



Consultation on amending allergen information provisions contained within domestic food information legislation for food prepacked for direct sale

January 2019



© Crown copyright 2018

You may re-use this information (excluding logos) free of charge in any format or medium, under the terms of the Open Government Licence v.3. To view this licence visit www.nationalarchives.gov.uk/doc/open-government-licence/version/3/ or email PSI@nationalarchives.gsi.gov.uk

This publication is available at www.gov.uk/government/publications

Any enquiries regarding this publication should be sent to allergenlabellingreview@defra.gsi.gov.uk

Allergen Labelling Review Team

Defra

Room 202, Zone 2

1-2 Peasholme Green

York

YO1 7PX

www.gov.uk/defra

Contents

1. Introduction	4
2. Context	4
General background on food hypersensitivity	4
Legislative background.....	5
Enforcement of regulations	5
Current allergen information provision.....	5
3. Scope of this consultation	8
Out of scope.....	8
4. Policy options.....	9
Non-regulatory option.....	10
Regulatory options	11
5. Questions.....	13
Section 1 - About you	13
Section 2 – Prepacked for Direct Sale (PPDS) definition	16
Section 3 - Policy options	17
Section 4 – Business size definition, exemptions and implementation.....	18
Section 5 - Impact assessment	20
Section 6 - Reporting non-fatal anaphylactic shock incidents (“near misses”)	22
6. Why we are consulting.....	23
7. How to respond.....	23
Confidentiality and data protection	24
Sharing responses	25
Appendix A - Allergenic foods.....	26
Appendix B – Glossary of terms	27
Appendix C – Reference material	30

1. Introduction

We are launching this consultation on proposed amendments to the domestic Food Information Regulations 2014 (FIR) (England) and parallel FIR regulations in Northern Ireland, Scotland and Wales relating to the mandatory information, form of expression and presentation of allergen labelling information for foods that are prepacked for direct sale (PPDS) to the consumer on the same premises from which they are sold.

Defra, the Food Standards Agency (FSA) in England, Wales and Northern Ireland, Food Standards Scotland (FSS), and the Department for Health and Social Care (DHSC) are working together in reviewing the current legal framework for allergen information for foods which are PPDS. A number of policy options have been developed to improve the provision of allergen information on which business and consumer groups, enforcement authorities and members of the general public are invited to contribute their views.

Whilst we are a member of the EU we are restricted in the changes that we are able to make to legislation regarding allergen information provision. For example, we are unable to change the definitions of non-prepacked foods and we are unable to change how information is provided to consumers for foods ordered by distance selling (e.g. via a takeaway). Over the longer term, we have an opportunity to review all of food labelling when the UK has left the EU.

2. Context

General background on food hypersensitivity

Food hypersensitivity is where people adversely react when eating certain foods and is divided 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. 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 in 100 people have coeliac disease, an auto-immune condition which causes damage to the gut lining when gluten is present in food.

An allergic reaction can be produced by a tiny amount of a food ingredient that a person is sensitive to, for example a teaspoon of milk powder, a fragment of peanut or just one or two sesame seeds. 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.

There is 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. Continuing fatalities and effects on public health have raised the issue of whether the current regulatory framework for the provision of allergen information for PPDS foods is sufficient to give consumers the information they need to make safe food choices.

Legislative background

The EU Food Information to Consumers Regulation (FIC) provides the legislative framework around the provision of food allergen information, and the Food Information Regulations 2014 (FIR) and equivalent regulations in Wales, Scotland and Northern Ireland, are the domestic regulations that establish the enforcement measures for the FIC in the UK. In 2011 the Food Information to Consumers Regulation (FIC) introduced new rules for Food Business Operators relating to the labelling and provision of allergen information. Food Business Operators are under a duty to ensure that all mandatory food allergen information must be accurate, available and easily accessible to the consumer. FIC allows for Member States to introduce national measures as to how information is to be made available for non-prepacked foods.

In the UK, in recognition of the wide variety of out-of-home eating establishments and following consultation with stakeholders including business and patient groups, FIR introduced a flexible approach for allergen information for non-prepacked foods, including PPDS food, to be made available by any means the food business chooses, including orally by a member of staff. Where the Food Business Operator chooses not to provide food allergen ingredients information on a menu, for example, there must be an indication to speak to a member of staff either on a label attached to the food itself or on a notice, menu, ticket or label that is readily discernible to the customer where the customer chooses the food.

Enforcement of regulations

Separate but parallel FIR enforcement regulations exist in each of the four countries of the UK. Enforcement of these regulations is undertaken by food enforcement officers within Local Authorities. Person(s) found guilty of an FIR offence may be liable to unlimited fines (England, Wales and Northern Ireland) and criminal sanctions. Breaches under FIR regarding allergens may also result in offences under the Food Safety Act 1990 (England, Wales and Scotland) or the Food Safety (Northern Ireland) Order 1991 which can result in fines or imprisonment. Within Local Authorities enforcement is shared between Trading Standards and Environmental Health.

