

# **Food Law**

## **Practice Guidance (England)**

---

(Issued October 2015)

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## Chapter 1 - Preface

This Practice Guidance is issued by the Food Standards Agency (FSA) to assist Competent Authorities with the discharge of their statutory duty to enforce relevant food law. It is non-statutory, complements the statutory Code of Practice, and provides general advice on approach to enforcement of the law where its intention might be unclear.

Competent Authorities should be aware that law relating to food is not necessarily made under the [Food Safety Act 1990](#). Law that applies to food is also contained in and/or made under, [the Animal Health Act 1981](#), [the European Communities Act 1972](#), [the Consumer Protection Act 1987](#), [the Trade Descriptions Act 1968](#), and directly under EC Regulations.

Competent Authority officers authorised under Section 5(6) of the Food Safety Act 1990 to carry out duties under that Act and Regulations made under it are not automatically authorised to deal with food law under other legislation. Separate authorisation in respect of other legislation is also required e.g. legislation made under the European Communities Act 1972, including [the Food Safety and Hygiene \(England\) Regulations 2013](#)<sup>1</sup> and the [Official Feed and Food Controls \(England\) Regulations 2009](#), under which officers may be generally or specially authorised.

This guidance updates all previous guidance issued with the Code of Practice (the Code).

Material in the previous guidance has been reviewed and updated to take account of the Food Safety and Hygiene (England) Regulations 2013, the Official Feed and Food Controls (England) Regulations 2009 and relevant EU Regulations.

This Practice Guidance also takes account of recommendations made by the EU Food and Veterinary Office (FVO) following their inspections of the UK's food control services.

Competent Authorities should be aware that Article 8(5) of [Regulation 852/2004](#) stipulates that guides to good practice (known in the UK as "Industry Guides to Good Hygiene Practice") drawn up under Directive 93/43/EEC shall continue to apply after the entry into force of this Regulation, provided that they are compatible with its objectives. The general spirit of the Regulation anticipates that guides to good practice be followed.

Attention is drawn to the guidance on the scope and conduct of official checks on establishments subject to approval under [Regulation 853/2004](#).

References to chapters and paragraphs are to the relevant parts of this document unless stated otherwise.

The guidance contained in this document is given in good faith, and accords with the FSA's understanding of relevant legal requirements.

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<sup>1</sup> SI 2013 No 2996

It should not, however, be taken as an authoritative statement or interpretation of the law as only the Courts have that power. Any examples given are illustrative and not comprehensive.

Competent Authorities are strongly advised to consult their own legal departments when considering formal enforcement action.

## **Chapter 2 - Communications**

### **2.1 Inter-authority Communication**

#### **2.1.1 Introduction**

This section applies to areas of England where there are two tiers of local authority and each tier is a Competent Authority.

#### **2.1.2 Single-tier Competent Authorities**

Where the same officer is responsible for enforcement of both food hygiene and food standards matters in an establishment, or feed hygiene and animal welfare on farm, the officer should decide whether it is appropriate to cover both matters at a single visit, even though an intervention may not be due under one of the Competent Authority's planned intervention programmes.

#### **2.1.3 Two-tier Food Competent Authorities**

See 2.1.1 of the Code

#### **2.1.4 Service to Consumers**

The division of enforcement responsibilities between District and County Council Competent Authorities in two areas may not be readily apparent to consumers.

Competent Authorities in these areas should therefore aim to provide their food law enforcement service that is, as far as consumers are concerned, as seamless, effective and accessible as possible.

#### **2.1.5 Regional and Local Liaison Groups**

See 2.1.4.1 of the Code.

The FSA's Regional Team work closely with local and regional partners across the nine English regions to promote the delivery of key FSA priorities.

## 2.2 Managing Incidents and Alerts

### 2.2.1 Food incidents

This section deals with food incidents and hazards that are identified by Competent Authorities. A schematic diagram of the food incident notification process that Competent Authorities should follow is contained in Annex 2 of the Code.

#### 2.2.1.1 Categories of food hazard

Competent Authorities should categorise food hazards according to the following criteria:

**A localised food hazard** - one in which food is not distributed beyond the boundaries of the Competent Authority and is not deemed to be a serious localised food hazard;

**A serious localised food hazard** - one in which food is not distributed beyond the boundaries of the Competent Authority but which involves *E. coli* O157, other VTEC, *C. botulinum*, *Salmonella typhi* 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; and

**A non-localised food hazard** – one in which food is distributed beyond the boundaries of the Competent Authority.

A Competent Authority should seek the advice of the FSA if it is in doubt as to whether a food incident amounts to a food hazard.

#### 2.2.1.2 Localised food hazards - media relations

See 2.2.1.5 of the Code.

#### 2.2.1.3 Deliberate contamination and malicious tampering

Food might be contaminated deliberately. If such an incident occurs, Competent Authorities should follow the arrangements in the Code, except where the deliberate contamination is thought to be due to malicious tampering. For the purposes of the Code, “malicious tampering” means the deliberate contamination of food by terrorist activity, or with a view to blackmail or extortion.

Arrangements for dealing with malicious tampering incidents have been established between the FSA and the police forces throughout the UK and if necessary the National Crime Agency will be involved in the investigation.

Competent Authorities should contact the FSA at the earliest opportunity if malicious tampering is suspected and hand over responsibility for dealing with such incidents to the police if requested by them to do so.

Competent Authorities should co-operate fully with police investigations into incidents of malicious tampering and respect police requests for confidentiality whenever possible, although there may be occasions when the need to alert consumers to the existence of a food hazard outweighs the need to maintain confidentiality.

#### **2.2.1.4 Information Received Locally Which May Indicate a Wider Problem**

Competent Authorities are responsible for investigating and dealing with food that fails to comply with food safety requirements in their areas. Competent Authorities may identify potential problems in a number of ways such as:

- following microbiological examination or chemical analysis of samples submitted to a Food Examiner or Public Analyst
- as a result of complaints from members of the public, either directly or through a third party, for example, the police, citizens' advice bureaux, etc.
- through notifications from a manufacturing company, trade association, wholesaler, retailer, importer or caterer
- Information from enforcement agencies in other countries;
- As a result of a notification from a GP of one or more cases of communicable diseases, including food borne illness, or from the Consultant in Communicable Disease Control (CCDC), or Public Health England – Centre of Infectious Disease, surveillance and Control (PHE – CIDSC).

The illustrations above are not intended to be comprehensive.

Following consultation with the Food Examiner and/or Public Analyst, samples of relevant foods or ingredients and appropriate samples (vomit, stool) from any persons affected should be obtained where possible and sent for examination/analysis. These items can be critically important in identifying the cause of the illness and may even save lives.

#### **2.2.1.5 Guidance on food complaints**

As a general rule anybody who may be prosecuted as a result of a consumer complaint should be notified that the complaint has been made as soon as reasonably practicable.

The Competent Authority should notify anybody who has an interest as soon as preliminary investigations indicate that a complaint may be well founded. Other potential defendants should be notified as they emerge.

Notification may be by any means, but should be confirmed in writing as soon as reasonably practicable. The written notification should include the date and nature of the complaint.

There might be exceptional circumstances in which notification might impede an investigation. In such circumstances notification should take place once it would no longer prejudice further investigations.

#### **2.2.1.6 Involvement of other competent authorities**

If an investigation of a complaint brings to light a problem or potential problem outside the area of the enforcing Competent Authority, the other Competent Authorities affected should be informed as soon as possible and, if appropriate, in accordance with the Home Authority Principle and the Primary Authority Scheme.

### **2.2.1.7 Scientific investigation of food complaint samples**

The authorised officer will need to consider whether food that is the subject of a complaint needs to undergo any scientific investigation. If the authorised officer is in any doubt, advice should be sought from the Public Analyst and/or Food Examiner who will be able to advise on the form of scientific investigation which may be appropriate, particularly where a combination of analysis and examination is required.

If the authorised officer considers that a food complaint sample requires analysis, it should be sent to the Public Analyst. If it requires microbiological examination, it should be sent to a Food Examiner. If any other investigation is necessary, the food should be sent to a suitably qualified expert who is able to give evidence in the event of a prosecution.

The subject of a complaint or other interested party might ask for a food complaint sample to be made available to help with an internal investigation. The Competent Authority should try to comply with any reasonable request provided that it does not compromise the proper storage, analysis, examination or evidential value of the sample.

### **2.2.1.8 Action by the Competent Authority - food incidents**

All relevant information is contained in the Code.

### **2.2.2 Food Alerts**

All relevant information on FSA communications and guidance is contained in the Code.

### **2.2.3 Documentation**

The following documents are provided for use by Competent Authorities:-

| <b>Reference</b>                              | <b>Forms</b>   |
|---|--|
| <b>See the Code of Practice / FSA website</b> | Food Incident Report Form can be found at <a href="https://www.food.gov.uk/enforcement/enforcework/report">https://www.food.gov.uk/enforcement/enforcework/report</a> . A copy of the form is also contained in Annex 3 of the Code of Practice.             |
| <b>FSA Website</b>                            | Notification of Incident to the Food Standards Agency for exchange of information on routine food matters can be found online at <a href="https://www.food.gov.uk/enforcement/enforcework/report">https://www.food.gov.uk/enforcement/enforcework/report</a> |

## **2.3 Communication between Competent Authorities**

### **2.3.1 Information Supplied to the FSA**

All relevant material on information to be supplied to the FSA is contained in section 2.3 of the Code.

#### **2.3.1.1 Approved establishment details**

In addition to the information contained in the Code (section 2.3.1.2) and this Practice Guidance ([section 3.3](#)), the Competent Authority should provide the FSA (at [approvals@foodstandards.gsi.gov.uk](mailto:approvals@foodstandards.gsi.gov.uk)) a copy of the food business operator's (FBO) application form and a copy of the approval issued by the Competent Authority to the FBO. This information will then be used to update the lists of approved food establishments published on the FSA's website.

### **2.3.2 Liaison with other Member States**

#### **2.3.2.1 Introduction**

This section deals with the administration of and the approach to the European liaison arrangements that are to be operated by the FSA from 1 April 2006. Detailed provisions on administrative assistance and co-operation with other Member States are set out in Articles 34 to 38 of [Regulation 882/2004](#).

#### **2.3.2.2 The role of the FSA**

The FSA is responsible for ensuring that official controls in the UK are carried out in accordance with Regulation 882/2004.

The FSA is the designated liaison body for the purposes of Article 35 of Regulation 882/2004 and, as such, is responsible for assisting and co-ordinating communication between competent authorities and the transmission and reception of requests for assistance. However, this does not preclude direct contacts, exchange of information or co-operation between the staff of Competent Authorities in different Member States.

In respect of requests for assistance from other Member States, the FSA is responsible for ensuring that all the necessary information concerning compliance, or otherwise, with UK food law is provided without delay, except for information which cannot be released because it is the subject of legal proceedings.

#### **2.3.2.3 The role of Competent Authorities**

The “European Principle of the Home Authority” adopted by the European Forum of Food Law Enforcement Practitioners (FLEP) forms the basis for the arrangements for information exchanges involving the UK. The role of the Competent Authority in the provision of administrative assistance will depend on whether it is acting as a “Home Authority”, “Enforcing Authority”, or “Originating Authority” which terms are defined as follows:

- “Home Authority” means the food law enforcement authority in the Member State which has geographical responsibility for the area in which the responsible decision-making base of the food enterprise is located (e.g. this may be the factory, the head office or address on the product label). In this context the Home Authority may be a Primary Authority. Where a Primary Authority partnership exists, this is the authority the other Member States should be liaising with. Member states may not be aware of the Primary Authority scheme and the partnerships in place. Contact may therefore be made directly to a Home Authority where Member States have enforcement queries. In these cases the Home Authority should pass any information to the Primary Authority, advising the Member State that this has been done;
- “Enforcing Authority” means the food law enforcement authority in a Member State which is investigating infringements or queries relating to food products received from other Member States;
- “Originating Authority” means the food law enforcement authority in a Member State in whose area a decentralised enterprise produces or packages goods or services. The Originating Authority has special responsibility for ensuring that goods and services produced within its area conform to legal requirements. The functions of the Home Authority and Originating Authority may be combined in some areas.

The Better Regulation Delivery Office (BRDO) administers the Primary Authority scheme, including approving and registering all Primary Authority partnerships. Where a Primary Authority is registered, any other Competent Authority (known as an ‘enforcing authority’ for the purposes of the scheme) proposing to take enforcement action against a food business within the scheme must contact the Primary Authority first. See 6.1.6 of this Practice Guidance for more information.

#### **2.3.2.4 Enquiries from Member States**

Requests for information or administrative assistance received by the FSA will be passed to the appropriate Primary/Home Authority for action. The subsequent response may be made either via the FSA or direct to the Enforcing Authority in the Member State concerned, if appropriate.

#### **2.3.2.5 Documentation**

In accordance with Article 36(2) of Regulation 882/2004, Competent Authorities must ensure that documents are forwarded without undue delay. Article 36(2) permits documents to be transmitted in their original form, or for copies to be provided.

#### **2.3.2.6 Disclosure of information**



Article 7 of Regulation 882/2004 sets out the general requirements in respect of transparency and confidentiality. Article 34 stipulates that Articles 35 – 40 of that Regulation, which deal with administrative assistance and co-operation between Member States “shall not prejudice national rules applicable to the release of documents which are the object of, or are related to, court proceedings, or rules aimed at the protection of natural or legal persons’ commercial interests”.

Competent Authorities should therefore ensure that any release of information is compatible with national legislation including that relating to Data Protection and Freedom of Information (see also 3.4 below).

