

Allergens - Local Authority Q&A

About this document

This is Version 2 – issued September 2021.

This Question and Answer (Q&A) document provides local authorities (LA) with guidance on the enforcement of allergen controls in food business establishments.

The focus of the document is on the catering and retail sectors, rather than manufacturing. It is not intended to be an exhaustive document, but to address some of the key questions that have been raised with the FSA.

If you have a question that is not answered in this document, before contacting the FSA, please follow the agreed approach for escalating enquiries, which is endorsed by the Food Hygiene Focus Group and Food Standards and Information Focus Group:

1. Liaise within your local authority.
2. Liaise with your county or regional food liaison groups.
3. Liaise with your local Food Hygiene or Food Standards Focus Group representative - if you do not know who this is, please email:
England - LAEngagement@food.gov.uk
Wales - lasupportwales@food.gov.uk
Northern Ireland - executive.support@food.gov.uk

To promote consistency, we also advise posting your queries on the Knowledge Hub. If you have followed the above approach and still have a question, please email the relevant address above.

This Q&A is intended to be an evolving document and we will continue to review and update the document in light of feedback received and any changes in relation to the FSA's allergen related work programmes.

Please note that the answers in this document are for guidance purposes only and do not provide a definitive position on the matters covered. LAs should seek the support and advice of their legal teams before commencing any formal legal action.

References to EU Regulations in this guidance should be read as references to retained EU law in respect of England and Wales. In respect of Northern Ireland, these are references to EU Regulations which apply in Northern Ireland under the Protocol to the Withdrawal Agreement. There are some significant differences between retained EU law and EU law, see Question 16.

Overview

Consideration of compliance with allergen requirements is a fundamental part of both food standards and food hygiene interventions. The FSA's advice is that, where relevant, compliance with allergen requirements is assessed at every planned intervention. This is irrespective of whether the officer is delivering a food hygiene, food standards or combined intervention.

Allergens should also be considered in lower risk premises where alternative enforcement strategy approaches are used and when undertaking non-official controls.

In a two-tier authority setting, or where there are separate food standards and food hygiene teams, LAs should have arrangements in place so their intervention activities are co-ordinated in relation to allergens.

In this document we refer to the **intentional** and **unintentional** presence of allergens in food. **Intentional** presence means allergens that are in food as intended ingredients or as a processing aid. The term **unintentional** presence is used where allergens are present in food due to cross-contamination that occurs on the premises or because ingredients used in food carry voluntary allergen labelling such as 'may contain' warnings (also referred to as precautionary allergen labelling).

There may be instances where a Food Business Operator (FBO) uses ingredients that they are unaware contains an allergen(s) e.g. mislabelled ingredients, or ingredients adulterated with undeclared allergens. Incidents of this nature are beyond the scope of this guidance and will need to be investigated to establish the facts and to determine an appropriate response.

Food business operating models

FBOs in the catering and retail sector will operate their businesses in a variety of ways, which in turn will inform how they choose to comply with allergen requirements.

Controls associated with the storage, handling and use of allergens will need to be in place at all times so that accurate information can be provided to consumers on the intentional and unintentional presence of allergens.

FBOs may decide to implement additional allergen controls when they receive a request for food that is free from a specific allergen (e.g. gluten or dairy free). Others may decide to have 'free from' allergen controls in place at all times, for example where 'free from' dishes are listed on a menu.

Officers will, therefore, need to consider compliance with allergen requirements on a case by case basis.

Refusal of service

A FBO might refuse to serve a consumer that asks about the presence of allergens. This refusal could be for a number of reasons and may also stray into other areas of law such as discrimination. It is not possible to provide specific advice on this scenario as any potential offences will depend on the facts of each case.

Complaints in relation to refusal of service should be investigated, where appropriate, to establish if the FBO is meeting their legal obligations in relation to the allergen requirements contained in this Q&A. LAs should seek their own legal advice for any wider issues.

Allergen waivers/disclaimers

FBOs might ask consumers to sign an allergen waiver/disclaimer before agreeing to serve them. Waivers and disclaimers do not exempt an FBO from complying with their legal responsibilities under food law. They must still provide consumers with accurate information on the intentional presence of allergens in the food they serve.

Where a FBO uses waivers/disclaimers, officers should satisfy themselves that the FBO is complying with the allergen requirements outlined in this Q&A.

Depending on the wording used, an allergen waiver or disclaimer may contain unfair terms (see the Consumer Rights Act 2015).

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Key changes/additions to Version 2

In Version 2 we:

- added advice on the use of allergen waivers in the 'About this document' section
- added Q2 to cover cereals containing gluten
- revised Q3 in relation to the application of HACCP and the wording with regards to staff training to make what is required clearer
- updated Q5 to reflect the forthcoming changes to the rules for prepacked for direct sale food
- added Q6 – 11 to cover the forthcoming changes to the rules for prepacked for direct sale food
- added Q12 to provide guidance on allergens in relation to donated food
- updated Q14 to reflect changes in enforcement responsibilities in relation to prepacked for direct sale food and to update references to legislation
- updated Q15 to reflect the current version of the Food Law Code of Practice in relation to allergen responsibilities in two-tier authority areas
- updated Q17 to reflect differences in legislation and food law requirements that exist between England/Wales and Northern Ireland
- updated Q18 to add offences in relation to prepacked for direct sale food
- updated the 'Further guidance and information' section
- added Annex A which is a prepacked for direct sale decision flow chart
- added Annex B which provides guidance on the interpretation and application of the forthcoming requirements in relation to prepacked for direct sale food

Food Business Operator responsibilities

Q1. Which food allergens do Food Business Operators need to be aware of?

Food Business Operators (FBO) must ensure that the food they provide is safe, taking into account the health sensitivities of consumers (for example, those with allergies or intolerances).

The 14 allergens

To comply with this requirement, FBOs must know if any of the 14 allergens, as defined in Annex II, Regulation (EU) No 1169/2011, are used as ingredients or processing aids in the food they provide (i.e. intentional presence). This is so they can provide accurate allergen information to consumers, enabling them to make safe food choices.

The 14 allergens, defined in Annex II, Regulation (EU) No 1169/2011¹, are:

- celery
- cereals containing gluten – namely wheat, rye, barley and oats
- crustaceans – such as prawns, crabs and lobsters
- eggs
- fish
- lupin
- milk
- molluscs – such as mussels and oysters
- mustard
- nuts – namely almond, hazelnut, walnut, Brazil nut, cashew, pecan, pistachio, Macadamia nut and Queensland nut
- peanuts
- sesame seeds
- soybeans
- sulphur dioxide and sulphites (at concentrations of more than 10 mg/kg)

There are some exemptions to the above list, such as fully refined soybean oil, which can also be found in Annex II, Regulation (EU) No 1169/2011.

FBOs must also determine the unintentional presence of the 14 allergens in the food they provide i.e. due to cross contamination risks or because the ingredients they use carry 'may contain' allergen warnings.

It is important to note that FBOs are not required to provide information on the unintentional presence of allergens to consumers under Regulation (EU) No 1169/2011² as this is voluntary food information (Article 36(3), Regulation (EU) No 1169/2011).

¹ <https://www.legislation.gov.uk/eur/2011/1169/body>

² The information that must be provided under Regulation (EU) No 1169/2011 is specified in point (c) of Article 9(1).

They should, however, make consumers aware of their presence to avoid placing unsafe food on the market (Article 14, Regulation EC No 178/2002).

Other allergenic ingredients

Consumers may ask about the intentional or unintentional presence of other allergenic ingredients, such as kiwis and strawberries.

In this scenario, the FBOs obligation to ensure the food it provides is safe is not limited to only providing information on the 14 allergens above. On receipt of such a request the FBO will need to assess the presence of the ingredient(s) specified by the consumer in their food and provide this information to the consumer so they can make an informed decision. Failure to provide accurate information about ingredients when requested could result in the FBO supplying food that is unsafe for the consumer (Article 14, Regulation EC 178/2002).