Current allergen information provision

Prepacked foods

Food which is prepacked, for example a ready meal sold in a supermarket, must be clearly labelled with all ingredients and allergenic ingredients from the list of 14 substances or products

causing allergies or intolerances, listed in Annex II of FIC and set out in Annex A of this document. Allergenic ingredients must stand out from other ingredients, for example by being in **bold** text.

The FSA's interpretation of prepacked foods, derived from Article 2(2)(e) of FIC, is provided here for clarity:

***“Prepacked foods:** This refers to any food put into packaging before being offered for sale for example a bar of chocolate, a sealed packet of crisps, a jar of sauce or a can of soup. All the following must apply:*

- *the food is either fully or partly enclosed by the packaging;*
- *the food cannot be altered without opening or changing the packaging;*
- *the product is ready for sale to the final customer or to a mass caterer.”*

As prepacked foods must be labelled with all ingredients, they are not in scope of this consultation.

Non-prepacked foods

Under FIC, non-prepacked food includes:

- food not packed, such as loose items sold to the consumer without packaging;
- food packed on the sales premises at the consumer's request; and
- food prepacked for direct sale (PPDS).

The focus of this consultation is prepacked for direct sale food.

Which category of non-prepacked a food falls into depends on where and when it is packed in relation to the point at which it is offered for sale. This can differ for the same products according to the way a business operates e.g. where a business prepacks some foods on the premises in anticipation of a peak period of sales (PPDS), but otherwise packs the food at the consumer's request.

For non-prepacked food, there is no requirement to label an individual product with the same mandatory information required for prepacked foods, however the allergen information must be readily available, including through indications to ask a member of staff, at the point where the intending purchaser chooses the product.

What are PPDS foods?

As FIC does not provide a specific definition of PPDS, we expect businesses and Local Authorities to follow the interpretation set out in FSA's technical guidance on allergen labelling provided below.

“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 made and sold from the premises in which they are made¹.”*

Examples of PPDS foods

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. 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.²

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

¹ <https://www.food.gov.uk/sites/default/files/media/document/food-allergen-labelling-technical-guidance.pdf>

² Allergen information provision for foods sold via Distance Communication is governed by Article 14 of FIC. Article 14 does not allow for National Measures as to how allergen information is provided. Online ordering such as direct online or telephone takeaway or restaurant ordering as well as direct online supermarkets and ordering hubs are required to provide allergen information to the consumer at the time of ordering “*on the material supporting*” the distance selling or “*through other appropriate means*” and at the time the food is delivered.

Not PPDS foods

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.

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.

3. Scope of this consultation

This consultation is focused on strengthening the provision of mandatory allergen information for PPDS foods.

The overarching objective of the policy is to improve the provision of information to consumers about food allergens present in PPDS foods so they have greater confidence in the safety of these foods.

This is particularly important because of the distinction made in FIC and FIR on food allergen information provision between prepacked foods and foods that are prepacked for direct sale (PPDS). Namely, that prepacked foods are required to be labelled with full ingredients, with any of the 14 specified food allergens emphasised, for example, in bold text, whereas for PPDS foods, it is permitted to provide information on allergenic ingredients orally or in writing. Concerns have been raised that it can be difficult for consumers to distinguish between prepacked and PPDS foods, and anecdotal evidence suggests that consumers assume that the absence of allergen information on food packaging means food allergens are not contained in the product, which may not be the case for PPDS foods.

Out of scope

The following issues fall outside the scope of this public consultation:

- The regulation of Precautionary Allergen Labelling (PAL) statements to indicate the unintentional presence of food allergens due to cross-contamination.

This consultation is concerned specifically with the provision of allergen information for intentional ingredients in PPDS foods. FSA guidance on PAL advises that it should only be used when there is a genuine, assessed, unavoidable risk that good manufacturing practice cannot avoid.

- Allergen labelling provision for non-prepacked food ordered via distance selling, for example a takeaway pizza ordered over the phone or via the internet.

Under FIC, mandatory allergen information for non-prepacked food sold via distance selling must be provided to the consumer at the time of ordering on the material supporting the distance selling or through other appropriate means, and at the time the food is delivered.

- Food not packed (such as meals served in a restaurant or café), and food packed on the sales premises at the consumer's request (such as a sandwich prepared in front of the customer, cheese or meat sold loose from a delicatessen counter or bread or pies sold at bakeries).

There is an expectation that in these circumstances, because foods are not already prepacked at the point that the consumer is making their choice, consumers will talk to staff about their allergy requirements so that they can make safe food choices. For example, consumers may request adaptations to the food, such as leaving out an ingredient, before the food is packed and sold. The consumer has a responsibility to tell the food business about their allergy or intolerance, and the business is legally required to provide accurate and clear information on food allergens making it a dual responsibility to help safe selection of foods. To encourage this practice, FSA launched the #EasytoAsk campaign supported by allergy patient groups to remind food businesses to ask customers about dietary needs and empower young people in particular, to ask about allergens when eating out.

