

Updates to the Food Standard Agency's Technical Guidance on Food allergen labelling and information requirements under the EU Food Information for Consumers Regulation No. 1169/2011

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Who will this consultation be of most interest to?

- Food Businesses that offer for sale prepacked for direct sale (PPDS) food (See Annex B)
- Food industry representative bodies
- Enforcement authorities
- Any other organisation or person wanting to know more about forthcoming changes to the legal requirements for the provision of allergen information for PPDS food.

What is the subject of this consultation?

The Food Information (Amendment) (England) Regulations 2019 (SI 2019 No. 1218) were laid before Parliament on 5 September 2019. These Regulations come into force on 1 October 2021 and will change the way in which food businesses in England are required to provide allergen information on prepacked for direct sale (PPDS) food. Separate equivalent legislation is planned in Wales and Northern Ireland.

The subject of this consultation is proposed updates to the Food Standards Agency's (FSA) Technical Guidance on Food allergen labelling and information requirements under the EU Food Information for Consumers Regulation No. 1169/2011 ("the FSA Technical Guidance"). These updates are principally to reflect these new legal requirements, but we are also taking this opportunity to propose some technical/drafting updates. The updates to the guidance will apply in England and are expected to apply in Wales and Northern Ireland. The FSA would therefore welcome the views and comment of stakeholders in England, Wales and Northern Ireland.

What is the purpose of this consultation?

To seek the views and comment of stakeholders in England, Wales and Northern Ireland on proposed updates to the Technical Guidance.

Responses to this consultation should be sent to:

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Updates to the Food Standard Agency's Technical Guidance on Food allergen labelling and information requirements under the EU Food Information for Consumers Regulation No. 1169/2011

Details

Background

The legislative framework around the provision of food allergen information is largely contained in the European Regulation on the provision of food information to consumers (EU) No. 1169/2011 (the EU FIC) which will continue to apply in the UK as "retained EU law" after EU Exit. The Food Information Regulations 2014 (FIR) and equivalent regulations in Wales, Northern Ireland and Scotland provide for the execution and enforcement of the EU FIC in the UK.

Current Requirements

The EU FIC requires food businesses to ensure that mandatory food allergen information relating to the 14 substances and products causing allergies or intolerances listed in its Annex II is accurate, available and easily accessible to the consumer. It allows Member States to make a distinction between prepacked foods and non-prepacked foods in how mandatory allergen information is provided to consumers.

The EU FIC requires that food which is prepacked (e.g. a ready meal sold in a supermarket) must have an ingredients list with any of the 14 listed allergens present emphasised in that list. For non-prepacked food, the food information requirements differ. Any food that does not fall within the definition of prepacked food under the EU FIC must be non-prepacked food. This currently includes but is not limited to: food not packed such as loose fruit and vegetables, food packed on the sales premises at the consumer's request and food prepacked for direct sale (PPDS).

The New Legislation

The Food Information (Amendment) (England) Regulations 2019 were laid before the Westminster Parliament on 5 September 2019. They will amend the domestic Food Information Regulations 2014 and require, from 1 October 2021, PPDS food to have on its packaging (or a label attached to its packaging) the name of the food and a list of ingredients with any of the 14 allergens listed in the EU FIC present emphasised in that list. The requirements in respect of other non-prepacked food, remain unaffected by the changes. The changes have been supported by Ministers England, Wales and Scotland. In respect to Northern Ireland, the Permanent Secretary of the Department of Health, in the absence of the Northern Ireland Executive endorsed these changes. Wales, Northern Ireland and Scotland are working towards introducing similar legislation within the same overall timescale.

Prepacked for Direct Sale Food

The new legislation applies to PPDS food only. Whether a food is PPDS is dependent on where and when it is packed in relation to the point at which it is offered for sale.

The Government's position on what constitutes PPDS food was set out in its 2019 Consultation on amending allergen information provisions contained within domestic food information legislation for food prepacked for direct sale:

www.food.gov.uk/news-alerts/consultations/amending-allergen-information-provisions-contained-within-domestic-food-information-legislation-for-food-prepacked-for-direct

An approach based on the Government's position which can be used to help determine whether or not a food is PPDS is provided at Annex B of this consultation document. This approach sets out three criteria, all of which must be met for a food to be PPDS.