It is recognised that there will be instances where an FBO is unable to assess the presence of other ingredients and provide accurate information e.g. during a busy service period. A FBO may also not be able to provide accurate ingredient information, for example because the request involves non-prepacked food supplied to the FBO that does not need to be accompanied by full ingredients information (e.g. a tray of bakery products supplied by another business).

The FBO must inform the consumer if they are unable to provide accurate ingredient information.

Q2. What about cereals containing Gluten?

Where foods have been voluntarily labelled as 'gluten-free' they must meet the requirements set in Regulation (EU) No. 828/2014³. This legislation sets out the conditions under which foods may be labelled as "gluten-free" (no more than 20 mg/Kg in the food as sold to the final consumer) or "very-low gluten" (no more than 100 mg/Kg gluten in the food as sold to the final consumer).

When a product contains one of the cereals mentioned in Annex II above (e.g. oats) and meets the relevant requirements of Regulation (EU) No. 828/2014, the statement 'gluten-free' or 'very low gluten' can be used on the product. However, the cereal mentioned in Annex II must still be indicated and emphasised in the list of ingredients.

Rules surrounding use of the terms "gluten-free" and "very-low gluten" apply to all foods, including non-prepacked foods such as those served in restaurants. No other statements to describe the absence or reduced presence of gluten are permitted. When gluten free oats are used in a gluten free product, the word "oats" would still need to be emphasised and declared in accordance with Article 21 and 9(1)(c) of the FIC.

³ Regulation (EU) No. 828/2014 enforced in Wales by The Food Information (Wales) (Amendment) Regulations 2016 and in Northern Ireland by The Food Information (Amendment) Regulations (Northern Ireland) 2016

Q3. What are the legal requirements for Food Business Operators in relation to allergens?

Food Information Regulations

Food Business Operators (FBO) are required to comply with the food labelling and food information requirements of Regulation (EU) No 1169/2011 on the provision of food information to consumers (FIC) and the Food Information Regulations (FIR)⁴.

Food businesses supplying food to other food businesses that is not intended for the final consumer and/or not intended for mass caterers must ensure that business to business sales of food are accompanied with sufficient and accurate information to enable subsequent food businesses to meet their responsibilities.

If an FBO provides non-prepacked food to consumers in a catering or retail setting, they can provide allergen information by any means, including orally⁵. Where the information will be provided orally, the FBO must indicate in writing that the information can be obtained by asking a member of staff. This can be achieved by having a written notice, menu, ticket or label that is clearly discernible at the point that the customer chooses their food to indicate that allergen information is available from a member of staff.

FBOs selling food through distance selling, such as over the telephone or via the internet, must ensure that mandatory allergen information is available to the consumer when they are deciding what to order. This can be in writing (on a website, catalogue or menu) or orally over the telephone. All food information, including allergen information, must be accurate. It is therefore important that allergen information that is provided online or in print is reviewed and updated to ensure it is accurate (e.g. when there has been a recipe change).

Allergen information must also be provided at the moment of delivery (Article 14, Regulation (EU) No.1169/2011). Although this can be by any means, best practice is to provide the information in a written form. This can be achieved by, for example, applying stickers to food containers to identify the dishes containing allergens, writing on the containers or providing a menu with allergen information for each dish.

Online food delivery platforms must also ensure that consumers can access mandatory allergen information when they are deciding what to order. Allergen information can either be provided on the food delivery platform website or

⁴ The FIC provides the legislative framework around the provision of general food information to consumers. Separate, but parallel enforcement regulations exist in each of the three countries of the UK. These are:

- The Food Information Regulations 2014
- The Food Information (Wales) Regulations 2014
- The Food Information Regulations (Northern Ireland) 2014

⁵ Does not apply where food is sold by means of distance communication (Article 14, Regulation (EU) No. 1169/2011)

consumers can be directed to obtain allergen information directly from the listed restaurant preparing the food before placing their order.

Placing unsafe food on the market

FBOs are not required to provide information on the unintentional presence of allergens under FIC as this is voluntary food information.

They must, however, avoid placing unsafe food on the market ([Article 14, Regulation \(EC\) No 178/2002](#)). When determining whether food is unsafe, regard is had to the information provided/available to consumers on the avoidance of health effects such as allergic reactions.

Where an FBO has identified the unintentional presence of allergens in the food they supply, they should bring this to the attention of consumers to avoid supplying unsafe food. Where this is not happening, FBOs should be encouraged to provide this information to consumers.

Unlike FIC, Article 14, Regulation (EC) No 178/2002 does not prescribe how an FBO should provide information to consumers, but the overarching principles of food information will apply i.e. the information must not mislead, or be ambiguous or unclear.

In a catering setting, the FBO may choose to provide detailed cross contamination information on menus, on a chalkboard or in an allergen information pack. Alternatively, they could have signage in place advising consumers of the allergen cross contamination risks that exist and to speak to a member of staff if further information is needed.

Food safety management system/HACCP

In accordance with Article 5 of Regulation (EC) No 852/2004, FBOs must put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles.

They must consider allergens as part of this requirement, which is supported by the [EU Commission Notice](#) on the implementation of food safety management systems.

For the purposes of HACCP based procedures, allergens should be treated in the same way as a chemical contaminant, because once present in the food, they cannot be removed through subsequent controls, such as applying heat. There are well established flexibilities that exist in relation to food safety management systems and HACCP based procedures. For example, in a catering setting FBOs can use Safer Food Better Business or the Safe Catering Pack in Northern Ireland and the specific allergens sections to achieve compliance. In lower risk settings, such as the retail of pre-packed food only, implementing prerequisite programs may be sufficient. Officers will need to make a judgement of what is required on a case by case basis.

To comply with Article 5, FBOs must conduct a hazard analysis and consider the following issues where relevant to their business:

- The presence of allergens in the ingredients they use to prepare food i.e. check the labels on prepacked foods, or the allergen information provided with any non-prepacked foods supplied by another business.
- The presence of allergens in any processing aids, such as the oil used for deep fat frying
- Is there enough space and/or separation in the premises to avoid cross contamination of allergens, when considering the food handling practices and procedures of the business and the allergens involved? Could an area of the premises be used if appropriate cleaning and procedures were put in place before food is prepared?
- The risk of allergen cross contamination. The FBO will need to carefully assess how food is stored, handled and prepared to identify any potential for cross contamination. Ingredients that could spill or become airborne will need to be stored appropriately (e.g. sealed containers).
- Risks from the personal hygiene and protective clothing of staff.
- Checks to ensure that ingredients used are as specified and what action to take when an ingredient is substituted or changed e.g. routine labelling checks, supplier notification guarantees, etc.

Following the hazard analysis, the FBO will need to identify any control measures that are needed to prevent cross contamination. These measures are likely to be critical control points as once present, allergens cannot be removed through subsequent controls.

Implementing a food safety management system based on HACCP principles will in turn help the FBO to provide consumers with accurate allergen information as covered in the sections above.

If an FBO cannot control the presence of allergens, they should tell consumers that the food they provide may contain the relevant allergen(s) so consumers can make an informed decision.

Staff training

FBOs must comply with the general requirement that food handlers are supervised and instructed and/or trained in food hygiene matters commensurate with their work activity. This applies to all staff regardless of their contractual status within an organisation and includes part-time, temporary and agency staff.

Appropriate staff training is critical to ensure compliance with allergen requirements and to protect food hypersensitive consumers. FBOs will need to consider the training needs of their staff, based on their food safety management system and HACCP assessments (where appropriate).