### **2.3.2.7 Use of Overseas Evidence in Criminal Proceedings**

Overseas evidence can only be used in criminal proceedings with the prior consent of the sending Member State. Where a Member State is party to an international agreement or convention on mutual assistance, the procedures laid down in such instruments must be followed.

EU Member States are parties to The European Convention on Mutual Assistance in Criminal Matters. This Convention requires that requests for information to be used as evidence in criminal proceedings be transmitted through the relevant authority.

The relevant authority in the UK is the “United Kingdom Central Authority”, which is part of the International Criminality Unit of the Home Office. The Central Authority liaises with the judicial authorities in Scotland.

All requests via the Central Authority must be notified to the FSA so that it can fulfil its role as the UK single liaison body.

The UK Central Authority address is:

UK Central Authority  
International Criminality Unit  
Home Office  
3<sup>rd</sup> Floor, Seacole Building,  
2 Marsham Street,  
London  
SW1P 4DF.  
Tel: 0207 035 4040  
Fax: 0 207 035 6985

Competent Authorities should ensure that any overseas evidence known, at the time of the request, to be required for use in criminal proceedings is obtained from the Member State by means of a letter of request under Section 3 of the [Criminal Justice \(International Co-operation\) Act 1990](#).

Competent Authorities are not “designated prosecuting authorities” for the purposes of the above-mentioned Act and letters of request must therefore be sought from a Justice of the Peace or a Judge.

Where Competent Authorities wish to use information that has already been supplied by another Member State, a letter of request should similarly be sought from a Justice of the Peace or a Judge.

The request must formally seek the consent of the Home Authority (or equivalent) in the Member State concerned to use the information in the proceedings.

#### **2.3.2.8 Non-compliance with legislation**

When, during the exchange of information, it is apparent that a trader has not complied with EU rules or national legislation, the Member State where the alleged non-compliance has taken place is required to report to the other Member State on action taken and steps to prevent a recurrence. Either Member State can then decide whether the report should also be copied to the European Commission. Competent Authorities should copy all reports to the FSA. The FSA will decide whether the Commission should be notified.

## Chapter 3 - Administration

### 3.1 Requirements to Deliver Official Controls

#### 3.1.1 Conflicts of Interest

All relevant information on conflicts of interest is contained in the Code.

#### 3.1.2 Powers of Entry

##### 3.1.2.1 Police and Criminal Evidence Act 1984 (PACE): Code of Practice B

PACE Codes of Practice including PACE Code of Practice B can be found on the Home Office Police website at the following address:

<http://www.homeoffice.gov.uk/police/powers/pace-codes/>

#### 3.1.3 Crown and police premises

This section deals with the approach to enforcement in Crown premises and in premises that are occupied by the police; it does not apply to premises that are occupied by the NHS or NHS Trusts since these are not Crown premises. The Code of Practice contains statutory guidance, which Competent Authorities must follow, regarding the enforcement of food law in such premises.

##### 3.1.3.1 Scope of Application - Food Safety Act 1990

The scope of [the Food Safety Act 1990](#) extends to police premises, most Crown premises (subject to the exemptions detailed below), and to people in the public service of the Crown. Authorised officers therefore have the power to enter police premises and most Crown premises to investigate complaints and to carry out interventions in the same way as they do in any other food business.

The provisions of the Food Safety Act 1990 do not, however, apply to Her Majesty the Queen or His Royal Highness the Prince of Wales personally, nor to premises occupied by them in their private capacities such as their private residences at Sandringham or Highgrove.

##### 3.1.3.2 Enforcement - Food Safety Act 1990 – Liability

Section 54(2) of the Food Safety Act 1990 says that the Crown is not criminally liable if it contravenes the Act or Regulations or Orders made under it. This means that the Crown cannot be prosecuted if it contravenes the Act etc.

A Competent Authority may, however, apply, in the Queen's Bench Division of the High Court, for a declaration that any act or omission of the Crown, which amounts to a contravention of the Food Safety Act 1990 or regulations made under the Act, is unlawful.

The identity of the proprietor of the food business concerned should be carefully considered if the question of action under food law arises.

Contract caterers operating on Crown premises can be prosecuted as they are not subject to this exemption. Careful consideration also needs to be given to the question as to whose failure gave rise to the contravention.

Although contract caterers operating on Crown premises can be prosecuted, structural failures might be the responsibility of the Crown itself.

Any application under Section 54(2) should be addressed to the Secretary of State or Head of Department and sent to the Solicitor for the relevant Government Department.

The summons should be sent to the principal officer of a non-Departmental Government body.

### **3.1.3.3 Position of individual civil or Government servants**

Although the Crown is immune from prosecution under the Food Safety Act 1990, individuals in the public service of the Crown can still be prosecuted in the same way as any other person. Failure to comply with the provisions of food law might therefore expose an individual civil or Government servant to the risk of prosecution.

Competent Authorities should not consider prosecuting an individual civil or Government servant as a substitute for action against the Crown. Such action should only be considered if the circumstances would have resulted in the prosecution of an individual in the case of any other business.

### **3.1.3.4 Statutory notices**

The service of an emergency prohibition notice does not itself make the recipient criminally liable. Such notices can therefore be served on the Crown where it is the food business operator concerned.

Emergency prohibition notices should be served on the appropriate Secretary of State or Head of Department and copied to the Solicitor as described above.

In order that such notices can be acted upon without undue delay, they should also be copied to the person in charge of the premises concerned, e.g. the Governor of a prison, or the Commanding Officer of a military establishment.

Competent Authorities should apply in the normal way to a Magistrates' Court for an emergency prohibition order on the whole or part of Crown premises, or to prevent the operation of a process or treatment, or use of a piece of equipment in a business run by the Crown.

It should be remembered, however, that although a Magistrates' Court can impose an emergency prohibition order, it cannot impose a prohibition order, since a prohibition order can only be made when there has been a conviction under relevant food law.

The food business operator in Crown premises can appeal in the normal way to a Magistrates' Court against an improvement notice and can also appear to argue against the imposition of an emergency prohibition order.

The Crown can also appeal against a refusal to issue a certificate lifting an emergency prohibition order.

A Competent Authority can apply for a declaration in the High Court if a business run by the Crown fails to comply with an emergency prohibition order.

### **3.1.3.5 Scope of Application – The Food Safety and Hygiene (England) Regulations 2013**

The scope of [the Food Safety and Hygiene \(England\) Regulations 2013](#) extends to police premises, Crown premises and to people in the public service of the Crown. Authorised officers therefore have power to enter police premises and Crown premises to investigate complaints and to carry out Interventions in the same way as they do in any other food business.

As there are no specific exemptions for certain members of the Royal Family or certain Royal residences as afforded by the Food Safety Act 1990 Competent Authorities should use discretion when exercising their powers in respect of Crown premises. In practice, Competent Authorities should adopt the same approach to the enforcement of the Food Safety and Hygiene (England) Regulations 2013 in respect of Crown premises as they do in respect of [the Food Safety Act 1990](#).

### **3.1.3.6 Enforcement – The Food Safety and Hygiene (England) Regulations 2013**

Unlike the Food Safety Act 1990, the Food Safety and Hygiene (England) Regulations 2013 do not exempt the Crown if it contravenes the Regulations. This means that the Crown can be prosecuted if it contravenes the Regulations. However, as mentioned above, Competent Authorities should use discretion when exercising their powers in respect of Crown premises and, in practice, should adopt the same approach to the enforcement of the Food Safety and Hygiene (England) Regulations 2013 in respect of Crown premises as they do in respect of the Food Safety Act 1990.

### **3.1.3.7 Conduct and Frequency of Interventions**

Food businesses in Crown and police premises, other than temporary or field catering facilities at military training camps, should be included in the Competent Authority's planned intervention programme in accordance with the Code of Practice.

Permanent kitchens serving military training camps should be subjected to interventions at times they are in use, within the bounds of security restrictions that will be dependent on the organisation using the facility at the time.

Mobile field kitchens should not be subject to interventions by the Competent Authority.

### **3.1.3.8 Photographs**

Before taking any photographs, making sketches or taking measurements on Group 3 premises (see section 3.1.2.8 of the Code), the authorised officer should discuss such matters with the escorting officer and take account of any requirements. Unless absolutely necessary to illustrate a possible contravention of the legislation, photographs on Group 3 premises should not include individuals. It should not be possible to identify any individual from any photograph taken within a prison or remand establishment.

### **3.1.3.9 Liaison with the Home Authority/ the Primary Authority/ the FSA**

Competent Authorities should report any difficulties encountered in the enforcement of food law in premises to which this Chapter applies to the appropriate Home Authority or Primary Authority, or, if there is no Home Authority or Primary Authority to the FSA.

## 3.2 Registration of Food Establishments

### 3.2.1 What is a food establishment?

A food establishment is defined in EU law as a “unit of a food business”. Such a unit undertaking any of the activities of a food business must be registered as a food establishment.

Registration is not required for establishments undertaking the following food activities:

- Occasional handling of food: The European Commission ‘guidance document on the implementation of certain provisions of Regulation (EC) No. 852/2004 on the hygiene of foodstuffs’<sup>2</sup> states that “somebody who handles, prepares, stores or serves food occasionally and on a small scale cannot be considered as an “undertaking” (i.e. those operations deemed not to have a “certain degree of organisation” and “a continuity of activities”) and is therefore not subject to the EU hygiene legislation<sup>3</sup>.” The FSA’s guidance document on ‘Community and charity food provision – guidance on the application of EU food hygiene law’<sup>4</sup>, has been published to provide clarity both for competent authorities and those running community and charity operations on which charity and community food provision might need registration;
- Primary production for private domestic use or the domestic preparation, handling or storage of food for private domestic consumption;
- Small quantities<sup>5</sup> of primary products supplied directly by the producer to the final consumer or to local retail establishments directly supplying the final consumer;
- Food establishments handling products of animal origin that are subject to approval under Regulation (EC) No 853/2004<sup>6</sup>; and
- Collection centres and tanneries which fall within the definition of food business only because they handle raw material for the production of gelatine or collagen.

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<sup>2</sup> [http://ec.europa.eu/food/food/biosafety/hygienelegislation/guidance\\_doc\\_852-2004\\_en.pdf](http://ec.europa.eu/food/food/biosafety/hygienelegislation/guidance_doc_852-2004_en.pdf)

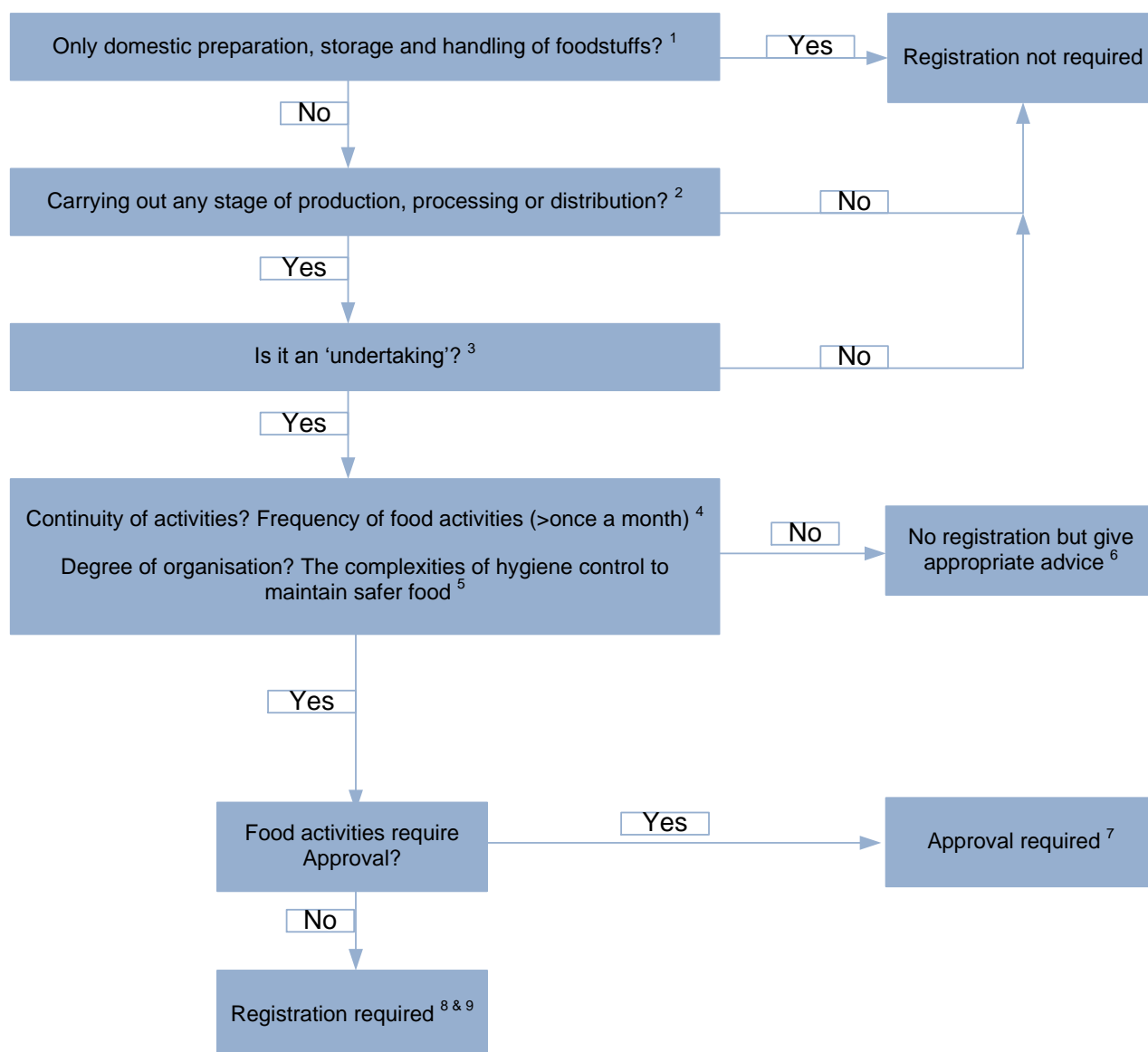
<sup>3</sup> However, such establishments remain subject to the provisions of the Food Safety Act 1990 and the general requirements of Regulation (EC) No.178/2002

<sup>4</sup> <http://www.food.gov.uk/sites/default/files/multimedia/pdfs/hall-provision.pdf>

<sup>5</sup> For further information see guidance on approval of food establishment at footnote 5.