Over the longer term, we have an opportunity to review all of food labelling when the UK has left the EU.

4. Policy options

Through this consultation we are seeking views on non-regulatory and regulatory policy options to improve the provision of allergen information to consumers for PPDS foods. An Impact Assessment has been prepared to assess the estimated impact of policy options on relevant stakeholders. While we do not expect there to be any costs to consumers, it is possible that businesses could choose to pass on any increase in costs they experience to consumers. More details about expected impacts for each option can be found in the corresponding sections of the Impact Assessment.

The overarching objective of the policies is to improve the provision of information to consumers about food allergens present in PPDS foods. All options are intended to address the policy objective, through a range of regulatory and non-regulatory means. Each option considers various measures that could be put in place to alleviate consumer concerns related to allergen information provision on PPDS foods. Options 1 to 4 represent a sliding scale moving from non-regulatory measures 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 leveraging regulatory measures in order to achieve the same objective of improving the provision of information to consumers.

We have considered a wide range of policy options with stakeholders and can confirm that no potentially viable option has been ruled out of detailed appraisal without substantive reasoning. The policy options for strengthening the UK allergen information provision framework are summarised below. Note that each option need not be considered as exclusive; options may be combined, for example, the non-regulatory option may build upon regulatory options in an escalating hierarchy, or different options may be applied to different sizes of businesses in a two-tiered approach. Government is not putting forward a preferred policy option at this time.

Non-regulatory option

Policy option 1 – Promote best practice

This option would not require a legislative change, but to effect change would entail additional activity to promote best practice within the current framework to encourage businesses and consumers to review their knowledge, skills and actions to ensure a safer environment for consumers. It would encompass best practice for all non-prepacked foods, including PPDS. Options for promoting best practice may include:

- Best practice guidance for the catering sector to be produced by the FSA and FSS and made available to all local authorities.
- Cross-stakeholder conference with businesses hosted by Defra, FSA and FSS to discuss best practice and encourage change without a legislative change.
- Public information campaign to highlight allergen knowledge and awareness for food businesses and the general public.

The main benefits of this option are that it has the potential to be designed and implemented in a shorter timescale than that required for a legislative change, and can be adapted to continue to be fit for purpose. It retains maximum flexibility for businesses to make allergen information available on PPDS foods in a way that best suits their business model whilst achieving the policy objectives. Some businesses are already taking action to strengthen their allergen information provision. The FSA and FSS see a public awareness/best practice campaign as essential, whatever the outcome of this review. In relation to this, FSA have launched the #EasytoAsk campaign and relevant businesses have indicated a willingness to directly support a larger repeat of this campaign in their approach to allergen labelling, which could significantly increase awareness. FSS will consider what additional work may be needed in the light of consultation responses.

As this is a non-regulatory measure, there is no guarantee that businesses will change their practices.

Regulatory options

Policy option 2 - Mandate “ask the staff” labels on packaging of food prepacked for direct sale, with supporting information for consumers in writing

In the absence of a full list of ingredients, or a list of the allergens contained within the product on the packaging, food prepacked for direct sale would include a label/sticker on the packaging advising consumers to “ask the staff” about allergens. When asked about allergens, 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.

This sticker 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. An example of what the sticker may look like is:



Of the regulatory options proposed, this option is the least costly to implement (see impact assessment) and is already being rolled out by a number of businesses. It would ensure that consumers are consistently prompted to be proactive in talking to staff about allergens when choosing PPDS foods. Anecdotal evidence indicates that it would normalise and encourage food allergic consumers to be proactive in talking to staff about their allergy requirements, so they can make safe food choices.

However, risks associated with this option include failure to provide sufficient information for those consumers who are not sufficiently confident to engage with staff, the availability of appropriately trained staff, and the risk which may ensue if food is taken off the premises and given to a third party food allergic consumer. Unlike the other regulatory options, this option does not carry the risk of mislabelling on the product packaging, but there is still a risk that the written information provided upon request may be incorrect. This risk applies to all options that put allergen information in writing, including options 3 and 4.

Policy option 3 - Mandate name of the food and allergen labelling on packaging of food prepacked for direct sale

This option introduces a regulatory measure requiring PPDS foods to have a label on the packaging to tell the consumer the name of the food and which of the 14 allergenic ingredients in Annex II of the FIC the product intentionally contains.

This option is less difficult for businesses to implement than full ingredient labelling, but more costly than option 2. It gives consumers clear, product specific information on the food packaging, enabling food allergic consumers to make informed choices when purchasing food products. Also, when the consumer takes the food off the premises to eat later or to give to a third party, the information about food allergens is available on the packaging. This option also allows businesses to make some non-allergenic ingredient substitutions without having to change the label on the packaging.