There are no specific training requirements under FIC, but officers may determine that allergen training is needed so that a FBO can comply with the hygiene requirements of Regulation (EC) No 853/2004 and specifically Article 5 requirements in relation to their role and the nature of the business. Relevant staff should be trained in the food allergen management procedures contained in the food safety management system to further support compliance with FIC.

Areas of training the FBO will need to consider and detail in the food safety management system include the following:

- All members of staff should know what to do when a customer asks about the presence of any allergens. Staff will need to know how to deal with the customer's request, or if they should involve another member of staff who has been trained to deal with allergens (e.g. a manager).
- What information staff should provide to a customer who enquires about the presence of allergens i.e. they must be able to tell the customer about the intentional use of the 14 allergens.
- How to deal with specific customer needs. For example, staff may need to discuss which allergens the customer needs to avoid and provide information on the unintentional presence of allergens due to cross contamination or the use of ingredients that carry 'may contain' warnings.
- How customer orders are handled and communicated to staff that select, prepare and serve the customer's food. This is particularly important where there are any specific allergen requirements (e.g. the customer orders a standard dish without a specific allergenic ingredient).
- How food should be handled and prepared to control the intentional and unintentional introduction of allergens, such as:
 - the storage and handling of allergenic ingredients
 - the use of standard recipes and ingredients
 - which areas of the premises should be used when preparing food
 - cleaning procedures prior to preparing food
 - which equipment staff must use to prepare food
 - food preparation practices and procedures that prevent/minimise cross contamination
- The personal hygiene of staff and any requirements regarding protective clothing.

Free [online training](#) is available that offers practical advice for anyone wanting to learn more about food allergies, such as managers and staff in the manufacturing and catering industries.

Q4. What allergen information must Food Business Operators provide?

Food information to consumers

Under Regulation (EU) No 1169/2011 on the provision of food information to consumers (FIC), Food Business Operators (FBO) must be able to provide business customers and consumers with accurate information on the intentional presence of any of the 14 allergens in the food they provide. This includes allergens used as an ingredient or a processing aid.

Placing unsafe food on the market

There is no legal requirement under FIC for FBOs to provide consumers with information on the unintentional presence of allergens as this is voluntary food information.

However, to avoid providing food that could be deemed unsafe (Article 14, Regulation (EC) No 178/2002), FBOs should be able to provide consumers with accurate information about the unintentional presence of allergens where required (e.g. in response to a consumer query).

FBOs should also provide this voluntary information to business customers so they are able to pass this onto consumers.

Any information on the unintentional presence of allergens provided to consumers or business customers must be based on a meaningful risk assessment⁶ by the FBO.

Misleading statements

FBOs must not make any statements about food that could mislead consumers. For example, they should not make any statements about the intentional or unintentional presence of allergens in their food if they have not properly assessed the presence to comply with FIC or completed a meaningful risk assessment. Where these assessments have not taken place, LAs should take the normal graduated enforcement approach to ensure the business meets its legal obligations.

If an FBO cannot prevent allergen cross-contamination or uses pre-packed ingredients that carry 'may contain' warnings, they should tell consumers that the food they provide may contain the allergen and may not be safe for people with an allergy to eat it. The consumer can then make an informed decision.

⁶ Officers will need to make a judgement, on a case by case basis, as to whether an FBO's risk assessment is suitable and sufficient.

Q5. What allergen information does non-prepacked/pre-packed for direct sale food require?

FBOs are required to inform customers if their food contains any of the 14 allergens as an ingredient or processing aid, either explicitly in writing or with a clear instruction about how to obtain the information (e.g. by providing a sign telling customers to ask a member of staff).

Allergen information for non-prepacked food, including foods prepacked for direct sale (PPDS), can currently be communicated through a variety of means to suit the nature of the food business.

New rules about the provision of allergen information in relation to PPDS foods come into effect on 1 October 2021. See below for further details.

Q6. What about food prepacked for direct sale (PPDS) after 1 October 2021?

Changes regarding PPDS food are being introduced through an amendment to the Food Information Regulations.⁷

From 1 October 2021, food businesses that offer for sale PPDS food will need to label it with the name of the food and a full ingredients list, with allergenic ingredients emphasised within the ingredients list. There are some exemptions, such as packaging or containers where the largest surface area is less than 10cm² ⁽⁸⁾ and drinks containing alcohol by volume of more than 1.2% (Article 16, Regulation (EU) No 1169/2011)

Changes to the Food Information Regulations

The following changes are being introduced by the amendment to the regulations:

- Requirement to list ingredients and emphasise allergenic ingredients for food that is PPDS
- The name of the food must be provided directly on the package of the food or on a label attached to the package.
- Makes it an offence not to comply with above requirements.
- Allows for improvement notices to be served regarding the above matters
- Changes the enforcement powers of LAs regarding PPDS

⁷ The Food Information (Amendment) (England) Regulations 2019
The Food Information (Wales) (Amendment) (No. 2) Regulations 2020
The Food Information (Amendment No. 2) Regulations (Northern Ireland) 2020

⁸ Allergens must still be labelled on these products

Q7. What is the definition of PPDS food?

PPDS food is food that is packed by a FBO before being offered for sale by the same FBO to the final consumer.

The food must be offered for sale:

- on the same premises; or
- on the same site⁹; or
- on other premises if the food is offered for sale from a moveable and/or temporary premises (such as marquees, market stalls, mobile sales vehicles)

A flow chart of the online food labelling tool can be found at Annex A.

Q8. What is prepacked in the context of PPDS food?

The definition of prepacked is taken from the definition of prepacked food as defined in Article 2(2)(e) of Regulation (EU) No 1169/2011:

‘any single item for presentation as such to the final consumer and to mass caterers, consisting of a food and the packaging into which it was put before being offered for sale, whether packaging encloses the food completely or only partially, but in any event in such a way that the contents cannot be altered without opening or changing the packaging; ...’

Therefore, prepacked in the context of PPDS food means any single item, consisting of the food and its packaging, that is:

- ready for presentation to the final consumer; and
- is partly or fully enclosed by the packaging; and
- cannot be altered without opening or changing the packaging.

Examples of food that are considered to be PPDS can be found at [Annex B](#)

Q9. What are the food labelling requirements under PPDS?

The label on PPDS food must show the name of the food and the ingredients list with the 14 allergens required to be declared by law emphasised within it.

This information must be provided in accordance with the existing legal requirements that apply to the naming of food and listing ingredients. The FSA has produced [guidance on the labelling of PPDS food](#).

⁹ In this instance ‘site’ refers to a building complex such as a shopping centre or airport terminal in which the same food business operates from more than one unit within the building complex.

Q10. What about distance sales and PPDS?

The PPDS labelling requirements do not apply to PPDS food that is supplied by means of distance selling, such as food that is purchased over the phone, internet or via apps. See Question 3 for information on the requirements regarding the provision of allergen information and distance sales.

Q11. Are there examples of how the PPDS rules apply?

Annex B contains examples of how the PPDS rules will apply to different food types and scenarios from 1 October 2021. This part of the Q&A will be updated with new examples, so please refer to this if you have a query about the application of PPDS.

If you have a question that isn't answered in Annex B, please email

PPDS@food.gov.uk

Q12. What are the allergen rules for donated food?

This question considers the donation of food to community food schemes such as food banks and community kitchens.

There are no exemptions under food law for food businesses that donate food. They must still comply with the food labelling and allergen information rules that apply to the food they are donating. This includes the PPDS requirements that come into effect on 1 October 2021. Donated food must also not be placed on the market if it is unsafe (Article 14, Regulation (EC) No 178/2002).

Food businesses donating non-prepacked food

A food business that donates non-prepacked food (e.g. fresh bread rolls that are not prepacked) to a community food scheme must, as a minimum, supply information on any allergens intentionally present in the donated food. To avoid placing unsafe food on the market, they should also supply information on the unintentional presence of any allergens.