<sup>6</sup> Link to guidance on the approval of food establishments: <http://www.food.gov.uk/sites/default/files/multimedia/pdfs/enforcement/approvalguidance.pdf>

Fig 1 provides a consideration tree to help determine which food activities require registration with the Competent Authority.



Explanatory notes:

1. Community Regulations do not apply to primary production for private domestic use or to the domestic preparation, handling or storage of food for private domestic consumption (Regulation 178/2002, Chapter 1, Article 1.3 and Regulation 852/2004, Article 1.2(b)).

2. This means any stage, including import, from and including the primary production of a food, up to and including its storage, transport, sale or supply to the final consumer (Regulation 178/2002, Chapter 1, Article 3.16).

3. 'Undertaking' is not defined in food law but the EC commission document suggests that an undertaking is not somebody who handles, prepares, stores or serves food occasionally and on a small scale.



4. Continuity of activities (Recital 9, Regulation (EC) No. 852/2004) – the FSA’s view is that generally operations providing food less frequently than on an average monthly basis should be considered as not having a continuity of activity and should not require registration (see below).

5. Degree of organisation (Recital 9, Regulation (EC) No. 852/2004) – the FSA’s view is that the following issues should be considered when deciding how much any given operation can be said to be organised: foodstuffs and risk, and nature of event. This is set out in more detail in the FSA’s Guidance on the application of EU food hygiene law to community and charity food provision.

6. Competent Authorities should advise that if food operations change, they should contact the relevant Competent Authority to check whether registration is subsequently required.

7. Approval guidance available at:

<https://www.food.gov.uk/sites/default/files/multimedia/pdfs/enforcement/approvalsguidance.pdf>

8. Template registration form available in the Code and online registration at: <https://www.gov.uk/food-business-registration>.

9. If the business is a childminder registered with OFSTED after 2014, then a separate food registration is not required. Details on the Memorandum of Understanding (MoU) between the FSA and OFSTED can be found here:

[https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/382381/Memorandum\\_of\\_understanding\\_between\\_Ofsted\\_and\\_FSA.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/382381/Memorandum_of_understanding_between_Ofsted_and_FSA.pdf).

### 3.2.2 Who is a food business operator?

Regulation 178/2002 defines a food business operator (FBO) as the natural or legal persons responsible for ensuring the requirements of food law are met within the food business under their control.

A **natural person** is a human being, as opposed to an artificial, legal or juristic person, i.e. an organisation that the law treats for some purposes as if it were a person distinct from its members or owner.

A **legal person** has a legal name and has rights, protections, privileges, responsibilities, and liabilities under law, just as natural persons (humans) do. Legal personality allows one or more natural persons to act as a single entity (such as a limited company - considered under law separately from its individual members or shareholders) for legal purposes.

When considering who to register as the FBO under Article 6(2) of Regulation 852/2004, Competent Authorities should request that the FBO identifies themselves, including the name of the operator in the case of legal persons, address and type of business entity on the registration form.

The types of business entity are defined according to the legal system for an individual country but may include incorporated bodies, partnerships, sole traders and other specialised types of organisation.

### **3.2.3 Registration procedure**

#### **3.2.3.1 Requirement to register a food establishment under Article 6(2) of Regulation (EC) No. 852/2004**

FBOs should be encouraged to register their establishment 28 days before they begin operating. Competent Authorities are encouraged to make information available to businesses on the requirements relating to registration.

There may be situations when an FBO registers as a food business in advance of 28 days before they intend to start operations. The FSA's view is that in such circumstances, Competent Authorities may find it useful to avoid inputting registrations onto their databases until they have confirmation that those businesses have started or have an imminent date to start operations. This could mean keeping a temporary record of such businesses with some periodic checks to verify if they have commenced food operations.

If registration relates to a business that includes more than one mobile unit, the FBO should provide details of all mobile units that they own (i.e. registration/identification numbers, identifying features, types of facilities, food types etc.). Annex 5 of the Code contains a model registration form; this can be amended to make provision for this additional information.

#### **3.2.3.2 Channels of registration**

Where information about the address of the establishment and the activity carried out is already available from other sources, that information may be used for registration purposes, as illustrated below:

- Establishments at the level of primary production that have been registered with the Rural Payments Agency (RPA) prior to 1 December 2006 are considered registered for the purposes of Article 6(2) of Regulation 852/2004.
- A joint agreement is in place between the FSA and Ofsted which removes the need for childminders in England to register separately as a FBO. Childminder registration with Ofsted is accepted for the purposes of food business registration under Regulation (EC) No. 852/2004. Childminders that undertake food activities remain legally defined as FBOs and subject to food law.

Ofsted routinely provide details of registered childminders to Local Education Authorities (LEAs) within higher tier authorities. It is recommended that a mechanism be in place for LEAs to pass this data to the relevant Competent Authority and where possible provide intelligence on which childminders are regularly supplying food.

Childminders are made aware of their duties in food law on registering with Ofsted and provided with targeted food safety advice. They are urged to

contact the relevant Competent Authority directly where their food activities may present a higher risk.

### 3.2.3.3 Change of ownership following registration

Competent Authorities may come across changes of ownership during interventions at food establishments. The FBO by virtue of Article 6(2) of Regulation 852/2004 is required to notify the Competent Authority of any significant changes, which includes change of ownership. Not complying with this requirement may be an offence under the Food Hygiene Regulations 2013.

**Table 1** outlines circumstances in which changes of ownership have been identified and therefore a new registration form should be completed by the FBO.

**Table 1 – Change of FBO scenarios – when a new registration is required.**

| Existing FBO (as stated on food establishment registration document)   | Change of FBO (assuming no other changes to the business)  | Registration status | Comments   | New registration required? |
|--|--|---------------------|--|----------------------------|
| Sole trader, partnership or incorporated company (e.g. Ltd, PLC, etc.) | Different sole trader, partnership or incorporated company takes over ownership.   | Expires             | Discontinuation of operator/s                          | Yes                        |
| Sole trader or Partnership   | Company incorporated (and registered), sole trader or partner/s become Director/s.   | Expires             | Creation of a company changes the legal matrix of FBOs | Yes                        |
| Sole trader  | Creation of a partnership where the sole traders is one of the partners.   | Retained*           | Continuation of operator                               | No                         |
| Partnership  | Dissolved and one of the partners takes over sole ownership and becomes a sole trader.   | Retained*           | Continuation of operator                               | No                         |
| Partnership  | New partner joins or a partner leaves (also refer to dissolved partnerships) as long as there is a continuation of at least one partner. | Retained*           | Continuation of operator                               | No                         |
| Incorporated company   | Company goes into administration and is being run as a going concern by the administrators.  | Retained*           | Discontinuation of operator/s                          | No                         |
| Incorporated company in administration                                 | Company taken over from administrators by a different sole trader, partnership or incorporated company.                                  | Expires             | Discontinuation of operator/s, registration expires    | Yes                        |
| Sole trader, Partnership or Incorporated                               | Bankruptcy, insolvency or in liquidation (wound up/dissolved).   | Expires             |  | Not applicable             |

| Existing FBO (as stated on food establishment registration document) | Change of FBO (assuming no other changes to the business) | Registration status | Comments | New registration required? |
|--|---|---------------------|----------|----------------------------|
| Company  |   |                     |          |                            |

\*Although the registration status is 'retained', the FBO should notify the change to the Competent Authority, and a record of this noted.

Other business types such as cooperatives, registered charities and other specialised types of organisation (e.g. establishments under the control of a board/committee) should be treated on a case-by-case basis to identify the natural person or legal person required to be compliant with food law within the food business under their control.

### **3.2.4 Multisite and satellite operations**

#### **3.2.4.1 Multiple premises constituting a single food establishment**

There are circumstances where a single registration, under the same FBO, is permissible of a food business operating at multiple sites. This is dependent on the associated sites comprising a single establishment meeting all the criteria laid out in 3.2.5.1 of the Code. However, it should be made clear to the FBO that non-compliance in one site, may result in the downgrading of the overall rating (both intervention and FHRS ratings) of the entire operation.

This flexible approach may be applied in circumstances whereby the single registration of multiple sites under the same food business operator as one retail operation is permissible. This is, however, subject to one or more of those sites having a genuine retail element. Due to the practicalities of an officer maintaining the necessary ongoing oversight and assessment of such set-ups operating as a single establishment, it is recommended that this flexibility is only applied to establishments within the same food authority boundary, unless on specific occasions as described in paragraph 3.2.4.2.

This flexibility is mainly to remove the need for the approval of smaller food businesses where the processing of products of animal origin (POAO) and the retail element (i.e. the place or point of supply to the consumer) are not at the same 'site' but there is a strong association between sites and a single 'controlling mind' overseeing the activities. However it can also apply to operations where none of the sites would require approval but could reduce the need for multiple registrations. The controlling mind will have sole and effective control of the HACCP based procedures from the production site through their own retail outlet/s to the final consumer.

The FSA accepts that with some businesses the "controlling mind" may be more than one person. However, the FSA does not consider that this could extend to operations where, although being one enterprise, different individuals manage different sites as separate legal entities in their own right.

There must also be a single system of integrated HACCP based controls. This may include risk based food safety management controls that are proportionate to the

activities being undertaken at the different sites, but they must form part of an overall system that is under the operational direction of the single “controlling mind”.

### **3.2.4.2 Enforcement and oversight of multi-sites operating as a single establishment**

There will be occasions where businesses meeting the criteria set out above operate across Competent Authority boundaries. Due to the practicalities of an officer maintaining the necessary ongoing oversight and assessment of such set-ups operating as a single establishment, it is recommended that the relevant competent authorities consider together whether it is practical to put in place a procedure that allows this flexibility in those circumstances. This is particularly pertinent in situations where it could result in a reduction in the regulatory burden to the business such as where approval would otherwise apply.

This flexibility is discretionary and will require authorised officers to assess on a case-by-case basis whether a business meets the single food establishment criteria. A record of the assessment and the supporting reasons should be recorded on the relevant establishment files. The FBO has the option not to adopt this arrangement and request for separate registrations of the multi-sites should they wish to do so.

The following are examples of where the concept of a ‘single food establishment’ flexibility **may** or **may not** be appropriate. These are in no way prescriptive or exhaustive and are for illustrative purposes only.

Examples of where a single food establishment registration may be appropriate:

#### **Example 1 - Catering for satellite sites**

*A catering establishment or ‘hub kitchen’ which doesn’t have a servery on site, but prepares food to be transported to one or several local retail outlets, or ‘satellite kitchens’ managed by the same FBO, to be served directly to the final consumer with no onward distribution . The food may be transported hot or cold but will not undergo any further processing at the retail end other than basic hot holding, reheating and perhaps some simple, low risk preparation.*

#### **Example 2 - Supply to retail outlet**

*A small manufacturing unit which produces speciality cheese to sell in its nearby high street deli shop. The same FBO or ‘controlling mind’ owns and manages the two premises, whose main focus is to sell direct to the final consumer with no further distribution to other retail businesses. The FBO has developed a HACCP plan and a food safety management system for the speciality cheese, which flows from production through to service at the deli (retail outlet).*

*Note: This type of business (manufacturing certain POAO) would be subject to approval, if the manufacturing unit’s products were mainly supplied to other businesses operated by other FBOs. (See 3.3 of the Code and this Practice Guidance)*

#### **Example 3 - Multi-units on the same site**

- a) *Motorway services: Several non-branded food retail units at a motorway service station, including a coffee shop, snack bar, and a restaurant are managed centrally by one FBO and all food supplied to the units is prepared in a central kitchen on site or bought in through the company’s approved supplier list. One food safety management system covers the operation*

as a whole.

- b) Motorway services: A branded coffee chain which has a main coffee shop plus two fixed smaller satellite units inside the service station and a mobile vehicle which operates within the curtilage of the site, all of which come under the same limited company and are overseen by the same on site manager or 'controlling mind'.*
- c) Superstore: A large supermarket which supplies its own on site petrol station with pre-packed food. Transfer, storage and display of food at the petrol station are accounted for in the HACCP plan for the store and is managed by the same 'controlling mind'.*

Examples of when this flexibility would not apply and therefore separate registration and/or approval of each establishment is appropriate:

**Example 1 - Catering for satellite sites**

*A catering company manufactures a variety of foods and supplies two restaurants. Although, the catering company also owns both of the restaurants, further high risk food production and processing takes place at the two restaurants and so each establishment has a separate food safety management system which is managed locally to control the different risks at the respective premises. In this case, the complexity of food controls at the different sites and the lack of effective control of the whole food safety management system by a 'single mind' means that the single establishment criteria are not fulfilled and the single establishment flexibility should not be applied.*

**Example 2 - Supply to retail outlet**

*A bakery supplies freshly baked food product such as meat pies to various retail outlets which are part of the same company. The branches are located in various local authority districts and each branch has a local manager to implement the company policies and procedures, including the food safety management procedures. The bakery and the outlets are not close enough in proximity for one FBO to manage them all effectively and there is more than one 'controlling mind' responsible for implementing the food safety procedures at each site. Because the main bakery site processes raw POAO and supplies the resulting products the retail outlets, this site could be subject to approval under Regulation (EC) No 853/2004.*

### **3.2.5 Moveable establishments**

#### **3.2.5.1 Trains and coaches**

Individual trains and coaches are not subject to separate registration but the FBO should register any other establishment or static unit undertaking activities of the food business. Registering Competent Authorities for the main establishment should inspect a representative number of train cars providing foodstuffs (such as buffets and dining cars) where the food service units across the stock are of similar design and operate to common food safety management procedures. Where main establishments and train victualing operations are co-located the registering Competent Authority itself can undertake these inspections.

