate.
- Some felt it was important to speak up regarding allergies while others felt shy in approaching businesses.
- Listing all ingredients is more helpful than no information and a 'may contain' warning.
- If the mandate is too rigid then shops will say there is nothing suitable for allergy sufferers.

#### Royal Environmental Health Institute of Scotland (REHIS) Allergens Event

- 1.5 At the invitation of REHIS, FSS delivered presentation and short workshop on the consultation. Attendees included mainly REHIS registered trainers along with enforcement officers, representatives from charities and food business operators.
- 1.6 Key themes to emerge from the workshop included:
- Encouraging food allergic teenagers/young adults to ask about food ingredients when eating out – common theme of reluctance to make a fuss when with their friends.
  - Businesses have responsibilities to produce safe food and label it accurately, and people should take responsibility for their food choices
  - There is interest in updating the list of allergens because it is not comprehensive.
  - A need for clarity about what is and isn't PPDS food. One business felt that it might be easier to sell all food loose. Others wondered why some foods were out of scope.
  - More allergy awareness training is needed for enforcement officers and businesses with understanding cross contamination risks of particular importance. The increasing use of 'may contain' statements emerged as a concern
- 1.7 Feedback was also provided on the UK consultation options, with those attending showing a preference for Option 4 (full ingredients labelling), followed by Option 3 (allergen labelling). Option 4 was seen as all-encompassing and protected the widest range of consumers although it would place the most

demands on businesses and require additional training for food businesses and enforcement officers. Option 3 was seen as positive for consumers, saving on the need to specifically ask for allergen information. However, it only covers the 14 allergens and extra time to label food and training would be needed. Option 2 could encourage consumers to ask for allergens information but doesn't make a significant change from the current approach. For Option 1, apart from some support from business for this approach alone, the use of guidance and best practice advice was seen as supporting the other options.

## ANNEX C

### Initial Assessment of Business and Regulatory Cost Impacts<sup>4</sup>

1.1 FSS is currently developing a full Business and Regulatory Impact Assessment (BRIA) to assess the potential impacts of the four policy options set out in the UK-wide consultation, to inform future policy development. This has been informed by the Defra impact assessment developed on a UK-basis, and will be further refined and tailored to reflect the range of affected businesses in Scotland, and any specific impacts on SMEs in the food and drink sector.

1.2 The initial cost assessment in the partial BRIA is as follows:

#### Option 1

1.3 For businesses, time will be needed to allow managers and staff to become familiar with any revised best practice guidance. The amount of time will depend on the extent and detail of any changes in best practice advice and the complexity of business activities. Further work will be required to fully assess these costs impacts. Given that businesses have been required to have allergen information available since December 2014, it is anticipated that refresher sessions and routine staff training would cover any updates. For consumers, there may be little if any impact on prices. For enforcement officers, time will also be needed to allow officers to become familiar with revised best practice.

#### Option 2

1.4 Under this option there will be a one-off familiarisation cost to business, estimated at **£180,000**, for allowing one hour to become familiar with revised legislation. There will also be additional costs depending on the amount of time needed to update systems to support written information for consumers and produce labels and / or stickers. For consumers, businesses may pass on some or all of the additional costs. For enforcement officers, familiarisation costs are estimated to be **£2500**.

#### Option 3

1.5 As above, there will be a one-off familiarisation cost to business, estimated at **£180,000**, for allowing one hour to become familiar with revised legislation. There will also be additional costs based on the time needed to update systems and produce labels and / or stickers, depending on the further details of how the information should be displayed. Time will also be needed to assess the effect and take corrective action in the event of recipe and ingredient changes. Costs for labelling changes range from around **£11 to £2000** per product, although the exact impact will depend on the size of the business, volume of product sold and complexity and frequency of any required labelling changes

---

<sup>4</sup> This is based on the UK-wide initial Impact Analysis carried out by Defra, supplemented with further work by FSS to start developing a Business Regulatory Impact Assessment (BRIA).

e.g. some businesses may use self-adhesive labels others may use pre-printed packaging. For consumers, businesses may pass on some or all of the costs. For enforcement officers, familiarisation costs are estimated to be **£2500**. It is also anticipated that additional time will be needed by enforcement officers to assess business systems and the accuracy of the labelling.

#### Option 4

- 1.6 As per Options 2 and 3, there will be a one-off familiarisation cost to business, estimated at **£180,000**, for allowing one hour to become familiar with revised legislation. There will also be additional costs based on the time needed to update systems to track ingredient information and produce labels and / or stickers. Time will also be needed to assess the effect and take corrective action in the event of recipe and ingredient changes. Costs for labelling changes range from around **£11** to **£2000** per product although the exact impact will depend on the size of the business, volume of product sold and complexity and frequency of any required labelling changes e.g. some businesses may use self-adhesive labels others may use pre-printed packaging. For enforcement officers, familiarisation costs only are estimated to be **£2500**. It is anticipated that additional time will be needed to assess business systems and the accuracy of the labelling.