There may be risks associated with this option and it may be challenging to implement correctly, particularly for small and micro businesses, incurring additional administrative, equipment and training costs. For instance, it will increase costs to business as generic packaging would necessarily disappear or need to be supplemented with another label. As mislabelling is the most common source of product recall for prepacked goods, adding a label could introduce the risk of mislabelling incidents, particularly in busy kitchen environments where products containing different food allergens are made simultaneously. As consumers trust labels, this could cause more incidents as consumers may eat wrongly labelled packaged food and may potentially discourage dialogue with staff. In addition, people who are allergic to ingredients that are not on the list of 14 allergenic ingredients laid out in Annex II of the FIC will not benefit from option 3. Overall, the risk of mislabelling is less for this option than the mislabelling risk associated with option 4. This option may also lead to businesses removing certain foods from their menu or limit changes to menus (e.g. one-off specials), thus reducing consumer choice in general. It may require new labelling processes to be instituted on business premises and would require substantial training of staff, to equip them with the knowledge and skills to implement allergen labelling procedures accurately. This option may prompt changes in business practices, e.g. moving from PPDS foods to packing foods on the premises at the consumer's request.

Policy option 4 - Mandate name of the food and full ingredient list labelling, with allergens emphasised, on packaging of food prepacked for direct sale

This option introduces a regulatory measure requiring PPDS foods to have a label naming the food and listing the full ingredients with allergens emphasised on the packaging.

Labelling will need to be compliant with Article 9 (1) a - c of FIC:

- a. the name of the food
- b. the list of ingredients

- c. any ingredient or processing aid listed in FIC Annex II or derived from a substance or product listed in Annex II causing allergies or intolerances used in the manufacture or preparation of a food and still present in the finished product, even if in an altered form, would be emphasised to stand out from the other ingredients in the list.

This option introduces a consistent approach to labelling of ingredients for food that is prepacked and prepacked for direct sale. It may give food allergic consumers more trust in the food they are eating and help consumers with food allergies and intolerances beyond those mandatorily defined by FIC. It doesn't rely on staff having to provide accurate information on allergens directly to consumers, but a labelling process will be required on the premises, and staff will need to be sufficiently trained to implement labelling procedures accurately. As with option 3, full ingredient labelling would increase costs to business as generic packaging would necessarily disappear or need to be supplemented with additional labelling. Adding a label may introduce the risk of mislabelling incidents, particularly in busy kitchen environments where products containing different allergens are made simultaneously, and this option carries the greatest mislabelling risk. As consumers trust labels, this could cause more incidents as consumers may eat wrongly labelled packaged food. This option may lead to businesses removing certain foods from their menu or limit changes to menus (e.g. one-off specials), to avoid the costs of extra labelling, potentially reducing consumer choice in general. Additionally, the cost of full labelling may potentially stifle innovation and new product development and may constrain supply chain purchases and availability.

5. Questions

Section 1 - About you

1. Would you like your response to remain confidential?

- a. Yes
- b. No

If you answered yes to this question please give your reason.

2. What is your name?

3. What is your email address?

4. Please tell us who you are responding as?

- a. An individual – You are responding with your personal views, rather than as an official representative of a business / business association / other organisation.
- b. Non-governmental organisation – In an official capacity as the representative of a non-governmental organisation / trade union / academic institution / other organisation.

- c. Business – In an official capacity representing the views of an individual business.
- d. Public sector body – In an official capacity as a representative of a local government organisation / public service provider / other public sector body in the UK or elsewhere.

If responding as an individual

5. What is your age?

- a. 0-15
- b. 16-24
- c. 25-34
- d. 35-44
- e. 45-54
- f. 55-64
- g. 65-74
- h. 75-84
- i. 85+

6. What nation of the UK do you live in?

- a. England
- b. Wales
- c. Scotland
- d. Northern Ireland

7. Do you or someone in your family have any food allergies or intolerances?

- a. Yes
- b. No

If responding as an organisation, business, or public body

8. What is the name of your business/ organisation?

9. Where does your business/organisation operate?

- a. England
- b. Wales
- c. Scotland
- d. Northern Ireland

If business

10. What is the size of your business?

- a. Micro (9 employees or less)
- b. Small (10 – 49 employees)
- c. Medium (50 – 249 employees)

- d. Large (250+ employees)

11. Do you sell products that are prepacked for direct sale (PPDS) as defined in FSA guidance³?

- a. Yes
- b. No

If 'yes', please answer questions 12 to 14. If 'no' please skip to question 15.

12. Approximately how many individual stock keeping units (SKUs)⁴ of PPDS products do you stock each day? (if you have seasonal products, please consider an average across the year)

- a. 1-10
- b. 11-19
- c. 20-29
- d. 30-49
- e. More than 50

13. What proportion of total units sold does this make up?

- a. Less than 10%
- b. 10-29%
- c. 30-49%
- d. 50-69%
- e. 70-89%
- f. 90% or more

14. What methods of allergen information provision do you currently provide on PPDS products?

- a. Provision of verbal information with visible prompts in store
- b. Written information available to consumers upon request
- c. Visible written allergen information somewhere in the store
- d. Allergen information on, or near, products
- e. Full ingredient labelling
- f. Other, please specify

Please provide additional details

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

⁴ A stock keeping unit (SKU) is a distinct type of item for sale and all attributes associated with the item type that distinguish it from other item types.