#### **3.2.5.2 Mobile food establishments**

A mobile food establishment is required to register with the Competent Authority (i.e. the registering Competent Authority) in which it is ordinarily kept overnight (e.g. this could be at the private residence house of the owner of a van). A non-permanent market stall is required to register with the Competent Authority in which its food stock is ordinarily kept. Following registration, the FBO should not be asked to register with any other Competent Authority in whose area it trades.

This does not limit other inspecting Competent Authorities carrying out official controls of the activities undertaken by a mobile food business or stall that operates in their area. However, inspecting Competent Authorities should contact the registering Competent Authority before any intervention to determine whether an inspection is due and if so, the type of intervention that may be appropriate in the circumstances. The registering Competent Authority has the discretion to decide whether it needs to undertake any specific intervention, e.g. in circumstances, where full inspection has been carried out by the inspecting Competent Authority in whose area the mobile operates. To ensure consistency and to avoid 'over inspection', the inspecting Competent Authority must provide the registering Competent Authority with information relating to interventions undertaken of mobiles operating their area.

Details of interventions and enforcement action should be passed to the registering Competent Authority as soon as possible, following an intervention. The registering Competent Authority should take account of information supplied in determining the Intervention Rating, and when this should be revised in accordance with Chapter 5.6 of the Code and recorded on the Competent Authority's database of food establishments.

Competent Authorities may use the following arrangements developed by Tees Valley Food Liaison Group as best practice when awarding ratings (both intervention and FHRS) for mobile food businesses in their area:

**Tees Valley Arrangement for Rating of Mobile Food Businesses**

*Under Article 6 (2) of Regulation (EC) 852/2004, mobile food establishments are required to register with the local authority in which they are ordinarily kept and for non-permanent market stalls, the local authority in which their stocks of food are ordinarily kept. Once the establishment is registered it should not be asked to register with any other local authority in whose areas it trades.*

*Mobile establishments and market stalls may be subject to inspection or other intervention by the local authority in whose area the establishment is found to be trading. In accordance with the Food Law Code of Practice, details of any intervention or enforcement activity carried out by a local authority should be passed to the local authority that has registered the business*

*The local authority that has registered the business shall determine the intervention rating, in accordance with Chapter 5.6 of the Food Law Code of Practice, and record this on the authority's food premises database. When making this determination the authority will consider any information supplied to it by other local authorities in respect to the business. In some cases the business may never trade in its area and it may be more appropriate for another LA to undertake responsibility for rating the business under FHRS by agreement.*

*The Tees Valley Local Food Liaison Group has considered the FHRS 'Brand Standard' as it relates to Mobile Food Traders and has agreed the following approach for traders operating within Tees Valley using three categories of trader:*

- 1. Those registered and operating within the same local authority; or*

2. Those registered in one local authority but trading primarily in another local authority area; or
3. Those registered in one local authority but trading at a number of different sites across a number of local authorities.

Arrangements for each of the above categories will be:

1. For the first category, the registering authority should undertake interventions, and rate the unit for FHRS.

2. For the second category the inspecting authority will liaise with the registration authority and will propose the following arrangement:

a) The inspecting authority will be responsible for rating for FHRS the mobile and any appeals, right to reply and rescoring requests.

b) The Registering Authority may continue to inspect but will not score the unit for FHRS to avoid duplication (Reason: 1: the public are more likely to search the FHRS website for food businesses at their trading address and 2: the registering authority will not have seen the food business operating.)

c) Inspecting Authority will forward a copy of the 'report of inspection' to the registering authority.

c). Registering authority will forward a copy of their 'report of inspection' if and when they inspect it so that account can be taken of this when calculating FHRS rating.

3. For the third category the Registering Authority will, if possible, inspect the unit and score for FHRS. If this is not possible, the registering authority will record the findings of the inspecting authority and issue the food hygiene rating. It remains the responsibility of an Inspecting Authority to liaise with the Registering Authority, forward a copy of any 'report of inspection' and avoid duplication of interventions where possible.

### **3.2.5.3 Mobile food business with multiple units**

In certain circumstances, registering Competent Authorities will need to consider whether a mobile retail unit is a separate establishment or can be considered for the discretionary single registration provision as described at section 3.2.4.1.

In cases where an FBO owns several mobile units selling a variety of different foodstuffs each of which is separately managed and each has distinctly separate HACCP-based procedures, each mobile unit should be considered for separate registration – they would not fall under the discretionary single registration.

### **3.2.5.4 Sources of information on mobile food establishments**

The Nationwide Caterers Association (NCASS) have developed NCASS Connect, an online database that allows FBOs to store documents such as registration documents, staff training records and HACCP-based procedures for the establishment. The database includes records for a range of catering establishments and mobile food businesses.

NCASS Connect: <http://www.ncass.org.uk/eho-area/home>



Free access to this service is available to Competent Authorities to view uploaded documents by NCASS members as well as any non-NCASS members using the service. The database may also help in obtaining information on a mobile trader scheduled to attend a local event and identify any that have not registered. NCASS currently have a Primary Authority Partnership with Cherwell District Council. See: <https://primaryauthorityregister.info/par/index.php/home> for further details, including details of any inspections plans.

### **3.2.5.5 Food hygiene rating scheme mobile trader's resources**

Template letters and other materials are available to help local authorities apply the guidance on mobile traders that is set out in the FHRs 'Brand Standard'. The materials include a template letter and form for an inspecting authority to forward intervention information, and template letters and an agreement to help transfer FHRs responsibility from one local authority to another. <http://www.food.gov.uk/enforcement/enforcework/hygienescoresresources/fhrs-mobile-traders>

### **3.2.6 Other types of establishments**

#### **3.2.6.1 Food businesses operating out of domestic premises such as home caterers and B&Bs**

The domestic preparation, handling or storage of food which is to be placed on the market (whether free of charge or not) and which meets the definition of a 'food business', is subject to registration requirements and should be registered with the Competent Authority where the undertaking takes place.

#### **3.2.6.2 Domiciliary care / assisted living care**

Food business registration will apply where it is considered that the care service operations fall within the legal definition of a 'food business'. If registration is required then the establishment itself should be registered even if some operations carried out by the establishment do not need to form part of the registration. For more information refer to the FSA's guidance on "The application of food hygiene legislation to domiciliary care, assisted living and care homes".<sup>7</sup>

#### **3.2.6.3 Food banks**

Food banks run by community volunteers, if they meet the definition of a food business, will require registration and will need to comply with food law proportionately. Some food banks will be exempt from registration if they do not meet the food business definition (i.e. Recital 9 of Regulation (EC) No. 852/2004). The

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<sup>7</sup> <http://www.food.gov.uk/sites/default/files/multimedia/pdfs/enforcement/guidance-domiciliary-care.pdf>

FSA's guidance on 'Community and charity food provision – guidance on the application of EU food hygiene law'<sup>8</sup>, should help you determine this.

#### **3.2.6.4 Food brokers**

Certain businesses are specialised in trading food (food brokers). While they may arrange for the movement of food between suppliers or to retailers, they do not necessarily handle the food or even store it on their establishment (which may effectively be an office). Provided they meet the definition of "food business" and "food business operator", then the registration requirement applies, and must be registered with the Competent Authority in which they undertake the work.

In respect of product of animal origin, Article 18 of Regulation (EC) No 178/2002, as amplified by Regulation (EC) No. 931/2011<sup>9</sup> on traceability requirements for food of animal origin, places a duty on the FBO, including food brokers, to be able to identify and provide specific traceability information to the competent authority.

#### **3.2.6.5 Internet sales**

Certain businesses offer their goods for sale via the internet. Although such trade is not specifically referred to in Regulation (EC) No. 852/2004, such businesses fall within the definition of a food business and the relevant requirements of food law are applicable to them. Such businesses must register with the most appropriate Competent Authority. This may be where they live, where their office is located or where the food stocks are stored.

#### **3.2.6.6 Temporary establishments**

Temporary food businesses which 'pop up' in different locations should be treated in the same way as mobile food establishments for the purposes of registration.

#### **3.2.6.7 Vending machines**

Vending machines are subject to the relevant provisions of Regulation (EC) No. 852/2004. The FSA does not see practical value in the registration of individual vending machines or the establishment on which they are sited if the only food related activity on those establishments relates solely to vending machines. However, distribution centres where food for stocking vending machines is stored and/or from which food is transported to vending machines for stocking should be registered with the relevant Competent Authority. The delivery vehicles used for the transport of food for stocking vending machines should be covered in the interventions at such establishments.

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<sup>8</sup> <http://www.food.gov.uk/sites/default/files/multimedia/pdfs/hall-provision.pdf>

<sup>9</sup> <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:242:0002:0003:EN:PDF>

### **3.3 Food business establishments subject to Approval under Regulation 853/2004**

Regulation (EC) No 853/2004 sets out specific requirements for FBOs handling certain products of animal origin (POAO) including the need for approval of establishments by the Competent Authority

Guidance in relation to the approval of food business establishments that handle POAO can be found at the following link:

<https://www.food.gov.uk/enforcement/sectorrules/approvalsguidance>

#### **3.3.1 Approval of product-specific establishments subject to approval under Regulation 853/2004**

##### **Competent authority files**

The following guidance will support Competent Authorities in order to ensure consistency in the content and structure of files produced for establishments which require formal approval.

A properly structured file containing all the relevant information is important to the Competent Authority. It provides a history of the establishment concerned and how it has developed; it provides continuity for new officers; it facilitates monitoring exercises and will assist the Competent Authority in demonstrating its competence.

Each file should contain:

- The application form;
- a plan or plans of the establishment indicating:
  - i. The layout of the establishment;
  - ii. The location of equipment;
  - iii. Work flows for each product line;
  - iv. Water distribution system within the establishment including all outlets and sampling points;
  - v. Drainage layout;
  - vi. Pest control - baiting and/or trapping points within the establishment and external areas;
- a synopsis of the establishment which briefly describes what type of establishment it is, products produced, volume of product, type of trade, number of employees, approval number and what it is approved for. This synopsis should be no more than one side of an A4 sheet;
- pre-approval inspection report;
- planned programme of works to achieve approval;
- approval notification document specifying:

- i. Details of activities to which the approval relates;
- ii. Approval number;
- iii. Classification;
- iv. Special hygiene direction(s);
- v. Any establishment-specific derogations that have been granted;
- vi. Any other conditions or limitations specified by the Competent Authority;
- vii. Any arrangements acceptable to the Competent Authority;

Note: All relevant information and documentation to be included in file;

- labels and commercial documents bearing the identification mark;
- letter indicating the Competent Authority's involvement in the planning and implementation of the establishment's hygiene training of staff;
- inspection reports on premises in chronological order;
- correspondence with establishment in chronological order;
- copies of notices or other formal action taken in chronological order;
- copy of company's emergency withdrawal plan and traceability system including names, telephone numbers, etc., of key personnel within the company;
- copy of any other documents that have been provided by, or copied at, the approved premises, including:
  - i. HACCP documentation;
  - ii. supplier information;
  - iii. product list;
  - iv. raw material, product and water sampling plans and test results\*;
  - v. other sampling plans and results e.g. environmental sampling\*;
  - vi. process records;
  - vii. management and key contact names and contact details;
  - viii. photographs and digital images;
  - ix. product recall procedures;

\*where FBOs are using alternative sampling plans or methods in accordance with Regulation (EC) No 2073/2005 on the microbiological criteria for foodstuffs, the Competent Authority's verification of the proposed alternative approach should be held on file.

- results of all samples taken by the Competent Authority;
- location of any off-site facilities

### 3.3.2 Approval Number / Identification marks

See 3.3.14 of the Code.

The requirements for the form of the identification mark which establishments subject to approval under Regulation 853/2004 must apply to their products as appropriate are set out in Annex II, Section I B of that Regulation. The Competent Authority must agree an identification mark with each establishment it approves which (a) incorporates the approval code it has allocated and (b) meets the requirements of Annex II, Section I B of Regulation 853/2004 including the need for the mark to be within an oval shape.

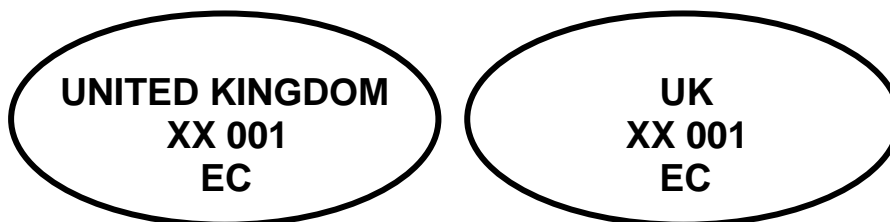
#### 3.3.2.1 Approval Identification Marks

##### Example Identification Mark Formats



Note: Other formats are acceptable provided they comply with the requirements of Annex II, Section I B of [Regulation 853/2004](#).