Proposed Updates to the Technical Guidance

The Technical Guidance covers the application of allergen provisions for prepacked, non-prepacked and prepacked for direct sale foods. It does not cover other labelling requirements (such as other general labelling e.g. minimum durability, country of origin, minced meat, quantities, additives, nutrition etc.).

We are seeking the views and comment of stakeholders in England, Wales and Northern Ireland on the proposed updates to the Technical Guidance. These updates are principally to reflect the requirements of The Food Information (Amendment) (England) Regulations 2019 and the anticipated legislation in Wales and Northern Ireland. We are also taking this opportunity to bring the Technical Guidance in line with the latest FSA guidance format and to propose some technical/drafting updates (e.g. to update/remove weblinks, improve clarity, update FSA contacts etc.). Stakeholders' views and comments on whether the approach as set out in Annex B should also be included in the Technical Guidance would also be welcomed.

The proposed updates are highlighted in yellow in the draft updated Technical Guidance document and are summarised in the table at Annex C.

Impact

We anticipate that the only impact arising from the proposed updates to the Technical Guidance will be initial familiarisation costs for both businesses and government (local authorities).

The familiarisation costs anticipated to arise from the new legislation have been assessed and are available in the final Impact Assessment published by Defra alongside the legislation which can be found at:

Familiarisation Costs to Businesses

We do not expect a need for businesses to re-familiarise themselves with the existing parts of the guidance as any steps they feel are necessary to take as a result of reading the guidance should be integrated into their food safety management systems they are required to have in place. Any re-familiarisation would therefore be entirely a commercial decision by the business.

However, businesses are anticipated to familiarise themselves with the parts of the updated Technical Guidance reflecting the new legislation, principally Part 3.

Defra have assumed that for small and micro businesses it would take one member of staff one working day (7.4 hours) to read and familiarise themselves with new legislation. For medium and large businesses, they have assumed that it will take one member of staff 1.5 working days (11.1 hours) to read and familiarise themselves with new legislation. In addition, they have assumed that there will be an additional hour of familiarisation cost (per outlet) to reflect the need to disseminate any new understanding/knowledge to other members of staff.

In line with Business Impact (BIT) guidance¹, we assume that this time adequately captures the total time required for businesses to familiarise themselves with the new legislation and the associated responsibilities, including familiarisation with the parts of the updated Technical Guidance reflecting the new legislation. These proposed changes may reduce the expected familiarisation costs as assumed in the final Impact Assessment because it aims to help businesses understand, and therefore comply with, the new legislation.

Familiarisation Costs to Government (Local Authorities)

As with businesses, we do not expect a need for local authorities to re-familiarise themselves with the existing parts of the guidance as any steps they feel are necessary to take as a result of reading the guidance should be part of their routine practices.

The familiarisation costs anticipated to arise from the new legislation itself have been captured by Defra in the final Impact Assessment. They have assumed that each Trading Standards Officer (TSO) and Environmental Health Officer (EHO) will take five working days (37 hours) to read and familiarise themselves with the new legislation. In addition to this, there will be an additional working day (7.4 hours) per local authority for EHO/TSOs to reach a consensus on how to proceed with the new legislation. The proposed changes to the Technical Guidance to reflect the new legislation may reduce the expected familiarisation costs for local authorities as assumed in the final Impact Assessment because it aims to make it easier for Local Authorities to understand and therefore enforce, the new legislation.

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https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/609201/business-impact-target-guidance-appraisal.pdf (Section 4.1)

Your views

The views and comment of stakeholders in England, Wales and Northern Ireland are sought on the proposed updates to the Technical Guidance.

Responses are needed by close on Friday 6 March 2020.

Please state, in your response, whether you are responding as a private individual or on behalf of an organisation/company (including details of any stakeholders your organisation represents).

Thank you on behalf of the Food Standards Agency for participating in this public consultation.

Annex A

Standard Consultation Information

Disclosure of the information you provide

Information provided in response to this consultation may be subject to publication or release to other parties or to disclosure in accordance with the access to information regimes (these are primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 2018 (DPA) and the Environmental Information Regulations 2004).

If you want information you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence.

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. Any automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding.

The Food Standards Agency will be what is known as the 'Controller' of the personal data provided to us.

Why we are collecting your personal data

Your personal data is being collected as an essential part of the consultation process, so that we can contact you regarding your response and for statistical purposes. We may also use it to contact you about related matters.