Section 2 – Prepacked for Direct Sale (PPDS) definition

FIC defines prepacked food, and what is not prepacked, but it doesn't provide a specific definition of prepacked for direct sale (PPDS). For the purpose of this consultation, we are using the FSA interpretation of PPDS below.

“Prepacked foods for direct sale (PPDS): 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 made and sold from the premises in which they are made.”*

15. Do you agree with this interpretation?

- Yes
- No

Please provide a justification for your response. If you answered 'no' to question 15, please indicate any other factors that you think should be taken in to account when considering whether a product is PPDS.

16. This consultation is focussed on the provision of allergen information for PPDS foods. Do you think government should consider reviewing in future the way that allergen information is presented to consumers for other types of non-prepacked food?

- Yes
- No

If yes, please answer questions 17. If 'no' please skip to question 18.

17. What other types of food should government review?

- Food packed on the sales premises at the consumer's request
- Food not packed, such as loose items sold to the consumer without packing and meals served in a restaurant or café
- Non-prepacked food ordered via distance selling, for example a takeaway pizza ordered over the phone or via the internet
- Other

Please provide a justification for your response.

Section 3 - Policy options

18. What is your preferred policy option and why?

- a. Option 1
- b. Option 2
- c. Option 3
- d. Option 4
- e. A combination of options
- f. I do not have a preference
- g. I don't agree with any policy option
- h. I do not have enough information to make a choice

Please provide a justification for your response.

If 'e'

19. You stated that your preferred policy option is a combination. What combination would you prefer?

- a. 2 and 3 based on business size
- b. 2 and 4 based on business size
- c. 3 and 4 based on business size
- d. Other, please specify

If a, b or c

20. You stated that you preferred a two tiered approach based on businesses size, do you think the lower tier option should apply to only micro businesses, or small and micro businesses?

- a. Micro
- b. Micro and Small

21. Policy option 1 outlines additional activity to promote best practice within the current framework to encourage businesses and to review their knowledge, skills and actions to ensure a safer environment for consumers. These options may include:

- Best practice guidance for the catering sector to be produced by FSA and made available to all local authorities;
- Cross stakeholder conference with businesses hosted by Defra and FSA to discuss best practice and encourage change without amendments to legislation;
- Public information campaign to highlight allergen knowledge and awareness for food businesses and the general public.

Do you have any other suggestions for what might be included to promote best practice and how government can support businesses in reaching this? Please include examples that may currently be used by businesses.

22. Do you think promoting best practice should be combined with the other policy options?

- a. Yes
- b. No
- c. Other, please specify

23. Option 2 mandates “ask the staff” labels on packages of food prepared for direct sale with a requirement for supporting information for consumers to be made available in writing. Do you think the written information should only include allergen information, or a full list of ingredients?

- a. Allergen information only
- b. Full list of ingredients
- c. I am indifferent
- d. Don't know

Please provide justification for your response.

24. For full ingredient labelling (option 4) do you think allergens should be emphasised (e.g. in bold text) as per FIC regulations for prepacked food?

- a. Yes
- b. No

25. We have proposed a number of policy options to improve the provision of allergen information for PPDS foods. Are there alternative options not proposed that we should be considering? An example of this could be mandating written information setting out which of the 14 allergens may be present in products on the premises.

- a. Yes
- b. No

If yes, please provide details of what alternative option you would like to see to improve the provision of allergen information for PPDS foods.

Section 4 – Business size definition, exemptions and implementation

26. For the purpose of this consultation, we define business size based on the number of employees in accordance with the categories below. Do you agree with this definition?

- Micro (0-9 employees)

- Small (10-49 employees)
- Medium (50-249 employees)
- Large (250+ employees)

- a. Yes
- b. No

If no

27. What criteria would you suggest we define business size by?

- a. Number of outlets/branches
- b. Turnover
- c. Number of units sold
- d. Other, please specify

Please give details about your proposed thresholds for micro, small, medium and large businesses.

28. Are there any policy options you think small and micro businesses should be exempt from?

- a. No, I think all businesses should be included in **all** policy options
- b. I think micro businesses should be exempt from **all** policy options
- c. I think small and micro business should be exempt from **all** policy options
- d. I think small and micro business should be exempt from **some** policy options
- e. I think micro businesses should be exempt from **some** policy options

If you have selected 'd' or 'e'

29. Which policy options do you think small and micro businesses should be exempt from?

Please provide a justification for your response

30. How long do you think businesses should be given to implement the new policy?

	Less than 6 months	6 months to a year	A year to two years	Up to three years	Up to 5 years
Option 1					
Option 2					
Option 3					

Option 4					
----------	--	--	--	--	--

Please provide a justification for your response

Section 5 - Impact assessment

31. We have estimated that there are 7,785 businesses in the UK that primarily sell PPDS foods, however we have limited data outlining the PPDS sector, and as such there is a difficulty in establishing which businesses will be affected by any changes to regulations regarding PPDS foods. Do you agree with this estimation? If you answered 'no', please provide supporting evidence relating to the size, or composition of the PPDS market.