##### Example Identification Marks



### 3.3.3 Enforcement in Approved Establishments

All relevant material on enforcement options in approved establishments is contained in the Code.

### 3.3.4 Documentation

#### Approval of product-specific establishments subject to approval under Regulation 853/2004 - template forms

Template forms which can be used by Competent Authorities in connection with the approval of product-specific establishments are provided as detailed the following table:

| Practice Guidance Reference | Documentation (template forms & guidance)   |
|-----------------------------|---|
| 3.3.4.1                     | <a href="#">Application for Approval</a>  |
| 3.3.4.2                     | <a href="#">Notification of Grant of Full Approval / Conditional Approval</a>   |
| 3.3.4.3                     | <a href="#">Notice of Decision Not to Grant Approval</a>  |
| 3.3.4.4                     | <a href="#">Notice of Decision to Withdraw Approval / Conditional Approval</a>  |
| 3.3.4.5                     | <a href="#">Notice of Decision to Suspend Approval / Conditional Approval</a>   |
| 3.3.4.6                     | <a href="#">Notification of Refusal to Grant Full Approval to an Establishment which is Conditionally Approved</a>  |
| See link provided           | <p>Guidance in relation to the approval of food business establishments that handle POAO can be found at the following link:</p> <p><a href="https://www.food.gov.uk/enforcement/sectorrules/aprovalsguidance">https://www.food.gov.uk/enforcement/sectorrules/aprovalsguidance</a></p> <p>An overview of the approval process set out in a flow chart is also included</p> |

As stated in Paragraph 3.3.4 of the Code, although the content of these documents is regarded as the minimum required, Competent Authorities may adapt them as necessary to meet local requirements.

### **3.4. Food Business Establishment Records**

#### **3.4.1 Data Protection / Freedom of Information**

This section contains information about the [Data Protection Act 1998](#) and the [Freedom of Information Act 2000](#) as they relate to food business records.

Competent Authorities should ensure that their data protection registration encompasses all their reasons for holding data, including its supply to other agencies for the purposes of ensuring public health and the effective enforcement of food law.

If Competent Authorities have any doubts about the release of data or information they should seek legal advice and/or contact the Information Commissioner's Office whose website can be found at [www.informationcommissioner.gov.uk](http://www.informationcommissioner.gov.uk).

### **3.5 Reports following intervention**

See 3.5 of the Code.

#### **3.5.1 Information Requirement**

##### **3.5.1.1 Establishment Record Files**

The FSA has produced the following guidance document that highlights the recommendation made by the Public Inquiry into the 2005 Outbreak of E. coli O157 in South Wales to assist Competent Authorities in effectively managing their establishment records

<http://www.food.gov.uk/multimedia/pdfs/enforcement/everyinspection.pdf>

In addition to the recommendations contained within the report of the public inquiry, Professor Pennington was subsequently clarified the follow recommendation:

**Recommendation 10:** *'Environmental Health Officers should obtain a copy of a business's HACCP/food safety management plan at each inspection, which should be held on the business's inspection file'*

With regard to the retention of HACCP plans by competent authorities, the primary concern was for retention of the core elements of the plan. Retention of the critical control points from a business's HACCP plan, rather than the entire plan is considered to be sufficient to ensure that Authorised officers looked at the performance of a business over time and did not miss danger signs from previous inspections.

#### **3.5.2 Retention of Establishment Record Files**

The retention of records in relation to food business establishments for 6 years does not apply to those establishments that no longer exist or those that have relocated outside the local authority. In these circumstances it is advisable to retain these records for a period on no less than 18 months. However, this does not apply to business that have relocated within the local authorities own boundaries.

This does not affect the requirement within section 3.5.2 of the Code to retain records of existing establishments.

### **3.5.3            Retention of Import Documentation**

See 3.5.3 of the Code

### **3.5.4            Model Intervention Report Form**

See 3.5.4 of the Code

### **3.5.5            Internal Monitoring**

See 3.5.6 of the Code

### **3.5.6            Competent Authority Management Information Systems (MIS)**

See 3.6 of the Code



## Chapter 4 - Qualifications and experience

### 4.1 Introduction – Qualifications and experience

This Chapter provides advice on the qualifications and experience required for officers undertaking official controls (food hygiene and food standards), including advice on assessing an officer's competency for delivering official controls.

Competent Authorities need to satisfy themselves through appraisal and assessment procedures that an officer can provide demonstrable evidence that they meet the competency (knowledge and skills) requirements set out in Chapter 4 of the Food Law Code of Practice (the Code).

The competencies in the Code recognise that an officer's authorisation can be broadened as the person gains experience and develops new competencies.

### 4.2 Authorisations

Competent Authorities should implement a documented procedure for the authorisation of officers carrying out official controls.

### 4.3 New members of staff

New members of staff must have a formal induction process and familiarise themselves with the Competent Authority's Enforcement Policy and internal procedures. As part of the induction, the lead officer should consider the officer's qualifications, experience, and CPD and carry out a competency assessment to determine the officer's level of authorisation.

### 4.4 Qualifications equivalent to the baseline qualification

Section 4.4 of the Code sets out the baseline qualifications for food hygiene and food standards official controls.

Table 1: Baseline qualifications

| Baseline qualification for food hygiene (other than official fish inspection at Border Inspection Posts) <sup>10</sup> . | Baseline qualifications for food standards <sup>11</sup> |
|--|--|
| Higher Certificate in Food Control   | Higher Certificate in Food Control, or from the Trading  |

<sup>10</sup> Please refer to section 4.6 of the Code in relation to import controls at Border Inspection Posts.

<sup>11</sup> For premises where quality assurance systems are to be assessed, officers should possess a Quality Assurance qualification e.g. Lead Auditor or the Higher Diploma in Consumer Affairs and Trading Standards, **or** equivalent professional experience and competency to enable them to assess quality assurance systems.

|  |   |
|--|---|
| <p>This qualification currently comprises the Higher Certificate in Food Premises Inspection with two additional 'modules' - the Food Inspection Endorsement and the Food Standards Endorsement.</p> | <p>Standards Qualifications Framework, the Diploma in Consumer Affairs and Trading Standards (DCATS) with Food Standards Service Delivery module, or the Higher Diploma in Consumer Affairs and Trading Standards (HDCATS) with Food Standards Service Delivery Module.</p> |
|--|---|

The qualifications in Table 2 are currently considered to be equivalent to those set out in section 4.4 of the Code:

**Table 2: Equivalent qualifications**

| <b>Official controls - hygiene</b>   | <b>Official controls – standards <sup>12</sup></b>   |
|--|--|
| <ul style="list-style-type: none"> <li>• A Certificate of Registration issued by the Environmental Health Registration Board EHRB (or one of its antecedents) to practice as an Environmental Health Officer/Practitioner; or</li> <li>• A Diploma in Environmental Health (or its antecedents) awarded by the EHRB or REHIS.</li> </ul> | <ul style="list-style-type: none"> <li>• A Certificate of Registration issued by the Environmental Health Registration Board EHRB (or one of its antecedents) to practice as an Environmental Health Officer/Practitioner;</li> <li>• A Diploma in Environmental Health (or its antecedents) awarded by the EHRB or REHIS.</li> <li>• Diploma in Trading Standards (or its antecedents);</li> <li>• Diploma in Consumer Affairs (DCA Part II) provided it includes the Food and Agriculture Paper or its antecedents;</li> <li>• A Higher Certificate in Food Premises Inspection issued by EHRB or IFST with Food Standards Endorsement;</li> <li>• The Higher Certificate in Food Standards Inspection issued by the Scottish Food Safety Officers Registration Board (SFSORB).</li> </ul> |

#### **4.5 Known qualifications with restrictions**

There are some qualifications that are not considered equivalent to those listed above, as they do not incorporate the underpinning knowledge required to undertake the **full** range of official controls (for food hygiene and food standards).

Therefore, holders of the qualifications in Table 3 should have the following restrictions applied to their authorisation:

<sup>12</sup> For premises where quality assurance systems are to be assessed, officers should possess a Quality Assurance qualification e.g. Lead Auditor or the Higher Diploma in Consumer Affairs and Trading Standards, or equivalent professional experience and competency to enable them to assess quality assurance systems.

Table 3: Qualifications with restrictions

| Food Hygiene Qualifications   |   |  | Food Standards Qualifications  |
|---|---|--|--|
| <p><b>Higher Certificate in Food Premises Inspection issued by EHRB, IFST or SFSORB</b></p>   | <p><b>Higher Certificate in Food Premises Inspection (issued by EHRB, IFST or SFSORB) with Food Standards Endorsement</b></p>   | <p><b>Ordinary Certificate in Food Premises Inspection issued by EHRB, IFST or SFSORB</b></p>  | <p><b>Trading Standards Qualification Framework (TSQF) Awards which includes:</b></p> <ul style="list-style-type: none"> <li>• <b>Certificate of Competence in Food Standards service delivery module;</b></li> <li>• <b>Core Skills Certificate in Consumer Affairs and Trading Standards with Food Standards service delivery module (CSCATS with Module Certificate in Food Standards); and</b></li> <li>• <b>Diploma in Consumer Affairs (DCA): Certificate of Competence in Food and Agriculture</b></li> </ul> |
| <p>Holders of this qualification should not be authorised to:</p> <ul style="list-style-type: none"> <li>• undertake inspection of food to determine fitness;</li> <li>• seize and detain food;</li> <li>• undertake food standards functions; and</li> <li>• undertake some Import Controls functions, as this requires the officer to be either an Environmental Health Practitioner or an Official Veterinary Surgeon<sup>13</sup>.</li> </ul> | <p>Holders of this qualification should not be authorised to:</p> <ul style="list-style-type: none"> <li>• undertake inspection of food to determine fitness;</li> <li>• seize and detain food; and</li> <li>• undertake some Import Controls functions, as this requires the officer to be either an Environmental Health Practitioner or an Official Veterinary Surgeon.</li> </ul> | <p>Holders of this qualification should only be authorised to inspect establishments with a Hygiene Intervention Rating C-E. They should not be authorised to:</p> <ul style="list-style-type: none"> <li>• undertake inspection of food to determine fitness;</li> <li>• seize and detain food;</li> <li>• undertake food standards work; and</li> <li>• undertake some Import Controls functions, as this requires the officer to be either an Environmental Health Practitioner or an Official Veterinary Surgeon.</li> <li>• serve Remedial Action Notices</li> <li>• service Hygiene Emergency Prohibition Notices</li> </ul> | <p>Officers holding one of these qualifications should only be authorised to inspect establishments with a Food Standards Intervention Rating of B and C.</p>  |

#### 4.6 Equivalency of qualifications

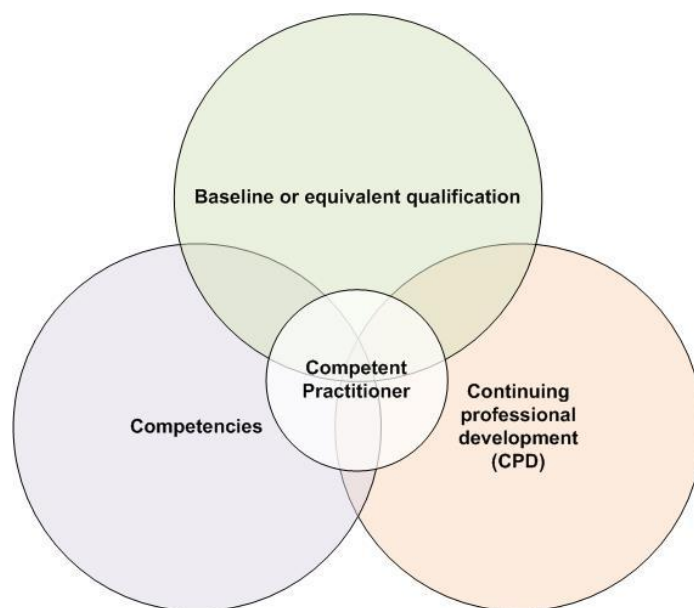
Those who do not hold the baseline qualification, but consider that their qualifications, training and experience are suitable to undertake specific enforcement activities outlined in the Code, should contact the relevant professional and awarding bodies for an equivalency assessment (fees may be applicable). The FSA should be consulted and informed of any determination in relation to the assessment of qualifications. The relevant bodies are the Chartered Institute of Environmental Health (CIEH), and the Chartered Institute of Trading Standards (CTSI).

<sup>13</sup> Please refer to section 4.6 of the Code in relation to import controls at Border Inspection Posts.

## 4.7 Competency framework

The competency framework is designed to assist Competent Authorities in determining the competency of their officers, including lead officers. Competency in this context is a combination of qualifications, technical and professional skills, knowledge and experience that enable an officer to be appropriately authorised to deliver official controls. The competency framework will allow those delivering official controls to demonstrate their competency to current and future employers, and the CPD requirements will ensure continued professional development.

Figure 1. Competent practitioner model (source: FSA, 2015)



Competent Authorities are best placed to determine the competency of their officers delivering official controls. Many Competent Authorities have existing competency-assessment tools that may meet the requirements laid down in the Code. These may continue to be used provided they meet the objectives of the competency framework outlined in the Code.<sup>14</sup>

The key points are:

- Appropriate qualifications, in conjunction with on-the-job experience and training, are required to develop and achieve competency and display proficiency.
- Competency *may* be demonstrated in other ways, so long as the desired outcome is achieved.