The Data Protection Act 2018 states that, as a government department, the Food Standards Agency may process personal data as necessary for the effective performance of a task carried out in the public interest. i.e. a consultation.

What we do with it

All the personal data we process is located on servers within the European Union. Our cloud-based services have been procured through the government framework agreements and these services have been assessed against the national cyber security centre cloud security principles.

No third parties have access to your personal data unless the law allows them to do so. The Food Standards Agency will sometimes share data with other government departments, public bodies, and organisations which perform public functions to assist them in the performance of their statutory duties or when it is in the public interest.

What are your rights?

You have a right to see the information we hold on you by making a request in writing to the email address below. If at any point you believe the information we process on you is incorrect you can request to have it corrected. If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer who will investigate the matter.

If you are not satisfied with our response or believe we are processing your personal data not in accordance with the law you can complain to the Information Commissioner's Office (ICO) at www.ico.org.uk, or telephone 0303 123 1113.

Our Data Protection Officer in the FSA is the Information Management and Security Team Leader who can be contacted at the following email address:
InformationManagement@food.gov.uk

Further information

If you require a more accessible format of this document please send details to the /named contact for responses to this consultation and your request will be considered.

This consultation has been prepared in accordance with HM Government consultation principles².

² www.gov.uk/government/publications/consultation-principles-guidance

What is prepacked for direct sale (PPDS) food?

From 1 October 2021, PPDS food will need to display, on its packaging or a label attached to it, the name of the food and a list of ingredients with the 14 allergens mandated by law emphasised. The changes will only affect prepacked for direct sale (PPDS) food. Products ordered over the phone or online are not affected by the changes.

For a food to be PPDS, it must meet all of the following three criteria:

1. Is the food presented to the consumer in packaging*?

↓ **Yes**

No → this is non-prepacked food

The food is “packed”

2. Is it packaged before the consumer selects or orders it?

↓ **Yes**

No → this is non-prepacked food

The food is “pre-packed”

3. Is it packaged at the same place** it is sold?

↓ **Yes**

No → this is prepacked food

The food is “pre-packed for direct sale”

If the answers to all three questions above are “Yes”, the food is PPDS.

Notes

* A single item (the food and its packaging) presented to the consumer. The food is completely or partially enclosed and cannot be altered without opening or changing the packaging. Foods in such packaging sold to other businesses are Prepacked food and already require allergen labelling. (See Article 2(2)(e) of the Food Information for Consumers Regulation No.1169/2011)

** Food (a) packaged by the same food business on the same site from which it is sold or (b) sold from temporary or moveable premises (such as a food truck or market stall) by the same food business that packaged it.

Annex C

Summary of proposed updates to the technical guidance

Section	Paragraph Number(s)	Description of Change	Change Type
Complete document	N/A	The Technical Guidance has been updated throughout to bring it in line with the latest FSA guidance format. All references to Scotland have been removed throughout the document as Food Standards Scotland is now the public sector food body for Scotland.	Format
Revision History	N/A	Updated to reflect the proposed amendments to the Technical Guidance.	Document Control
Contents	N/A	Updated to reflect updates to Technical Guidance; new Part 3, new page numbers etc.	Drafting
Introduction	1 (1-3 in draft)	New paragraphs 1 and 2 inserted to provide background on EU FIC and reflect the changes in requirements of new legislation.	To reflect requirements of new allergen labelling legislation *
	3 (5 in draft)	Wording revised to improve clarity on the requirements for precautionary allergen statements.	Drafting improvements
Intended Audience	5 (7 in draft)	Revised to include information on those who may not have to register as a food business from paragraphs 26 and 75 including the weblink to relevant FSA guidance in this area.	Drafting improvements
Purpose of guidance	6 (8 in draft)	Updated to reflect that the new allergen labelling legislation relating to England will amend the Food Information Regulations 2014.	To reflect requirements of new allergen labelling legislation*
Legal Status of Guidance	7-9 (9 -11 in draft)	Updated to align with the latest FSA guidance format and indicate that 'Best Practice' appears in shaded boxes.	Format
General Background on allergens	10-13 (12 – 14 in draft)	Paragraph 11 (12 in draft) updated to reflect the latest estimates of UK citizens who have food allergies and who have coeliac disease. Paragraph 13 (now 14) revised to remove historic (pre-EU FIC) references.	Drafting improvements