- a. Yes, I agree
- b. No, (please provide supporting evidence)

32. Option 2 requires written allergen information to be provided to consumers upon request. This is currently a non-monetised cost as it is unclear the extent to which businesses already provide this information on their premises. Do you have any supporting evidence to help us quantify these costs? Please include any evidence as to how many businesses are currently doing this, and if you're a business, whether you are currently doing this, and the costs of doing so?

33. We have based our calculation of the labelling costs on previous research, which outlines that minor labelling changes cost in the range of £10 - £1,800 per stock keeping unit (SKU). Uprating these to 2018 prices, we assume that the cost of re-labelling to be £10.99 per SKU for small and micro businesses, and £1978.59 per SKU for medium and large businesses. Do you agree with these costs?

- a. Yes, I agree with these cost estimations
- b. No (please provide supporting evidence)

34. We have assumed that, on average, a business selling PPDS foods will have 20 different products, however this is not currently based on evidence. Do you agree with this assumption? Please provide any supporting evidence if possible.

- a. Yes
- b. No

35. We currently do not have sufficient evidence to accurately calculate the labelling costs of Option 4: Name and full ingredient labelling. Anecdotal evidence, however, suggests that these costs would be higher than the other options. Do you have any supporting evidence relating to the costs of full ingredient labelling?

- a. Yes, please provide further details
- b. No

36. Are there any other cost assumptions or calculations that are incorrect, or you wish to submit additional evidence for?

- a. Yes, please provide further details
- b. No

If yes, are you referring to a specific policy option?

- a. Option 1
- b. Option 2
- c. Option 3
- d. Option 4
- e. All options

37. Are there any costs which we have not considered?

- a. Yes, please provide details
- b. No

If yes, are you referring to a specific policy option?

- a. Option 1
- b. Option 2
- c. Option 3
- d. Option 4
- e. All options

38. Will cost of implementing any of the policy options lead to changes in how businesses operate (for example, how PPDS products are sold, or prepared or packed)?

- a. Yes, please provide details
- b. No

If yes, are you referring to a specific policy option?

- a. Option 1
- b. Option 2
- c. Option 3
- d. Option 4

- e. All options

39. Are there any impacts to consumers, businesses, or government that have not been considered?

- a. Yes, please provide details
- b. No

If yes, are you referring to a specific policy option?

- a. Option 1
- b. Option 2
- c. Option 3
- d. Option 4
- e. All options

40. Do you have any further evidence or data you wish to submit for us to consider for our final impact assessment or any specific comments on the methodology or assumptions made?

- a. Yes, please provide further evidence which could be used to improve our estimates.
- b. No

If yes, are you referring to a specific policy option?

- a. Option 1
- b. Option 2
- c. Option 3
- d. Option 4
- e. All options

Section 6 - Reporting non-fatal anaphylactic shock incidents (“near misses”)

If someone with a food allergy eats that food allergen in a catering establishment without knowing it, they could have an allergic reaction that becomes an anaphylactic shock. If they receive medical help and it proves to be non-fatal, this is a near miss. Incidents of suspected food allergy reactions are not currently automatically communicated to the relevant Local Authority nor to the FSA. Consequently, non-compliant food businesses may not be reported to enforcement bodies and continue to operate, posing a potential health risk to those with a food hypersensitivity.

The FSA have been working with local authorities in Yorkshire, on a pilot scheme to improve the notification of incidents between businesses, Local Authorities and the NHS. The reported near misses would trigger a priority inspection of the food business through the relevant Local Authority ensuring that non-compliances are identified and solved. Such

a system would also allow Local Authorities to work with specific Food Business Operators to help them better understand their obligations and requirements and understand the significance of the potential health and financial consequences of non-compliance.

41. Serious, non-fatal incidents of anaphylactic shock relating to consumption of a food allergen in a catering establishment are not currently automatically communicated to the relevant authorities. We invite your views on how the relevant authorities (e.g. NHS, Local Authority and FSA) can work more cooperatively together and with the public to increase local awareness and share data on the quality of food allergen management from local businesses so that rapid inspection action can be taken.

6. Why we are consulting

Defra, alongside the FSA in England, Wales and Northern Ireland, Food Standards Scotland and DHSC, values the importance of this period of consultation to ensure that, if there are changes to be made to the current landscape, we have listened to all interested parties.

By publishing this consultation Defra, FSA and FSS also wish to meet the obligation to consult under Article 9 of EU Regulation 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety and under the Food Safety Act 1990 and Food Safety (Northern Ireland) Order 1991.

7. How to respond

Consultation launched: 25 January 2019

We encourage respondents to provide not just their opinions but also the supporting facts and reasoning to inform the evidence base for the development of final proposals. Respondents do not have to answer all the questions and so can choose those of specific interest. Questions which you do not wish to respond to can be left blank.