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<sup>14</sup> The FSA is working with the Better Regulation Delivery Office (BRDO) to map the relevant RDNA Modules to the competency framework in the Code. When this is complete, Competent Authorities may wish to use the RDNA tool to assess officer competencies. The FSA will inform Authorities when this work is completed. For information on the RDNA process: <http://www.rdna-tool.bis.gov.uk>.

- Competency should be reviewed on an ongoing basis, i.e. as part of an Authority's appraisal process.

Each of the specified competencies has the following components:

- Statement of competence; and
- A description of what this might look like in practice.

Please note that the description of how the competencies might look in practice (i.e. could be demonstrated) is not an exhaustive list.

The framework outlines 13 competencies for **Lead Food Officers**, grouped under 3 broad categories; and 19 competencies for **Authorised Officers**, grouped under 5 broad categories. Lead Food Officers should also be able to demonstrate the relevant competencies for Authorised Officers, as a matter of course.

## 4.7.1 Competency assessment structure and case studies

Table 4: competency assessment structure

| Step 1  | Step 2  | Step 3   |
|---|---|--|
| <p>Ensure that the officer has the baseline qualification (or equivalent), or one of the qualifications which will require restrictions to be placed on the authorisation (see <b>Known qualifications with restrictions</b> in Table 3).</p> <p>These qualifications will give the underpinning knowledge required to undertake official controls as well as providing a start on the development of competencies.</p> | <p>Determine the relevant competencies for the role and consider whether the officer can satisfy the Authority that he/she meets those competencies.</p> <p>If an officer does not have the necessary competencies, there should be a discussion with the Lead Food Officer about how the development needs can be addressed. Until such gaps have been filled, the officer's authorisation to deliver official controls should be appropriately restricted.</p> <p>An officer would be able to demonstrate the relevant competencies by various means, alone or in combination, but not exclusively restricted to the following:</p> <ul style="list-style-type: none"> <li>• Holding appropriate qualifications – both academic and professional</li> <li>• Having undertaken assessed practical training that requires application of academic and professional knowledge</li> <li>• Successful completion of training courses, including short courses and e-learning, e.g. on matters related to official controls, specialised processes, enforcement sanctions etc.</li> <li>• Having carried out accompanied inspections/visits under the supervision of an appropriately authorised (competent) officer</li> <li>• Having carried out a specific piece of work, e.g. drafting of notices, production of witness statements, gathering evidence, building elements of a prosecution file, carrying out sampling to specified protocol etc.</li> </ul> <p>Officers are encouraged to maintain a record of evidence containing details of qualifications, training, and details of specific food safety experience which helps to demonstrate that they have met the relevant competencies laid down in the Code.</p> <p>Where necessary, appropriate redaction should be carried out to ensure confidentiality and compliance with data protection requirements.</p> | <p>Officers should be able to provide evidence that they have met the CPD requirements detailed in the Code.</p> <p>Following the assessment, the lead food officer, in consultation with the individual officer, should be able to identify development needs which can be used to inform an officer's personal development plan and their CPD priorities.</p> <p>To assist officers in determining the most appropriate way to address development needs and undertake appropriate CPD, the Guidance for Regulators Information Point (GRIP) may be consulted. This can be accessed via the following link: <a href="http://www.regulatorsdevelopment.info/grip/">http://www.regulatorsdevelopment.info/grip/</a>.<sup>15</sup></p> <p>Officers should also consider appropriate training courses, for example those provided by the FSA, BTSF and professional bodies and organisations including CIEH and TSI.</p> |

<sup>15</sup> The FSA will be working with BRDO to review and update material on GRIP site so that it will support the competencies required by the Code.

The following case studies have been provided as **examples**. They are not intended to be prescriptive or exhaustive.

**Case study 1** - assessing and authorising a newly qualified officer who holds the baseline qualification or equivalent (or a qualification to which a restriction must be applied)

A copy of the officer's qualification is endorsed by the Lead Food Officer and placed in the officer's file. In order to properly develop relevant experience post-qualification, a structured training programme is developed. This includes elements such as shadow visits, accompanied inspections, notice and letter drafting, food poisoning investigations, complaints investigation, sampling etc. Specialist training, for example provided by FSA courses, also provides key elements of the officer's professional development. Ongoing assessment of developing competence allows the Lead Officer to monitor progress and determine suitability for authorisation. A newly qualified officer would need to gain sufficient experience and be able to demonstrate understanding and competency before they are authorised to inspect complex processes (i.e. approved premises) or take certain enforcement action. It is the Lead Food Officer's responsibility to determine when this is appropriate on a case by case basis.

**Case study 2** – assessing and authorising an experienced qualified officer who holds the baseline qualification or equivalent (or a qualification to which a restriction must be applied)

A copy of the qualification is endorsed by the Lead Food Officer and placed in the officer's file. The officer provides evidence of their CPD record and has met the CPD requirements. Previous assessments will have been carried out to determine specific authorisations. An experienced officer will be asked to assess themselves against the competencies in the Code framework. The officer will be expected to indicate which competencies they meet and provide a brief description of how they have been met. The officer will need to consider how this might be evidenced. The Lead Officer then discusses this self-assessment with the officer and seek evidence to confirm that the competencies have been met. The record of competency assessment is documented and the Lead Food Officer appropriately authorises the officer, who is then subject to the Authority's monitoring and verification processes. Please note that if an experienced officer is assessed and does not meet the competencies, the Lead Food Officer and the officer work should together to identify any gaps in knowledge, experience etc., and how this can be addressed, e.g. through formal courses, online resources, gaining practical experience etc. The officer's authorisation would need to be appropriately restricted until competency is demonstrated.

**Case study 3** – an officer returning to food work after an extended break

An officer returning to food work must have the baseline qualification or equivalent (or a qualification to which a restriction must be applied). A copy of this qualification is endorsed by the Lead Food Officer and placed in the officer's file. The Lead Food Officer will ask the officer to assess themselves against the competencies in the Code framework. The returning Officer indicates that do not meet all of the competencies as they have been out of food related work for some time. The Lead Food Officer and the returning officer work together to identify any gaps in knowledge, and how this can be addressed, e.g. through formal courses, online resources etc. Reference is made to RDNA and GRIP. A structured training and development programme is produced to assist the returning officer build up experience and develop the necessary competencies. The returning officer would need to gain sufficient experience and be able to demonstrate that they have developed the required competencies before they can be fully authorised to carry out official controls and carry out certain enforcement actions. It is the Lead Food Officer's responsibility to determine when this is appropriate on a case by case basis.

#### **4.7.2 Lead Food Officer Competencies**

An appropriate line manager (such as a service manager or Assistant Director with responsibility for the Competent Authority's food service) should work with the lead food officer to assess their competency. This is expected to involve the lead food

officer carrying out a self-assessment against the competency framework, providing evidence of how they meet/can meet the competencies, and discussing any development needs with their line manager.

There is likely to be a difference in how competencies are demonstrated between an existing lead food officer and a recently promoted/appointed lead food officer. This is because there is an expectation within the Code that a lead officer will have full knowledge of the area, and will have carried out the relevant management tasks previously.

However, newly appointed or promoted lead food officers should be able to describe and explain how they are *capable* of satisfying the competencies. It is expected that this will have been tested at the recruitment and/or job interview stage.

As a newly promoted/appointed officer develops, they should be able to provide examples of how competencies have been demonstrated. LAs might choose to carry out in-year assessments to satisfy themselves that the relevant competencies have been developed.

Lead food officers moving from other LAs should be able to provide real life examples of how they have demonstrated the necessary competencies in their previous employment.

To provide further assurances, lead food officers are encouraged to participate in inter-authority audit and peer review of lead food officer competencies. This will help with the development of consistent approaches to competency assessment.

The lead food officer framework is made up of 3 clusters with 13 competencies. However, lead food officers should hold the baseline or equivalent qualification and also be able to demonstrate the relevant competencies for authorised officers as a matter of course. Below is a list of all the competencies with a high-level summary of each one.

The Code recognises that the lead food officer role may be performed by more than one person. Competencies relevant to an individual's role should be taken into account when carrying out assessments. Lead officer competencies could be demonstrated *between* the officers fulfilling the lead officer role.



### 4.7.3 Lead Officer Competency Assessment guidance

| Cluster No. | Statement of Competence                   |
|-------------|---|
| 1           | Local and specialist knowledge            |
| 2           | Legislation and centrally issued guidance |
| 3           | Planning of an official control programme |

#### Local and specialist knowledge:

| Cluster No. 1 | Statement of Competence – Lead officer   | What this could look like in practice   |
|---------------|--|---|
| 1.1           | Knowledge and understanding of the area for which he/she is acting as the Lead Food Officer - this may include more than one Competent Authority area. | <ul style="list-style-type: none"> <li>• Able to describe the area for which he/she is acting in terms of the type of food businesses, specific risks, demographic/ profile, business churn, etc.</li> <li>• Able to explain how they keep abreast of local changes, maintaining databases, links to other departments etc.</li> </ul>  |
| 1.2           | Knowledge and understanding of the hazards that can occur in premises within the authority's area and risk management techniques.                      | <ul style="list-style-type: none"> <li>• Able to describe the types of businesses and the potential risks they pose.</li> <li>• Able to explain how to implement a risk-based approach to inspections and interventions in accordance with the Code.</li> <li>• Able to explain inherent hazards and appropriate controls within specialist processes which are relevant to premises in that Authority.</li> <li>• Able to explain how to respond to food incidents, recalls, RASFF, etc.</li> </ul> <p><i>Note: The officer may have experience in delivering official controls in the types of premises that occur in the authority's area, and/or have attended training for example in HACCP for specialist cheese making, sous-vide, inland imported food controls, etc. And/or involvement in specialist groups/forums.</i></p> |
| 1.3           | Knowledge and understanding of   | <ul style="list-style-type: none"> <li>• Able to explain what specialist auditing and quality assurance skills are.</li> </ul>  |

| <b>Cluster No. 1</b> | <b>Statement of Competence – Lead officer</b>  | <b>What this could look like in practice</b>  |
|----------------------|--|---|
|                      | when specialist auditing and quality assurance skills are needed to deliver official controls. | <ul style="list-style-type: none"> <li>• Able to describe premises where specialist auditing skills are required, for example in some manufacturing premises and/or approved premises.</li> </ul> |

**Legislation and centrally issued guidance:**

| <b>Cluster No. 2</b> | <b>Statement of Competence – Lead officer</b>   | <b>What this could look like in practice</b>   |
|----------------------|---|--|
| 2.1                  | Understands relevant EU and National food hygiene or standards legislation and can advise on their application.   | <ul style="list-style-type: none"> <li>• Can explain what EU and National food hygiene and/or standards legislation is in place in England.</li> <li>• Can supply specific examples of when they have advised on the application of EU and national food legislation.</li> <li>• Able to describe how the legislation is applied in different types of food businesses, for example, premises where Regulation 853/2004 is applicable.</li> <li>• Able to explain how they will keep up to date with changes in legislation and guidance, for example, attending update training, reading FSA communications, attending relevant regional meetings etc.</li> <li>• Able to describe how update information will be cascaded to members of the food team, for example, via CPD sessions within the LA.</li> </ul> |
| 2.2                  | Understands, interprets and applies the Framework Agreement on Food Law Enforcement with Local Authorities, the Food Law Code of Practice and associated Practice Guidance appropriately. | <ul style="list-style-type: none"> <li>• Able to explain what the Framework Agreement on Food Law Enforcement, the Code and associated Practice Guidance are.</li> <li>• Can interpret how the Framework Agreement on Food Law Enforcement, the Code and associated Practice Guidance should be applied in their LA.</li> <li>• Able to describe how to implement appropriate procedures that will support effective decisions on enforcement, intervention ratings etc.</li> <li>• Able to explain an appropriate system of checking that procedures are complied with, for example internal monitoring.</li> </ul>   |
| 2.3                  | Understands and can advise on the application of the full range of enforcement sanctions available and proportionate application of food law.   | <ul style="list-style-type: none"> <li>• Able to describe the full range of enforcement options available.</li> <li>• Able to explain when each of these could be used, providing real life or practical examples.</li> <li>• Able to describe guidance relevant to enforcement activities, e.g. The Regulators Code.</li> </ul>   |