If the community food scheme serves this non-prepacked food, say as part of a meal, they can make the allergen information available to their customers by any means, including orally, who in turn can make an informed decision.

Community food schemes will need to comply with the new PPDS labelling requirements when they come into force on 1 October 2021. Therefore, the amount of information supplied with donated, non-prepacked food will determine whether they can use that food for PPDS purposes.

Food businesses donating prepacked food for further processing

A food business that donates prepacked food that is intended for further handling and preparation before it is supplied to a consumer, must provide the mandatory particulars, including allergen information, to the community food scheme. This can be provided on the outer case of the food, a label attached to the outer food packaging or on commercial documents.

Food businesses donating prepacked food

Donations of prepacked food, such as tinned or packeted goods, will already carry mandatory food information, including allergen information that can be passed onto consumers.

Food businesses donating PPDS food

If a food business donates PPDS food, the status of the food will change as it is no longer being supplied directly to consumers. In this scenario, the donated PPDS food becomes prepacked food and will need to comply with the relevant labelling requirements.

Members of the public and others donating food

Members of the public and other organisations that do not need to [register as a food business](#) are not legally required to provide information on the presence of allergens in the food they donate.

Whilst there is no legal requirement to provide allergen information, it should be encouraged and it is considered best practice to do so.

Where a member of the public donates homemade food to a community food scheme, they are not legally required to comply with food information requirements, including the provision of allergen information. However, the community food scheme will need information on the intentional presence of any allergens so they can pass this information onto consumers who in turn can make an informed decision.

Local Authority responsibilities

Q13. Who is responsible for the enforcement of allergen requirements?

All LAs have a critical role to play in the enforcement of allergen requirements.

Food Information Requirements

Under Regulation 9 of the Food Information Regulations (FIR) it is the duty of a food authority¹⁰ within its area and a port health authority within its district to enforce the regulations.

In England, the definition of 'food authority' for the purposes of FIR excludes non-metropolitan district councils where there is a county council. Under Regulation 9(2) of the England FIR these non-metropolitan district councils may enforce the regulations within its area in relation to:

- the requirement to provide mandatory allergen information for non-prepacked food sold other than by distance sale; and
- the requirement to display a sign indicating that detailed allergen information will be provided by a member of staff if a food business operator chooses to provide such information orally.

From 1 October 2021, in England, District Councils in the area of a County Council will no longer have enforcement powers in relation to PPDS food. Depending on local arrangements, District Councils may wish to advise businesses about the new PPDS requirements, and/or refer any non-compliances to the County Council food team.

Interventions

The other critical area of allergen enforcement relates to assessing the effectiveness of allergen controls in a food business so that the food information provided to consumers is accurate (see Question 16 for further details).

The allergen requirements and controls that should be covered during food hygiene and food standards interventions are listed below. As mentioned elsewhere, it is critical that LAs agree how allergens are enforced in a two-tier setting or where different teams enforce food hygiene and food standards to ensure there are no gaps in the overall assessment of allergen compliance.

Requirements to be covered during interventions:

- Provision of allergen information in relation to non-prepacked and prepacked for direct sale foods
(Regulation 5, Food Information Regulations)

¹⁰ The definition of 'Food authority' can be found in Regulation 2 of the respective FIR for England, Wales and NI.)

- Allergen controls during storage, delivery, food preparation and service
(Article 4(2), Annex II, Chapter IX, Para 2 and 3 Regulation (EC) No 852/2004)
(Article 4(2), Annex II, Chapter IX, Para 9 (applies to NI only), Regulation (EC) No 852/2004)
- Food Safety Management System
(Article 5, Regulation (EC) No 852/2004)
- Staff training
(Article 4(2), Annex II, Chapter XII, Para 1, Regulation (EC) No 852/2004)
(Chapter XIa, Para 1 and 2, Regulation (EC) No 852/2004 (applies to NI only))
- Placing unsafe food on the market
(Article 14, Regulation (EC) No 178/2002)

The precise scope of what is covered will depend on the purpose and nature of the intervention, the competence/authorisation of the officer and any agreements with other LAs on how allergens are enforced.

Complaints

How complaints are handled should be agreed in two-tier authority settings or where there are separate food standards and food hygiene teams, to ensure investigations are co-ordinated and effective.

The reasons for any non-compliance may not become clear until an officer starts their investigation. Where needed, the initial investigating officer should seek the assistance of an officer with the appropriate competence as the investigation progresses.

Q14. How should allergen responsibilities be agreed in two-tier authority areas?

District and County councils must discuss and agree how they will enforce allergen requirements and ensure established arrangements for ongoing liaison are in place (see the Food Law Code of Practice).

Agreements between councils should set out the arrangements in place to enforce allergens provisions for non-prepacked and prepacked for direct sale foods. Implementing these agreements should ensure that there is a clear and consistent approach to enforcement of allergen provisions by councils in two-tier areas.

Councils are encouraged to use a Memorandum of Understanding (MoU) to record their local arrangements. Matters which could be included in these agreements are:

- Details of which authority is responsible for:
 - provision of advice on allergens, and if appropriate, the circumstances where each authority would provide advice

- pro-active interventions on allergens, such as during programmed inspections or audits
- reactive interventions, such as those which arise following a consumer complaint or an incident
- allergen related samples
- Enforcement action, setting out the types of enforcement action available, the circumstances when each authority may take enforcement action and provisions for support, as appropriate.
- Communication details, such as appropriate contact email addresses and telephone numbers. This could also include emergency contact details, for example out-of-hours contacts, if appropriate.
- Referral procedure, detailing the circumstances when matters will be referred to the other authority or other interested parties.
- Details of where authorities may collaborate, for example, as part of local or regional projects.

To ensure consistency, Competent Authorities may also want to agree their approach to the following:

- Advice – setting out which guidance documents will be provided to Food Business Operators, signposting to other sources of guidance (e.g. FSA's allergy e-learning course), allergen workshops, best practice advice to be included and standard lines to use.
- Enforcement – setting out a structured approach to allergen related enforcement, which could be in the form of decision trees that are consistent with each authority's enforcement policy.
- Monitoring and reporting arrangements to ensure that the agreed approach is working in practice.

The FSA is aware that MoUs for this purpose are already in use, so would encourage these are shared, between authorities or on platforms such as Knowledge Hub, to minimise duplication of effort and aid consistency of approach.

Q15. How should allergen responsibilities be agreed in unitary authorities?

LAs that have responsibility for food standards and food hygiene should have internal procedures and policies in place that cover how allergen requirements are to be enforced. This is particularly important where separate teams or officers deliver food standards and food hygiene official controls.

Q16. What allergen information and controls should LAs cover during interventions?

Allergen requirements apply to all food businesses. Therefore, compliance with allergen requirements should be considered during all food interventions.

The extent of what is covered during an intervention will depend on the type of business and intervention (hygiene, standards or combined), local arrangements and any agreements that exist with other competent authorities.

LAs may wish to undertake focused allergen inspections (i.e. a partial inspection) where these are permitted in the Food Law Code of Practice.

Officers should always check, prior to undertaking an inspection, whether the business is covered by a Primary Authority Partnership and whether there is a relevant inspection plan or assured advice in place in relation to allergen information and management.

The FSA has produced an example [aide-memoire](#) that LAs may wish to use when carrying out an assessment of allergen controls. A number of other examples of template documents like this have been produced by LAs and are available on the Knowledge Hub.

Food information requirements

Initially, officers can check that Food Business Operators (FBO) are providing consumers with allergen information in a written format or verbally. Where allergen information is provided verbally in a catering/retail setting, a written notice, menu, ticket or label that is clearly discernible at the point that the customer chooses their food must be provided to indicate that allergen information is available from a member of staff. Clearly discernible is not defined in legislation so the everyday meaning should be applied. Officers will need to make a judgement on a case by case basis.