Section	Paragraph Number(s)	Description of Change	Change Type
Main Allergen Labelling Changes	14-16 (15–18 in draft) 18	Updated to provide an explanation of the changes brought about (in England) by the Food Information (Amendment) (England) Regulations 2019. Paragraph removed to better align with new requirements	To reflect requirements of new allergen labelling legislation *
Mandatory Obligations	19 (20 in draft)	Wording revised to reflect new legislation. Sentence added to improve clarity.	To reflect requirements of new allergen labelling legislation / Drafting Improvements
Part 1: Guidance for businesses providing prepacked food	27 (29 in draft) 31 (33 in draft) 34 (36 in draft) 36 (38 in draft) 39 (41 in draft) 40 (42 in draft) 41 (43 in draft) 43 (45 in draft) 44 (46 in draft) 48 49 (50 in draft), 56 (56 in draft), 61 (61 in draft), 67 (67 in draft) 68 (68 in draft) 70 (70 in draft) 71 72 (71 in draft)	Broken webpage link removed. Updated to refer to current Commission Implementing Regulation 828/2014 and provide an example. Page number references updated. “ “ “ Title of EU legislation corrected. Wording revised to improve clarity. Page number reference updated. Paragraph 48 removed as information was duplicated in Paragraph 49 (50 in draft). Wording revised to improve clarity. “ “ “ “ “ Paragraph removed to better align with EU FIC. Wording revised to improve clarity. FSA webpage link removed and replaced with weblink to Food Drink Europe guidance on precautionary allergen labelling.	Drafting / Drafting Improvements

Section	Paragraph Number(s)	Description of Change	Change Type
Part 2	Part 2 - Title 74 (74 in draft) 75 76 77 (75 in draft) 78 (76 in draft) 79 (77 in draft) 82 (80 in draft) 84 (82 in draft) 86 (84 in draft) (87 in draft) Example Box after paragraph 89 (after paragraph 88 in draft) 90 (89 in draft)	Reference to prepacked for direct sale foods removed. Material on prepacked for Direct Sale (PPDS) removed and moved to new Part 3 / Page number reference updated. Paragraph removed. Material on those who may not need registration as a food business moved to paragraph 7 in the draft. Paragraph removed to remove the reference to best practice guidance on allergen management relating to Scotland as the guidance no longer applies to Scotland. Wording revised to improve clarity. “ “ “ “ “ “ Paragraph inserted to improve clarity. Re-labelled as ‘Best Practice’ to align with new FSA guidance format / wording revised to improve clarity. Paragraph after bullet points appears in ‘Best Practice’ box to align with new FSA guidance format.	Drafting Improvements / To remove material on PPDS and move to new Part 3
Part 3 (New)	N/A (92 – 106 in draft)	New text and examples added on prepacked for direct sale food to reflect legislative changes in England and planned legislation in Wales and Northern Ireland.	To reflect requirements of new allergen labelling legislation *
Enforcement	94 & 95 (108 in draft) 97 (109 in draft) 98 (110 in draft)	Historic (Pre-EU FIC) references removed. Updated to refer to new allergen labelling requirements. Wording revised to improve clarity.	Drafting Improvements / To reflect requirements of new allergen labelling legislation *
Glossary	N/A	Entries for Distance selling, Non-prepacked food, Prepacked food	Drafting improvements /

Section	Paragraph Number(s)	Description of Change	Change Type
		revised to improve clarity and more closely reflect wording of EU FIC. New entry for “food business” reflecting definition in Regulation (EC) No. 178/2002. Entry for Prepacked foods for direct sale updated to reflect Government position.	To reflect requirements of new allergen labelling legislation*
References and Resources	N/A	Weblinks removed and replaced by weblinks to current FSA resources.	Update (Resources)
Relevant Legislation	N/A	List of relevant legislation and associated weblinks updated.	Update (Resources)
Review	N/A	New review statement and date included, reflecting latest FSA guidance format.	Format
Contact	N/A	Updated to reflect current FSA, FSA Wales and FSA Northern Ireland contacts.	Update (Resources)

* [The Food Information \(Amendment\) \(England\) Regulations 2019 \(SI 2019 No. 1218\)](#) and planned legislation in Wales and Northern Ireland.