**Planning of an official control programme:**

| <b>Cluster No. 3</b> | <b>Statement of Competence – Lead officer</b>  | <b>What this could look like in practice</b>  |
|----------------------|--|---|
| 3.1                  | Can appropriately apply national and local priorities to the profile of food business establishments and points of entry in the authorities' area when planning a programme of official food controls. | <ul style="list-style-type: none"> <li>• Able to explain how to develop a risk based service plan for delivering the Authority's food safety functions.<br/>As for 1.1, 1.2, and 1.3 above.</li> </ul>  |
| 3.2                  | Can identify skill or knowledge gaps in officers delivering official food controls.  | <ul style="list-style-type: none"> <li>• Can explain how they (will) assess officers who are responsible for delivering official controls using the competency framework.</li> <li>• Can explain how they draw up personal development plans and monitor progress.</li> <li>• Can explain how they link assessed competencies to officer authorisations.</li> </ul> <p><i>Note: This may involve use of RDNA, 1-1s, appraisals, and/or an in-house system that the LA has developed.</i></p>  |
| 3.4                  | Understands the process of raising and managing food incidents as set out in the Code of Practice, including responses to infectious disease outbreak(s).  | <ul style="list-style-type: none"> <li>• Able to explain necessary notification for different types of incident.</li> <li>• Able to explain when it would be appropriate to generate a RASFF notification, liaison with necessary parties, including the FSA etc.</li> <li>• Able to explain appropriate response to infectious disease outbreak notifications.</li> </ul>  |
| 3.5                  | Understands how local contingency arrangements apply to the management of serious food related incidents e.g. infectious disease outbreak.   | <ul style="list-style-type: none"> <li>• Able to describe the local arrangements for managing serious food-related incidents</li> </ul> <p><i>Note: This may include training in incident management and contingency planning and use of local emergency plans.</i></p>   |
| 3.6                  | Understands the role of Home Authorities and Primary Authority Partnerships in co-ordinating the delivery of official controls and ensures it is applied by the authority.                             | <ul style="list-style-type: none"> <li>• Able to explain what is meant by Home Authority and Primary Authority partnerships.</li> <li>• Able to describe the procedures in place for dealing with businesses that are part of a Primary Authority partnership.</li> <li>• Able to explain how monitoring will ensure that the LA complied with the requirements of the Regulatory Enforcement and Sanctions Act.</li> </ul> <p><i>Note: This may include attendance at BRDO training.</i></p> |

| Cluster No. 3 | Statement of Competence – Lead officer  | What this could look like in practice   |
|---------------|---|---|
| 3.7           | Understands how to comply with local and national data gathering and reporting requirements.                        | <ul style="list-style-type: none"> <li>• Able to describe what LAEMS is and how to use it.</li> <li>• Able to describe what UKFSS is (if used in the LA) and how to use it.</li> <li>• Able to describe what the food fraud database is and how it should be used.</li> </ul>   |
| 3.8           | Co-ordinates consistent delivery of official controls within the authority and between other Competent Authorities. | <ul style="list-style-type: none"> <li>• Able to explain how consistency will be monitored in the authority between officers, for example, overseeing a programme of accompanied official controls as part of internal performance appraisal/monitoring procedure.</li> <li>• Able to describe ways in which delivery of official controls is consistent with other authorities.</li> </ul> <p><i>Note: This may include consistency training, participation in Inter Authority Audit, participation in sector or countywide meetings/forums etc.</i></p> |

#### 4.7.4 Authorised Officer Competency Assessment guidance

Lead Food Officers will need to ensure that authorised officers achieve the necessary training and experience to enable them to achieve the relevant competencies and that their authorisation is appropriate for their level of competency.

The Authorised Officer framework is made up of 5 clusters with 19 competencies.

| Cluster No. | Official Control / Type of Role   |
|-------------|-----------------------------------|
| 4           | Inspection of Food Establishments |
| 5           | Use of Enforcement Sanctions      |
| 6           | Sampling                          |
| 7           | Import and Export controls        |
| 8           | Reactive investigations           |

##### Inspection of Food Establishments:

| Cluster No. 4 | Statement of Competence - Authorised Officer  | What this could look like in practice   |
|---------------|---|---|
| 4.1           | Comprehensive understanding of HACCP-based procedures. Has the ability to apply that knowledge taking account of flexibility principles contained within Article 5 of Regulation (EC) No. 852/2004. | <ul style="list-style-type: none"> <li>• Able to describe their experience of assessing, influencing the development of, and/or developing HACCP based systems, providing examples.</li> <li>• Satisfactory performance during accompanied official controls as part of internal performance appraisal/monitoring procedure.</li> </ul> <p><i>Note: this may include suitable specific HACCP qualifications/training.</i></p>   |
| 4.2           | Can determine and identify hazards and risks that occur in establishments and products. Understands the principles of risk assessment related to food types; and processing methods and products.   | <ul style="list-style-type: none"> <li>• Able to describe their experience in delivering relevant interventions in a range of premises types where hazards have been identified and risks assessed, providing examples.</li> <li>• Satisfactory performance during accompanied official controls as part of internal performance appraisal/monitoring procedure.</li> <li>• Satisfactory inspection paperwork when assessed/monitored at LA.</li> </ul> <p><i>Note: This may include attendance at appropriate training e.g. sous vide, pasteurisation, vacuum packing etc.</i></p> |
| 4.3           | Understands relevant EU and   | <ul style="list-style-type: none"> <li>• Able to explain the requirements of EU and National food hygiene and/or standards legislation.</li> </ul>  |

| Cluster No. 4 | Statement of Competence - Authorised Officer  | What this could look like in practice   |
|---------------|---|---|
|               | National Food Hygiene or standards legislation and can advise on their application. Understands how to assess compliance with the requirements of EC and National food hygiene and standards legislation with further reference to the Food Law Code of Practice and Practice Guidance. | <ul style="list-style-type: none"> <li>• Able to explain the requirements of establishments that could fall under 853/2004 and how the requirements of 853/2004 are applied within that LA.</li> <li>• Able to describe experience of assessing business compliance in a range of business types.</li> <li>• Satisfactory performance during accompanied official controls as part of internal performance appraisal/monitoring procedure.</li> </ul> <p><i>Note: Inspections for the purposes of the approval of establishments that are subject to approval under 853/2004 should only be undertaken by officers who have a detailed knowledge of enforcement and experience in regulating approved establishments.</i></p> |
| 4.4           | Able to determine the appropriate course of action to remedy non-compliance, including when it is appropriate to escalate enforcement action.   | <ul style="list-style-type: none"> <li>• Able to describe experience in determining the most appropriate course of action in a range of premises types, including examples of when the action was taken to achieve a suitable outcome.</li> <li>• Satisfactory performance during accompanied official controls as part of internal performance appraisal/monitoring procedure.</li> </ul> <p><i>Note: The FSA provides enforcement sanction training for officers.</i></p>   |
| 4.5           | Can make a Food Hygiene/Standards Intervention Rating assessment of risk using section 5.6 of the Food Law Code of Practice.  | <ul style="list-style-type: none"> <li>• Able to describe experience of delivering official controls and intervention ratings in a range of business types.</li> <li>• Satisfactory performance during accompanied official controls as part of internal performance appraisal/monitoring procedure.</li> <li>• Satisfactory inspection paperwork when assessed/monitored at LA.</li> </ul>   |
| 4.6           | Understanding of the common food types and understanding of hazards associated with their use.  | <ul style="list-style-type: none"> <li>• Able to describe experience of food inspection and determination of fitness, providing examples.</li> <li>• Able to describe the common types of food present in establishments in the authority's area, and the hazards associated with their use.</li> </ul>   |

### Use of Enforcement Sanctions:

| Cluster No. 5 | Statement of Competence - Authorised Officer   | What this could look like in practice  |
|---------------|--|--|
| 5.1           | Can clearly differentiate between legal requirements and recommendations of good practice by avoiding 'gold plating' and 'regulatory creep'. Can provide advice and enforce based on levels of compliance with regard to consistency and proportionality based on the hierarchy of risk. | <ul style="list-style-type: none"> <li>• Able to describe examples of legal requirements and recommendations relevant to a range of businesses.</li> <li>• Able to explain how they would provide advice to FBOs, including advice given to those starting new food businesses.</li> <li>• Demonstrates understanding of a graduated approach to enforcing food law during accompanied inspections and visits.</li> <li>• Satisfactory inspection paperwork when assessed/monitored at LA.</li> </ul> <p><i>Note: The FSA provides enforcement sanction training for officers.</i></p> <p><i>Officers should only be authorised to serve HEPN/HEPOs and RANs if they have demonstrated the ability to make sound judgements with regards to these actions.</i></p> |
| 5.2           | Understands levels of authorisation, enforcement policies and procedures for appeal.   | <ul style="list-style-type: none"> <li>• Able to explain any limitations on their authorisation.</li> <li>• Able to describe what an enforcement policy is and how they can access the LA's policy.</li> <li>• Able to explain procedures for appeal, for example in respect of improvement notices and FHRS scores (as appropriate).</li> </ul>   |
| 5.3           | Understands the legal framework with regard to the use of enforcement powers including the role of Primary Authorities and Home Authorities.   | <ul style="list-style-type: none"> <li>• Able to explain the various enforcement powers available to use and when it is appropriate to use each.</li> <li>• Able to explain Primary Authority principles, including how to access the Primary Authority Register.</li> </ul> <p><i>Note: This may include attendance at BRDO training.</i></p>   |
| 5.4           | Can demonstrate an understanding of how to serve Notices; gather evidence; prepare cases for prosecution and apply knowledge to comply with the requirements of PACE and RIPA, where appropriate.  | <ul style="list-style-type: none"> <li>• Able to describe understanding of serving notices, providing examples.</li> </ul> <p><i>Note: The officer should be able to describe their understanding for each of the enforcement notices that they are to be authorised for, e.g. service of improvement notices, use of RANs, use of HEPNs, use of Compliance Notices under Additive Regulations. The officer must be able to demonstrate that they are capable of making sound judgements for each of the notice types.</i></p> <ul style="list-style-type: none"> <li>• Able to describe understanding of evidence gathering, statement taking, case preparation and involvement in interviews under PACE.</li> </ul>  |

| Cluster No. 5 | Statement of Competence -<br>Authorised Officer | What this could look like in practice  |
|---------------|---|--|
|               |   | <ul style="list-style-type: none"> <li>• Able to explain RIPA and its application.</li> <li>• Able to describe the Authority's procedures in preparing files for legal proceedings.</li> </ul> <p><i>Note: This may involve successful participation in relevant courses – i.e. gathering evidence, investigative techniques, use of enforcement sanctions, drafting of notices etc.</i></p> |

### Sampling:

| Cluster No. 6 | Statement of Competence -<br>Authorised Officer   | What this could look like in practice   |
|---------------|---|---|
| 6.1           | Understands formal /informal sampling methodologies and the role of the Public Analyst and Food Examiner.     | <ul style="list-style-type: none"> <li>• Able to describe how informal and formal sampling should be completed.</li> <li>• Able to explain the role of the Public Analyst and Food Examiner.</li> </ul> |
| 6.2           | Is aware of national and local sampling priorities. Can use UKFSS and searchable database, where appropriate. | <ul style="list-style-type: none"> <li>• Able to describe national and local sampling priorities.</li> <li>• Able to describe how to use UKFSS (if appropriate).</li> </ul>                             |
| 6.3           | Can interpret sampling results and make a judgement on appropriate action based on risk.                      | <ul style="list-style-type: none"> <li>• Able to describe examples of food sampling and taking appropriate risk-based follow up action.</li> </ul>  |

### Import and Export controls:

| Cluster No. 7 | Statement of Competence -<br>Authorised Officer   | What this could look like in practice  |
|---------------|---|--|
| 7.1           | Understands the legal framework with regard to Imported / Exported food and how to assess | <ul style="list-style-type: none"> <li>• Able to describe the legal framework with regard to Imported/Exported food.</li> <li>• Able to describe how to access the current list of restricted food items, country-specific requirements, and border control requirements.</li> </ul> |



| Cluster No. 7 | Statement of Competence - Authorised Officer  | What this could look like in practice   |
|---------------|---|---|
|               | compliance.   | <ul style="list-style-type: none"> <li>• Able to explain how to assess compliance with the Imported/Exported food legal framework in the context of the LA where the officer is working.</li> </ul> <p><i>Note: This may include completion of FSA Imported Food or other appropriate training, and familiarisation with the FSA's Resource Pack - Inland Enforcement of Imported Feed and Food Controls.</i></p>   |
| 7.2           | Can determine the most appropriate course of action and the range of enforcement sanctions available.   | <ul style="list-style-type: none"> <li>• Able to describe the range of enforcement sanctions relevant to Imported/Exported food.</li> <li>• Able to explain how they would determine the most appropriate course action, for example in some typical scenarios relevant to that LA.</li> <li>• Satisfactory performance during accompanied official controls as part of internal performance appraisal/monitoring procedure.</li> </ul> <p><i>Note: This may include completion of FSA Imported Food or other appropriate training, and familiarisation with the FSA's Resource Pack - Inland Enforcement of Imported Feed and Food Controls.</i></p> |
| 7.3           | Can identify food species and comment on fitness at Border Inspection Posts (also see Chapter 4.6)  | <ul style="list-style-type: none"> <li>• Must be a qualified Environmental Health Practitioner or Official Veterinary Surgeon to carry out official fish inspection.</li> <li>• Satisfactory performance when carrying out accompanied food species identification and fitness determination at BIP.</li> </ul> <p><i>Note: This may also include completion of FSA official fish inspection training or other appropriate training</i></p>   |
| 7.4           | Can demonstrate an understanding of controls at points of entry include carrying out systematic documentary checks, random identity checks and sampling for analysis, as appropriate. | <ul style="list-style-type: none"> <li>• Able to describe the controls in place at points of entry.</li> <li>• Able to describe how systematic documentary checks are carried out.</li> <li>• Able to describe how random identify checks are carried out.</li> <li>• Able to explain when sampling for analysis may be appropriate, providing examples.</li> <li>• Able to explain how to use GRAIL and TRACES, providing examples.</li> <li>• Satisfactory performance when carrying out controls at point of entry.</li> </ul> <p><i>Note: This may include completion of FSA Imported Food or other appropriate training.</i></p>                 |

**Reactive investigations:**

| Cluster No. 8 | Statement of Competence -<br>Authorised Officer   | What this could look like in practice   |
|---------------|---|---|
| 8.1           | Understands how to conduct an investigation and gather evidence in accordance with PACE and RIPA, where appropriate. Is then able to analyse information and determine an appropriate course of action. | <ul style="list-style-type: none"> <li>• Able to describe experience of conducting investigations, providing examples.</li> <li>• Able to describe understanding/experience of evidence gathering, statement taking, case preparation and involvement in interviews under PACE.</li> <li>• Accompanied investigations and/or satisfactory monitoring as part of internal performance appraisal/monitoring procedure.</li> <li>• Able to describe understanding/experience in determining the most appropriate course of action in a range of premises types and scenarios.</li> </ul> <p><i>Note: This may include attendance on an FSA Evidence and Investigation Skills/Local Authority Investigation Skills training or similar training course.</i></p> |
| 8.2           | Can identify when it is appropriate to engage with other agencies and stakeholders in particular when investigating food incidents and or infectious disease outbreaks.                                 | <ul style="list-style-type: none"> <li>• Able to explain when it is appropriate to work with other agencies on food incidents. For example, liaising with Public Health England; GPs; other Competent Authorities, including the FSA.</li> <li>• Able to explain when it is appropriate to work with other agencies on infectious disease outbreaks. For example, liaising with Public Health England; GPs; other Competent Authorities, including the FSA.</li> </ul>  |

## **4.8 Continuing Professional Development (CPD)**

### **4.8.1 Introduction**

One of the key components in ensuring competence is ongoing CPD. Whilst qualifications can be the starting point to achieving and demonstrating competency, practical experience, reflective practice, continual learning and continual professional development are required to develop and maintain the necessary skills for competent practice.