During an inspection, officers should make relevant and appropriate checks to verify that allergens are understood and are being adequately controlled by the food business, thereby ensuring any food information provided to consumers is correct.

For example, officers should check for allergens in the ingredients and processing aids used in different food products, and whether these are declared on the corresponding labelling or allergen matrix. They should also check ingredient specifications against the ingredients held by the business. The number of checks carried out will depend on the nature, scale and compliance history of the business.

Similarly, in a catering/retail environment, the same checks should be carried out and assessed against the FBO's own assessment of the allergens intentionally present in food offered by the business. Officers should check menu items and assess these against the ingredients used and the food handling practices of the business. Food sampling is a useful way to check and verify compliance with allergen requirements.

Placing unsafe food on the market

Officers should check what arrangements the FBO has in place to make consumers aware of the unintentional presence of allergens in the food they provide. Any claims about the unintentional presence of allergens must be based on the FBO completing a meaningful risk assessment.

FBOs have flexibility in how they choose to make consumers aware about the unintentional presence of allergens, so officers will need to consider compliance on a case by case basis.

Food hygiene requirements

During a food hygiene inspection officers should assess food business compliance with allergen requirements. Officers should cover the following areas as part of their inspection and, where appropriate, should expect to see documented procedures and that these are implemented at the business. Consideration should be given, but not limited, to:

- **Food Safety Management System**

Article 5(1), Regulation (EC) No 853/2004 states: "Food Business Operators shall put in place, implement and maintain a permanent procedure or procedures based on the principles of HACCP (Hazard Analysis and Critical Control Points)".

Allergenic ingredients and processing aids must be considered as a hazard as part of the business's Food Safety Management System (FSMS). Allergen cross contamination risks should be identified. Adequate controls should be in place to prevent cross contamination where an allergen needs to be specifically excluded from a dish, for example, where there is a request for such, or the dish is declared to be free from an allergen (e.g. gluten or dairy free).

A procedure should be implemented (i.e. staff trained) covering the action to be taken when a consumer asks about food allergens or declares an intolerance. This procedure should also cover what happens when a customer asks about cross contamination or if the ingredients carry any 'may contain' warnings.

- **Cross contamination risks**

- i) Annex II, Chapter IX, Para 2, Regulation (EC) No 852/2004 states: “Raw materials and all ingredients stored in a food business are to be kept in appropriate conditions designed to prevent harmful deterioration and protect them from contamination”.

Raw materials and ingredients should, where required, be stored to protect them against the risk of cross-contamination from allergenic ingredients. How allergenic ingredients need to be stored will depend on the ingredient and their potential to cause cross contamination (e.g. allergenic ingredients that can become airborne).

- ii) Annex II, Chapter IX, Para 3, Regulation (EC) No 852/2004 states: “At all stages of production, processing and distribution, food is to be protected against any contamination likely to render the food unfit for human consumption, injurious to health or contaminated in such a way that it would be unreasonable to expect it to be consumed in that state”

Steps should be taken to control the risk of cross-contamination from the 14 allergens at all stages including handling, preparation, storage, service and delivery.

FBOs must identify the intentional and unintentional presence of allergens in the food they provide. This regulation requires FBOs to ensure that accidental allergen cross contamination, which would potentially make food unsafe for consumers, does not occur.

- iii) Annex II, Chapter V, Para 1(a), Regulation (EC) No 852/2004 states: “All articles, fittings and equipment with which food comes into contact are to be effectively cleaned and, where necessary, disinfected. Cleaning and disinfection are to take place at a frequency sufficient to avoid any risk of contamination”.

Appropriate steps should be taken to ensure equipment, surfaces, utensils and crockery are cleaned to remove any allergenic residues prior to use, where this is necessary to ensure food does not contain allergenic ingredients. Consideration should be given to complex equipment (e.g. vacuum packers and slicers). Cleaning equipment should not be a source of allergen contamination.

- iv) Annex II, Chapter VIII, Para 1, Regulation (EC) No 852/2004 states: “Every person working in a food-handling area is to maintain a high degree of personal cleanliness and is to wear suitable, clean and, where necessary, protective clothing”

Food handlers must ensure their personal protective clothing is clean and not a source of allergen cross contamination where this needs to be controlled. They must also thoroughly wash their hands where this is required to reduce the risk of allergen cross contamination.

- v) Annex II, Chapter X Para 1, Regulation (EC) No 852/2004 states: “Material used for wrapping and packaging are not to be a source of contamination”

Packaging materials, such as vacuum packing bags and reusable food containers, must be protected against cross-contamination from allergenic ingredients where required and must not be a source of contamination.

- **Cross contamination risks (Northern Ireland only)**

- vi) Recent amendments to 852/2004 apply to Northern Ireland only: Annex II, Chapter IX Para 9, Regulation (EC) No 852/2004 states: “Equipment, conveyances and/or containers used for the processing, handling, transport or storage of one of the substances or products causing allergies or intolerances, referred to in Annex II to Regulation (EU) No 1169/2011, shall not be used for the processing, handling, transport or storage of any food, not containing that substance or product, unless the equipment, conveyances and/or containers have been cleaned and checked at least for the absence of any visible debris of that substance or product”.

Equipment, conveyances and/or containers that are in contact with one of the 14 allergens should not be used for the processing, handling, transport or storage of other food, unless it has been adequately cleaned and then checked for the absence of allergenic substance prior to use.

- **Training**

Article 4(2), Annex II, Chapter XII, Para 1, Regulation (EC) No 852/2004 states: “Food business operators are to ensure that food handlers are supervised and instructed and/or trained in food hygiene matters commensurate to their work activity”

All staff should be adequately supervised and instructed and/or trained in allergen management and the control of cross contamination (i.e. findings from the HACCP assessment). Consideration should be given to all staff including front of house, chefs, bar staff and cleaning staff. Staff should also be trained on any in-house procedures, such as dealing with allergen queries from consumers.

- **Food Safety Culture (Northern Ireland only)**

Recent amendments to Regulation (EC) No 852/2004 apply to Northern Ireland only:

Annex II, Chapter XIa, Para 1, Regulation (EC) No 852/2004 states: “Food business operators shall establish, maintain and provide evidence of an appropriate food safety culture by fulfilling the following requirements:

- (a) commitment of the management, in accordance with point 2, and all employees to the safe production and distribution of food;
- (b) leadership towards the production of safe food and to engage all employees in food safety practices;

- (c) awareness of food safety hazards and of the importance of food safety and hygiene by all employees in the business;
- (d) open and clear communication between all employees in the business, within an activity and between consecutive activities, including communication of deviations and expectations;
- (e) availability of sufficient resources to ensure the safe and hygienic handling of food”.

Annex II, Chapter XIa, Para 2, Regulation (EC) No 852/2004 states:

“Management commitment shall include:

- (a) ensuring that roles and responsibilities are clearly communicated within each activity of the food business;
- (b) maintaining the integrity of the food hygiene system when changes are planned and implemented;
- (c) verifying that controls are being performed timely and efficiently and documentation is up to date;
- (d) ensuring that the appropriate training and supervision are in place for personnel;
- (e) ensuring compliance with relevant regulatory requirements;
- (f) encouraging continual improvement of the food safety management system of the business, where appropriate, taking into account developments in science, technology and best practices”.

Food business operators must ensure that roles and responsibilities in relation to allergen controls are clearly communicated to, and understood by, all staff. Management commitment to engaging all staff on these matters will increase awareness and improve behaviour of employees in relation to all aspects of food safety including allergen controls.

Q17. What are the potential offences for non-compliance with allergen requirements?

There are a range of offences that may be considered in relation to non-compliance with the regulations surrounding allergen information and controls. It is not possible to provide detailed guidance on the offences below as each case will need to be considered on its merits, the facts that are established and any defences that might exist, such as due diligence.