Please respond by 29 March 2019

Please respond through the online survey (Citizen Space) accessible via the following link: <https://consult.defra.gov.uk/agri-food-chain-directorate/consultation-on-amending-allergen-information>

If you cannot respond online, you can request a copy of the survey and a response form by e-mailing allergenlabellingreview@defra.gsi.gov.uk. Queries and completed surveys can also be sent here.

Alternatively you can respond via post at the addresses below, specifying which question(s) you are responding to:

Allergen Labelling Review Team
Defra
Room 202, Zone 2
1-2 Peasholme Green
York
YO1 7PX

Confidentiality and data protection

This consultation document and consultation process have been planned to adhere to the Consultation Principles issued by the Cabinet Office.

Representative groups are asked to give a summary of the people and organisations they represent and where relevant who else they have consulted in reaching their conclusions when they respond.

Information provided in response to this consultation, including personal data, may be published or disclosed in accordance with the access to information regimes these are primarily the Environmental Information Regulations 2004 (EIRs), the Freedom of Information Act 2000 (FOIA) and the Data Protection Act 2018 (DPA). We have obligations, mainly under the EIRs, FOIA and DPA, to disclose information to particular recipients or to the public in certain circumstances.

If you want the information that you provide to be treated as confidential, please be aware that, as a public authority, the Department is bound by the Freedom of Information Act and may therefore be obliged to disclose all or some of the information you provide. In view of this it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the Department.

This consultation is being conducted in line with the Cabinet Office “Consultation Principles” and be found at: <https://www.gov.uk/government/publications/consultation-principles-guidance>

If you have any comments or complaints about the consultation process, please address them to:

Consultation Coordinator
Area 1C, 1st Floor
Nobel House

17 Smith Square,

London, SW1P 3JR.

Or email: consultation.coordinator@defra.gsi.gov.uk

Sharing responses

This consultation is about potential changes to the Food Information Regulations **2014** in England and similar regulations in Northern Ireland, Scotland and Wales. It is a joint UK-wide consultation with Defra, the Food Standards Agency (FSA) in England, Wales and Northern Ireland, the Food Standards Scotland (FSS), and the Department for Health and Social Care (DHSC). Any responses to this consultation will be shared with the FSA in England, Wales, Northern Ireland, the FSS and DHSC to help make any potential changes to the regulations that are necessary to protect public health in the UK.

Appendix A - Allergenic foods

There are 14 substances or products causing allergies or intolerances which (unless exempted⁵) are legally considered to be mandatory information for consumers under FIC. This requirement is extended to all foods provided to consumers and includes food that is:

- Prepacked (e.g. a bar of chocolate, a sealed packet of crisps, a jar of sauce or a can of soup);
- Not prepacked (e.g. restaurant meals);
- Packed at the consumer's request (e.g. a deli sandwich prepared, wrapped and handed to the customer); or
- Prepacked for direct sale (PPDS; e.g. a sandwich prepacked before the customer chooses it).

If a food product contains or uses an ingredient or processing aid derived from one of the substances or products listed below, it will need to be declared by the Food Business Operator to the consumer on the packaging for prepacked foods, or, for non-prepacked foods, by any means the Food Business Operator chooses, including orally by a member of staff.

1. Cereals containing gluten, namely: wheat (such as spelt and khorasan wheat), rye, barley, oats and their hybridised strains and products thereof
2. Crustaceans and products thereof;
3. Eggs and products thereof;
4. Fish and products thereof,
5. Peanuts and products thereof;
6. Soybeans and products thereof,
7. Milk and products thereof (including lactose),
8. Nuts, namely: almonds, hazelnuts, walnuts, cashews, pecan nuts, Brazil nuts, pistachio nuts, macadamia or Queensland nuts, and products thereof,
9. Celery and products thereof;
10. Mustard and products thereof;
11. Sesame seeds and products thereof;
12. Sulphur dioxide and sulphites >10mg/kg or 10mg/L;
13. Lupin and products thereof;
14. Molluscs and products thereof.

This list is consistent across the EU and cannot be amended by individual Member States.

⁵ Some ingredients made from the allergens listed above will not cause an allergic reaction because they have been highly processed (for example fully refined soya oil or wheat glucose syrups). This is because the allergen/protein has been removed and the product has been assessed by the European Food Safety Authority (EFSA) as not possessing an allergenic risk to the consumer. A full list of exemptions is available at [Annex II of FIC](#)

Appendix B – Glossary of terms

Coeliac disease: Coeliac disease is an autoimmune condition. This is where the immune system – the body's defence against infection – mistakenly attacks healthy tissue. In coeliac disease, the immune system mistakes substances found inside gluten as a threat to the body and attacks them. This damages the surface of the small bowel (intestines), disrupting the body's ability to absorb nutrients from food.