- **Allergen specific offences**

- Regulation 10, Food Information Regulations 2014**

- Regulation 10, Food Information (Wales) Regulations 2014**

- Regulation 10, Food Information Regulations (Northern Ireland) 2014**

- Makes it an offence not to comply with the requirements to provide accurate allergen information to consumers as laid down in Regulation (EU) No 1169/2011 on the provision of food information to consumers e.g. failing to list allergens within an ingredients list.

With regards to the new PPDS food labelling requirements that come into effect on 1 October 2021, it will be an offence not to comply with Regulation 5A(1)(b) which relates to the labelling of allergens as required by Article 9(1)(c) of Regulation (EU) No 1169/2011.

Regulation 12(1), Food Information Regulations 2014
Regulation 12(1), Food Information (Wales) Regulations 2014
Regulation 12(1), Food Information Regulations (Northern Ireland) 2014

Makes it an offence not to comply with the requirements of an Improvement Notice.

- **Other offences to consider**

Regulation 19, Food Safety and Hygiene (England) Regulation 2013
Regulation 17, Food Hygiene (Wales) Regulations 2006
Regulation 17, Food Hygiene Regulations (Northern Ireland) 2006

Makes it an offence not to comply with the hygiene requirements in relation to cross-contamination, cleaning, HACCP, personal hygiene and training.

Regulation 19, Food Safety and Hygiene (England) Regulation 2013
Regulation 4, General Food Regulations 2004 (Wales)
Regulation 4, The General Food Regulations (Northern Ireland) 2004

Makes it an offence to place unsafe food on the market (Article 14, Regulation (EC) No 178/2002). Food is deemed to be unsafe if it is injurious to health or unfit for human consumption.

When determining whether any food is unsafe, regard shall be had to the particular health sensitivities of a specific category of consumers (e.g. those with allergies or intolerances). For example, food sold containing undeclared allergens used as an ingredient in that food would be considered unsafe.

Regard shall also be had to the information provided to consumers concerning the avoidance of adverse health effects from a particular food or category of foods.

Article 16, Regulation (EC) No 178/2002

This regulation requires that the “labelling, advertising and presentation of food, including the information made available, should not mislead consumers”. Therefore, inaccurate allergen information could be considered to mislead consumers.

Section 14, Food Safety Act 1990
Article 13, Food Safety (Northern Ireland) Order 1991

Makes it an offence for anyone to sell to the purchaser’s prejudice, any food which is not of the nature, substance or quality demanded by the purchaser.

Section 15, Food Safety Act 1990
Article 14, Food Safety (Northern Ireland) Order 1991

Makes it an offence to falsely describe or present food. More particularly, it is an offence for food labelling to falsely describe or to mislead as to the nature, substance or quality of the food. The section also applies in relation to the advertising and presentation of food.

Regulation 6(2), Food Safety and Hygiene (England) Regulations 2013
Regulation 6(2), Food Hygiene (Wales) Regulations 2006
Regulation 6(2), Food Hygiene Regulations (Northern Ireland) 2006

Makes it an offence not to comply with the requirements of a Hygiene Improvement Notice.

- **Non-food legislation**

In more serious cases, such as where there has been a fatality, LAs may wish to consider provisions under the Health and Safety at Work etc Act 1974. Advice on this is beyond the scope of this Q&A.

Q18. What enforcement powers are available for non-compliance with allergen requirements?

LAs with responsibility for enforcing Regulation (EC) No 852/2004, have enforcement powers under the hygiene regulations¹¹ in relation to allergen management and cross contamination.

Except where circumstances indicate immediate action is required, officers should take a graduated and educative approach. The action taken should be reasonable, proportionate, risk-based, and consistent with good practice and in accordance with the authority's enforcement policy and the Food Law Code of Practice and associated Practice Guidance. In deciding the type of enforcement action to take, consideration will be given to the nature of the breach and the history of compliance of the Food Business Operator (FBO); or an assessment of the FBO's willingness to undertake the work identified by the officer.

Food Information Regulations Improvement Notice

Regulation 12, Food Information Regulations allows authorised officers to serve a Food Information Regulations Improvement Notice (FIRIN)¹² on a FBO where there is non-compliance with food information requirements (see Part 2, Schedule 5 of FIR). For example, an FIRIN could be served where there is non-compliance with the mandatory requirement to emphasise the presence of the 14 allergens in an ingredients list.

FIRINs would be inappropriate where breaches exist in respect of food hygiene, or where breaches exist in respect of food standards which pose a potential and imminent risk of injury to health and it is considered swift enforcement action is needed.

In appropriate cases, LAs may take a criminal prosecution for an allergen information contravention and also issue a FIRIN to require measures to be taken by the FBO to make the business compliant.

See the Food Law Code of Practice and Practice Guidance for further advice on the use of FIRINs.

Unlike an Improvement Notice, FIRINs do not have a minimum 14-day compliance period so can be used to address non-compliances within a short timescale.

¹¹ Regulation 6(2), Food Safety and Hygiene (England) Regulations 2013
Regulation 6(2), Food Hygiene (Wales) Regulations 2006
Regulation 6(2), Food Hygiene Regulations (Northern Ireland) 2006

¹² England/Wales - Section 10 of the Food Safety Act 1990
Northern Ireland - Article 9(1) & (2) of The Food Safety (Northern Ireland) Order 1991

Hygiene Improvement Notice

The domestic hygiene regulations allow authorised officers to serve a Hygiene Improvement Notice for non-compliances with food hygiene requirements in relation to allergen management and the control of cross-contamination e.g. no food safety management system based on HACCP principles, partially documented/implemented food safety management system or inadequate training of food handlers.

Hygiene Emergency Prohibition Notice/Order

The domestic hygiene regulations allow authorised officers to apply Emergency Hygiene Prohibition Notices and orders where the health risk condition is fulfilled (see Regulation 7 of the respective hygiene regulations for the definition of the health risk condition).

We are aware that some LAs have issued Hygiene Emergency Prohibition Notices to prevent food from being served to consumers who disclose a food allergy. To date none of these notices have been subject to an appeal and considered by a higher court, so no legal precedent has been set on their use in this respect.

As a reminder, following the service of an Emergency Hygiene Prohibition Notice, a court shall only issue a prohibition order if they are satisfied that the health risk condition is fulfilled at the relevant food business. To satisfy themselves that the health risk condition has been fulfilled, LAs will need to demonstrate to the court that at least one of the following involves a risk of injury to health:

- (a) the use for the purposes of the business of any process or treatment;
- (b) the construction of any premises used for the purposes of the business, or the use for those purposes of any equipment; and
- (c) the state or condition of any premises or equipment used for the purposes of the business.

Therefore, if LAs have concerns that food contains undeclared allergens (i.e. those used as an ingredient) or dangerous levels of cross contamination they should satisfy themselves that a process, treatment, piece of equipment or the premises has given rise to the allergen related health risk condition . If not, their application for an order might be unsuccessful.

Where use of a HEPN/HEPO would not be appropriate, LAs should address any non-compliances through the normal graduated approach to enforcement, including the use of Improvement and Hygiene Improvement Notices as appropriate. Where an immediate risk of injury exists which cannot be addressed by a HEPN, officers should consider using their powers to seize and detain unsafe food.

Seizure/detention of food

If an officer is satisfied that food may be unsafe, as defined in Article 14 of Regulation (EC) No 178/2002, they may ask the FBO to dispose of it voluntarily or take action to remove it from sale. If the food is removed from sale using Section 9 of the Food Safety Act 1990, it will need to be brought before a Justice of the Peace to seek an order for it to be condemned and destroyed. This approach can be used to remove any immediate risk posed by unsafe food.