Distance selling: This refers to the selling and buying of goods or services (for purposes of these guidance notes – prepacked, prepacked for direct sale and non-prepacked foods) without direct face to face contact; for example, selling food by internet (internet shopping, online takeaway aggregators etc.), mail order, telephone or television.

Food allergen: The substance in a food that can cause an allergic reaction in certain people is called an allergen. These are normally proteins and in some people, the immune system thinks allergens are foreign or dangerous. The EU states 14 specific foods which are of public health importance (most potent and prevalent food allergens in Europe) which are listed in Annex II to the EU FIC. However, the list is not exclusive and many people can be allergic to foods not on this list.

EU Food Information to Consumers Regulation (No.1169/2011; FIC): On 25 October 2011, the European Parliament and the Council adopted Regulation (EU) No 1169/2011 (1) on the provision of food information to consumers (FIC). The overall aims of FIC are: to allow consumers to have the information they need to make informed and healthy food choices, and to ensure they are not being misled; and to protect consumers with food allergies and intolerances by providing them with sufficient and clear information to make safe food choices. FIC has applied since 13 December 2014, with the exception of the provisions concerning the nutrition declaration which have applied since 13 December 2016.

Food Information Regulations 2014: The main purpose of the Food Information Regulations (FIR), and equivalent regulations in Wales, Scotland and Northern Ireland, is to put enforcement provisions in place to enable certain provisions of EU Regulation (EU) No 1169/2011 on the provision of food information to consumers (FIC) to be enforced. In addition, the Regulations take advantage of derogations contained in FIC and carry forward some (EU permitted) national measures, including provision allowing information on allergens for non-prepacked foods to be provided in any manner including orally.

Food allergy: An adverse reaction to a food that involves the immune system and can be a potentially life-threatening condition. Symptoms can appear within minutes, or up to several hours after a person has eaten a food they are allergic to. There is no cure for food allergy. An allergic individual must avoid the food which makes them ill.

Food business operator: This is defined in EU Regulation No. 178/2002 (Article 3(3)) (General Food Law) as 'the natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control'. A food business (as referred to in Article 3(2)) is also defined in the same regulation, as 'any

undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to any stage of production, processing and distribution of food’.

Food intolerance: A food intolerance is difficulty in digesting certain foods and having a physical reaction to them. Food intolerances do not involve the immune system and are generally not life-threatening. However, they can make someone feel very ill or affect their long-term health. Examples of food intolerance include lactose and gluten intolerance.

Ingredient: This is defined in Article 2(2)(f) of FIC as ‘any substance or product, including flavourings, food additives and food enzymes, and any constituent of a compound ingredient, used in the manufacture or preparation of a food and still present in the finished product, even if in an altered form; residues shall not be considered as ‘ingredients’.

Label: This is defined in Article 2(2)(i) of FIC as ‘any tag, brand, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed or impressed on, or attached to the packaging or container of food’.

Mass caterer: This is defined in Article 2 (2)(d) of EU FIC as ‘any establishment (including a vehicle or a fixed or mobile stall), such as restaurants, canteens, schools, hospitals and catering enterprises in which, in the course of a business, food is prepared to be ready for consumption by the final consumer’.

Non-prepacked foods:

- In a physical retail environment this is likely to apply to foods which are sold loose from a delicatessen counter (e.g. cold meats, cheeses, quiches, pies and dips), fresh pizza, salad bars, bread sold in bakery shops, meat from butchers, pick and mix confectionery (including individually wrapped sweets and chocolates), etc.
- In a catering environment this is likely to apply to foods which are not sold prepacked, for example food from a takeaway, or meals served in a canteen or a restaurant.

Packed on the sales premises at the consumer’s request:

Examples may include:

- Foods that are freshly prepared and wrapped after the consumer has placed their order, for example a 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.

Prepacked foods: This refers to any food put into packaging before being offered for sale for example a bar of chocolate, a sealed packet of crisps, a jar of sauce or a can of soup. All the following must apply:

- the food is either fully or partly enclosed by the packaging;
- the food cannot be altered without opening or changing the packaging

- the product is ready for sale to the final customer or to a mass caterer. (Adapted from the definition in Article 2 (2)(e) of EU FIC).

Prepacked foods for direct sale (PPDS): 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 made and sold from the premises in which they are made.

Examples of PPDS may also include foods pre-weighed, packed and sealed from delicatessen counters, in store bakeries or sweet shops.

Appendix C – Reference material

Regulations

[The Food Information to Consumers Regulation \(EU 1169/2011; FIC\)](#)

[The Food Information Regulations 2014](#)

[The Food Information \(Wales\) Regulations 2014](#)

[The Food Information \(Scotland\) Regulations 2014](#)

[The Food Information Regulations \(Northern Ireland\) 2014](#)

[The Food Safety Act 1990](#)

[The Food Safety \(Northern Ireland\) Order 1991](#)

Guidance

FSA guidance (England, Scotland, Wales and Northern Ireland): [Food allergen labelling and information requirements under the EU Food Information for Consumers Regulation No. 1169/2011: Technical guidance](#)