Remedial Action Notices

Officers can consider the use of Remedial Action Notices (RANs). In Wales and Northern Ireland this is an enforcement option in relation to all food businesses, but in England it is only an option in approved establishments. Where RANs are used officers must satisfy themselves that a breach of the relevant Hygiene Regulations exists. The Hygiene Regulations are defined as the domestic hygiene regulations and 'the Community Regulations'. The Community Regulations are in turn defined as Regulations 852 and 853/2004, 2073/2005, 2015/137, 2017/185 and the Official Control Regulations package¹³.

Further guidance on the use of RANs can be found in the Food Law Code of Practice and Practice Guidance.

Additional powers

Where LAs have serious concerns about the adequacy or lack of allergen controls an FBO has in place, they may want to take immediate action to control the risk to consumers.

The use of seizure/detention powers should be used where it is considered appropriate. It is recognised that using these powers is unlikely to offer a sustainable solution where there are problems with continued non-compliance.

Where use of a HEPN is also not appropriate, it is acknowledged that LAs do not currently have a formal emergency sanction they can use to prevent an FBO from supplying food that may contain undeclared allergens. We will be considering options for how this might be addressed.

Q19. What about the use of voluntary procedures?

We are aware that some LAs are using voluntary procedures where they find FBOs do not have satisfactory allergen knowledge or controls in place.

These voluntary procedures may involve the FBO agreeing not to make any unreliable or unjustifiable statements about the suitability or safety of food for a consumer with allergies or inaccurate assurances about the absence of allergens. The wording of a voluntary agreement must be clear and easy to understand so that the FBO knows what they should do, on a voluntary basis, to comply with the agreement.

¹³ Regulation (EU) 2017/625 and regulations made under it

In accordance with the Regulators' Code¹⁴, the wording of voluntary agreements must also make clear the voluntary status of the document and must not imply or suggest that the document has any formal legal standing. The use of words such as 'notice' should be avoided to minimise the potential for misunderstanding.

As with other voluntary procedures, there is no legal sanction where an FBO breaches such an agreement and LAs should use these agreements with caution.

Where LAs use voluntary procedures they must follow this up to ensure the FBO complies with food law requirements.

¹⁴ <https://www.gov.uk/government/publications/regulators-code>

Food Hygiene Rating Scheme

Q20. Should allergen controls be considered as part of the Food Hygiene Rating Scheme?

The Food Hygiene Rating Scheme is specifically designed to provide consumers with information about hygiene standards found at the time of an inspection. The scope of the scheme does not include compliance with the Food Information Regulations 2014 or Regulation (EU) No 1169/2011 on the provision of food information to consumers (FIC).

The Food Law Code of Practice - Practice Guidance is clear on this matter, and states:

“The provisions on allergens in the Food Information Regulations 2014 relate to food labelling and information so should not form part of this assessment since these are food standards requirements.”

The failure to comply with the requirements of the FIC Regulations should not impact on the hygiene intervention rating and subsequently the food hygiene rating.

However, the overall level of compliance and performance of the business against food hygiene requirements should be taken into account.

The England and Northern Ireland Practice Guidance¹⁵ also states that:

“Consideration of the control of cross-contamination, **including any allergen-related contamination identified in preparing food specifically for consumers with a food allergy or intolerance, should be part of the general assessment of hygiene procedures during a food hygiene inspection.** These controls should be part of a business’s food safety management system and should be taken into account when giving the confidence in management score.”

Therefore, officers should assess the Food Business Operators (FBO) levels of (current) compliance with food hygiene and safety procedures under Part 2 of the food hygiene scoring system¹⁶.

The adequacy of the FBOs assessment of risk and subsequent procedures for allergen management should be taken into consideration by officers in the overall assessment of the ‘confidence in management/control procedures’ scores.

¹⁵ To be considered in Wales as part of future Code of Practice and Practice Guidance reviews

¹⁶ See relevant Food Law Code of Practice, Food Establishment Intervention Rating Schemes, Food hygiene scoring system, Part 2: Level of (current) compliance.

Food incidents, product recalls and withdrawals

Q21. When should an allergen issue be reported to the FSA?

LAs are required to report serious localised food hazards and non-localised food hazards to the appropriate FSA incidents team¹⁷ at the earliest opportunity and to confirm the details in writing using the [FSA incident report form](#).

A serious localised food hazard is one in which food is not distributed beyond the boundaries of the competent authority but which involves or may involve: Allergens, *E. coli* O157, other Verocytotoxin-producing *Escherichia coli* (VTEC), *Clostridium botulinum*, *Salmonella typhii* or *Salmonella paratyphi*, or which the competent authority considers significant because of, for example, the vulnerability of the population likely to be affected, the numbers involved or any deaths associated with the incident.¹⁸

Where a death has occurred and is thought to be linked to an allergic reaction to food, LAs should provide the following additional information to the FSA:

- The coroner's office dealing with the death
- Known information about the cause of death
- Details of the enforcement authorities that may be involved in the investigation, e.g. police
- Date of death
- Identify who the LA lead officer dealing with the incident is, including their name, email address and telephone number
- Information on the actions taken by the officer in relation to instruction to the FBO i.e. withdrawal/recall actions, FBO investigations etc.

Where there is a food incident involving allergens and the food has been distributed beyond the boundary of the originating LA, this should be reported to the appropriate FSA incidents team at the earliest opportunity (a non-localised food hazard).

The FSA should also be notified where there is a serious localised hazard, such as the local distribution of incorrectly labelled food (see relevant section of the Food Law Code of Practice).

LAs should always seek advice from their FSA incidents team if it is in doubt as to whether a food incident should be raised.

¹⁷ Contact details

FSA Incidents Team England - foodincidents@food.gov.uk

FSA Consumer Protection Team Northern Ireland – incidents.ni@food.gov.uk

FSA Consumer Protection Team Wales - wales.foodincidents@food.gov.uk

¹⁸ The definition of a serious localised food hazard is being considered as part of the current Food Law Code of Practice review.

Q22. Does cross-contamination with allergens render food unsafe?

If allergens are present in food due to unidentified or accidental cross contamination, they may pose a similar level of risk as allergens that are intentionally present as an ingredient i.e. the level of cross contamination could cause an allergic reaction in food hypersensitive consumers.

For example, if an allergen used in a manufacturing/catering setting has not been properly controlled and poses a risk of cross-contamination that may make the food unsafe. The FSA considers situations such as this to be allergen incidents and LAs should inform their respective FSA incidents team.

Q23. When should a product recall/withdrawal be undertaken?

Food that has been imported, produced, processed, manufactured or distributed and poses a safety risk (e.g. contains undeclared allergens) should be withdrawn from the market.

A recall will be required where a product has reached the final consumer and other measures are not sufficient to achieve a high level of health protection. Where the product may have reached consumers, they should be made aware of the reason for its recall (e.g. press release, point of sale notices).

Where appropriate, officers involved in a recall/withdrawal should take steps, such as reviewing production records, to satisfy themselves that other products placed on the market by the Food Business Operator are not also affected.

Q24. What if a Food Business Operator is unable or unwilling to recall/withdraw unsafe food?

Food Business Operators (FBO) should have systems in place to undertake effective product recalls and withdrawals. The FSA's [Guidance on Food Traceability, Withdrawals and Recalls](#) is intended to assist FBOs and Competent Authorities to comply with food law. It provides guidance on roles, responsibilities and actions to take during food safety withdrawals and recalls.

As already mentioned (see Question 2), effective allergen management systems should be in place to prevent the occurrence of allergen incidents. Where an allergen incident does occur, the FSA expects the food business to undertake a root cause analysis of the incident and to share this with the FSA. The FSA has provided a root cause analysis [e-learning course](#).

LAs are responsible for taking the appropriate enforcement action if FBOs are not complying with food law. Country specific legislation¹⁹ gives LAs the power to enforce Article 19, Regulation (EC) No 178/2002 i.e. where an FBO does not fulfil their legal obligations regarding food safety including withdrawal/recall of a food.

¹⁹ Food Safety and Hygiene Regulations (England) 2013

In this situation, the FSA should be notified if the FBO is unable to identify:

- all of the businesses that may have been supplied
- the scale or breadth of distribution, including not knowing if it has not been distributed beyond their own boundary.

Q25. How should allergen issues be notified to the FSA?

Food incidents that need to be notified to the FSA, should be notified at the earliest opportunity, by the quickest available means and confirmed in writing on the [incident report form](#). LA contact details should be provided for officers that can progress food safety actions and provide additional information out-of-hours. This should include a named contact, email address and telephone number.

Q26. What will the FSA do when notified about a potential allergen issue?

On receipt of the notification, the information will be assessed, the incident classified to determine the level of priority and level of resource expertise and capacity necessary to deal with the incident. Once all information is gathered to enable an assessment of the situation, Risk Management Advice (RMA) will be sought from the FSA policy experts. The policy division will assess whether a risk assessment is necessary to enable RMA advice to be provided.

In the event a product recall is advised as being necessary, an assessment will be made to determine if the FSA should publish an allergy alert or not. This is done on a case by case basis and considers things like:

- the number of products affected,
- the breadth of distribution
- whether it is a localised or widespread distribution
- whether the FBO has the ability to contact all consumers directly to inform them e.g. when internet sales have occurred
- the number of products unaccounted for based on the actions already undertaken by the business.

From the point of notification, the FSA aims to provide RMA in 24 hours. Therefore, it is essential for the business to be able to meet their obligations outlined in Article 19 of Regulation (EC) No 178/2002 i.e. to have systems in place to provide traceability information to the competent authority on demand. It is also essential that LAs are able to respond to the FSA's request for information promptly. The FSA will need various information to enable an assessment of the risk and provision of RMA. This will include the quantities of food affected and the scale of distribution.

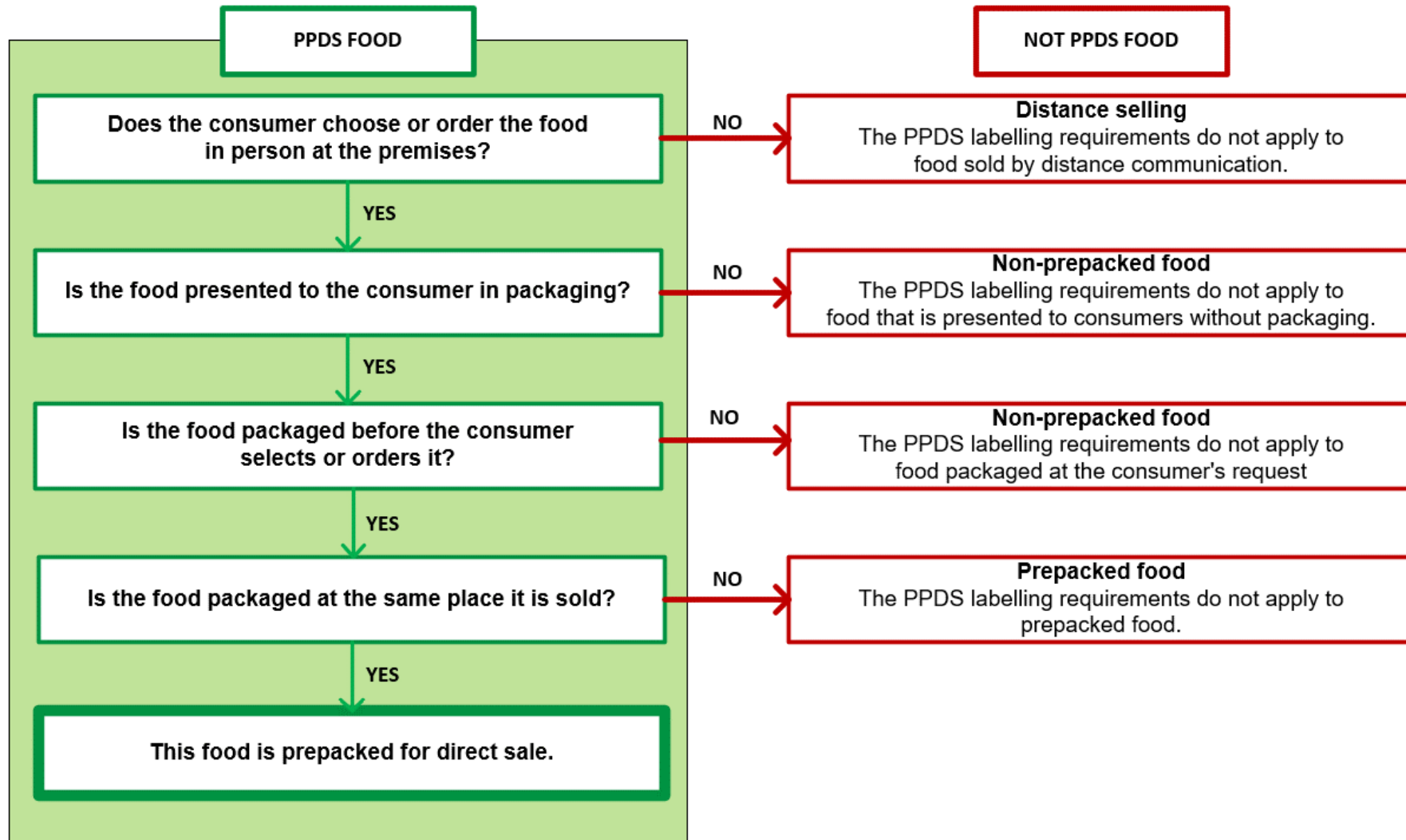
General Food Regulations 2004 (Wales)
General Food Regulations (Northern Ireland) 2004

In the event there has been distribution outside the UK, the FSA must notify the affected countries no later than 48 hours from the point of detection of the incident. Notification is done via the Rapid Alert System for Food and Feed (RASFF). The alert includes the UK's risk advice, the actions taken in the UK and any actions required in their country.

Further guidance and information

- FSA Food Hypersensitivity material on [Smarter Communications](#)
- FSA Food allergen labelling and information requirements [Technical Guidance](#)
- FSA Advice on [allergen labelling for prepacked for direct sale food](#)
- FSA Online [Allergen Training](#)
- FSA Allergen Information and Control of Cross-contamination [aide-memoire](#)
- FSA [Allergy and Intolerance Information](#)
- FSA Advice to LAs on the [allergen labelling requirements of wheat varieties](#)
- Government Chemist [E-Seminar: Introduction to food allergen risk assessment](#)
- Codex Code of Practice on [Food Allergen Management for Food Business Operators](#)
- FSA allergy campaign materials can be found on [Smarter Communications](#)
- Further Information and Guidance can be found on the [Knowledge Hub](#)

Annex A – Prepacked for direct sale flow chart



Prepacked for direct sale flow chart – accessible version

Question 1: Does the consumer choose or order the food in person at the premises?

No: Distance selling: The PPDS labelling requirements do not apply to food sold by distance communication.

Yes: Next question.

Question 2: Is the food presented to the consumer in the packaging?

No: Non-prepacked food: The PPDS labelling requirements do not apply to food that is presented to consumers without packaging.

Yes: Next question.

Question 3: Is the food packaged before the consumer selects or orders it?

No: Non-prepacked food: The PPDS labelling requirements do not apply to food packaged at the consumer's request.

Yes: Next question.

Question 4: Is the food packaged at the same place it is sold?

No: Prepacked food: The PPDS labelling requirements do not apply to prepacked food.

Yes: The food is prepacked for direct sale.

Annex B – Pre-packed for direct sale examples

Annex B will be updated with questions and queries we receive about PPDS food.

Annex B can be accessed [here](#).