Professional bodies such as the CIEH and the CTSI operate their own CPD requirements for their respective membership, which includes providing CPD evidence as part of membership or Chartered Status. The professional bodies should be contacted directly if there are any questions on their respective CPD requirements.

Officers who are not members of professional bodies should still maintain a record of their CPD, which should be countersigned by the Lead Food Officer.

### **4.8.2 CPD requirements**

Those carrying out official controls should undertake a minimum of 20 hours CPD each year. The Code requires that at least 10 hours CPD must be spent on 'core' food areas. 'Core' is defined as CPD that will directly assist an officer in their professional/working capacity (i.e. training on the delivery of official controls). The remainder can be made up from learning related to 'other professional matters' i.e. CPD that will support an officer's profession.

### **4.8.3 'Core' CPD**

Annex II of Regulation (EC) No. 882/2004 outlines the subject matters for the training of staff performing official controls. Attending training courses and/or undertaking relevant distance learning/e-learning activities in the following subject areas are considered as 'core food matters' training and should make up the 10 hours 'core' CPD:

- Different control techniques, such as auditing, sampling and inspection;
- Control procedures;
- Feed and Food Law;
- Different stages of production, processing and distribution and the possible risks from human health, and where appropriate for the health of animals and plants and for the environment;
- Assessment of non-compliance;
- Hazards in animal, feed and food production;
- The evaluation of the application of HACCP procedures;

- Management systems such as quality assurance programmes that feed and food business operate and their assessment insofar as these are relevant for feed or food law requirements;
- Official certification systems;
- Contingency arrangements for emergencies, including communication between Member States and the Commission;
- Legal proceedings and the implication of official controls;
- Examination of written, documentary material and other records, including those related to proficiency testing, accreditation and risk assessment, which may be relevant to the assessment of compliance with feed or food law; this may include financial and commercial aspects;
- Any other area, including animal health and animal welfare, necessary to ensure that official controls are carried out in accordance with this Regulation.

#### **4.8.4 FSA Competent Authority training**

The FSA has a continuing programme of quality update training for competent authority officers enforcing food and feed law.

<https://www.food.gov.uk/enforcement/enforcetrainfund/enforcertraining>

##### **4.8.4.1 FSA online training**

The FSA has made available a number of training tools to help officers with their work. These include an interactive tool on food allergy, videos on food sampling and food hygiene, and online imported food training.

<https://www.food.gov.uk/enforcement/enforcetrainfund/onlinetraining>

##### **4.8.4.2 Better Training for Safer Food (BTSF)**

Better Training for Safer Food is a European Commission training initiative covering food and feed law, animal health and welfare and plant health rules. It trains European Union member state and candidate country national authority staff involved in official controls in these areas.

<https://www.food.gov.uk/enforcement/enforcetrainfund/btsf>

#### **4.8.5 ‘Other professional matters’ CPD**

Examples of ‘other professional matters’ CPD may include but is not limited to:

- Attending training courses/conferences not linked to official controls but supporting professional development;
- Shadowing experienced (internal or external) colleagues to develop knowledge of a specialist process, such as cheese making; meat products; shellfish/fishery products etc.;

- Attendance at court to review food-related cases;
- Participation in scenario-based case studies (e.g., notice drafting, Intervention Rating, etc.);
- Writing relevant articles for peer-reviewed journals/papers;
- Undertaking relevant distance learning or e-learning activities;
- Making presentations to colleagues on relevant food subjects, particularly new/changes to legislation or food-related developments.

#### **4.8.6 Evidence of CPD attainment**

Most 'Core' CPD is likely to be evidenced by the established practice of certification from a training provider. 'Other professional matters' may be demonstrated by another means of supportive evidence, e.g. publication in a peer-reviewed journal.

If shadowing experience or participation in scenario-based case studies includes reflective practice that is documented by the officer, and countersigned by the Lead Officer, this may count as core CPD. The Lead Officer will need to assess this on a case by case basis.

#### **4.8.7 Recording CPD**

Officers should maintain a record of their CPD, which can be recorded electronically. The record should include the following information as a minimum:

- Date/s of activity;
- Type of activity;
- Hours spent on activity ('core' or 'other professional matters' );
- Copy of certification or counter signature from a manager or colleague that the stated activity took place.

#### **4.8.8 Use of online training courses**

The FSA recognise that Competent Authorities may wish to consider the use of online training providers for the training of their officers. Competent Authorities will need to assess these courses on a case-by-case basis to determine suitability, and may wish to consider the following:

- Course content
- Course administration
- Training provider communication – does the course clearly outline how communication between the course provider and student will be facilitated?
- Course design – is the course material up-to-date and based on the latest information? Has the course material been piloted? Has the course been peer-reviewed?
- Assessment – are there assessments/assignments that the student undertakes throughout the course? Does the course provide feedback on

assessments/assignments? Do the assessments count towards recognised academic awards?

- I.T support – what support is provided? What IT requirements are needed to undertake the course? Are specialist programmes/software required to complete the course?
- Course evaluation – how does the course provider monitor the effectiveness of the course? How often is the course material checked for accuracy?
- Governance of student identity – how does the course provider ensure that the person enrolled on the online course is the person completing the course? What evidence will be provided to demonstrate that the person has completed the course and met the required outcomes?
- External accreditation – has the course been accredited by an external body?

## **Chapter 5 – Organisation of Official Controls**

### **5.1 Food Service Plans**

#### **5.1.1 Requirement for a Written Service Plan**

See relevant section of Code of Practice

### **5.2 Interventions and the delivery of Official Controls**

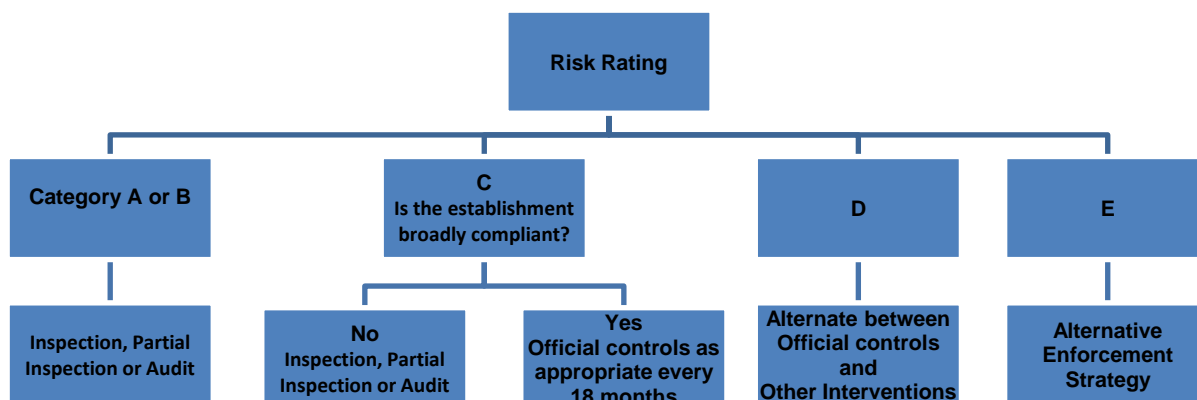
#### **5.2.1 Interventions and Official Control Delivery**

This section deals with delivery of interventions at food establishments. Interventions are activities that are designed to monitor, support and increase food law compliance within a food establishment. Interventions are activities that include, but are not restricted to, 'Official Controls'.

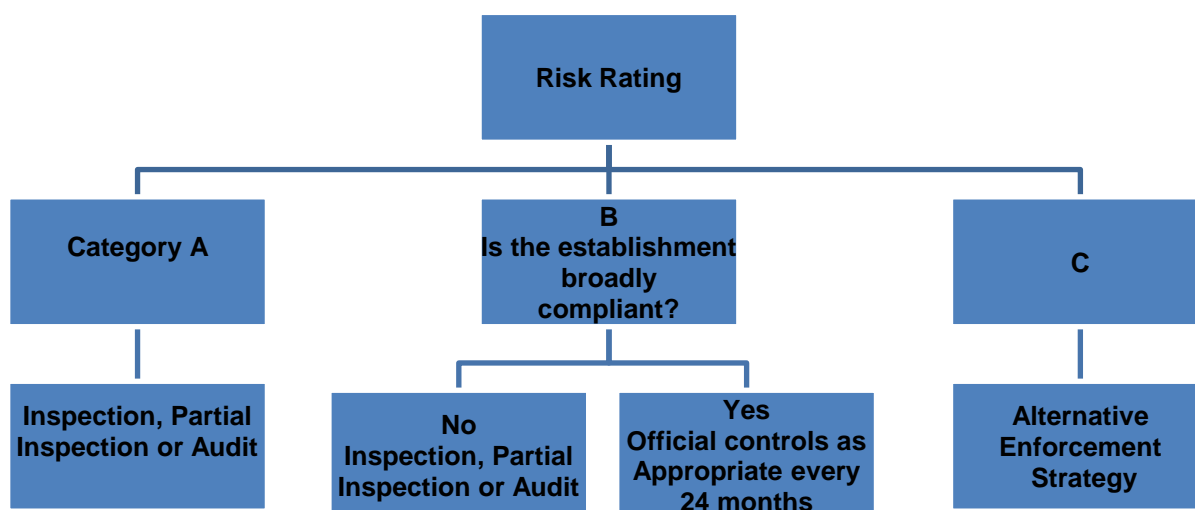
When selecting the type of intervention to use at an establishment, the authorised officer must have regard to the limitations as laid down with Chapter 5.2.1 of the Food Law Code of Practice (England) and the authority's own enforcement policy. The officer, when selecting from the available intervention types, should choose the intervention that will be most effective in maintaining or improving business compliance with food law.

The flow charts set out below indicate the types of intervention that can be undertaken to meet the minimum intervention frequency required by Chapter 5.6 of the Code. This guidance does not apply to other controls or interventions carried out in addition to those which meet the minimum frequency.

##### **5.2.1.1 Intervention types for Hygiene**



### 5.2.1.2 Intervention types for Standards



The flexibility in the type of intervention used is intended to allow the Competent Authority to adopt the most effective use of resources to achieve compliance. However, it also recognises that there are certain EU restrictions to Official Controls

The number of Official Controls undertaken by Competent Authorities is collected by the FSA through LAEMS returns to satisfy the reporting requirements of EU Regulation 882/2004. The UK data, including individual Competent Authority returns, are also published on the FSA website and reported to the FSA Board.

### 5.2.1.3 Intervention types

The range of intervention types available are designed to allow the enforcing officer to best select the type of action undertaken at the visit to the establishment ( See 5.2.1 of the Code of Practice for the different types of interventions Competent Authorities may use).



The type of intervention undertaken by the officer should, in addition to being based on the intervention risk rating score, be based on the conditions found at the establishment at the time of the visit.

However, at the subsequent visit the type of intervention undertaken should be based on the conditions found at the establishment, and should not be confined to the intervention suggested at the time of the last scheduled visit. Should the officer, in the process of undertaking an intervention other than an inspection, partial inspection or audit gather sufficient information in the course of the visit by considering some or all of the elements listed in Chapter 5.2.2 of the Code , they should consider revising the risk rating. The intervention would then be considered an inspection, partial inspection or audit and should be recorded as such.

The following intervention types are classed as official controls:

- Inspections
- Audits
- Sampling visits
- Monitoring visits
- Surveillance visits
- Verification visits

### **5.2.1.3 Interventions at product-specific establishments subject to approval under Regulation 853/2004**

The minimum number of food hygiene interventions at establishments subject to approval under Regulation 853/2004 must be conducted as necessary in accordance with Chapter 5.6 of the Code of Practice. The Competent Authority must keep the approval of establishments under review when carrying out official controls.

## **5.2.2 Inspections/Audits**

See relevant section of the Food Law Code of Practice

### **5.2.2.1 Carrying out an inspection or audit**

#### **Inspections, partial inspections and audit**

The circumstances below are examples of when the intervention must be recorded as an inspection, partial inspection or audit. These include:

- A programmed inspection or audit
- Inspection to risk rate a new food business or establishment which has not previously been rated
- Investigation of complaints about food or a food establishment which require inspection of some aspect of the food business

- Where a scheduled intervention of another type is no longer appropriate due to a change in conditions at the establishment that become apparent when the officer is on site and more intensive action is required.

When carrying out inspections Competent Authorities have discretion based on their professional judgement and file history, to cover only certain parts of the establishment's inspection. Circumstances that may warrant a partial inspection of the food establishments may include:-

- Partial inspection or audit of a large/complex establishment, where the inspection would look in detail at a particular process or operational area within the business.
- Partial inspection as part of a focused food hygiene or food standards campaign.

The authorised officer must only consider revising the risk rating following an inspection, partial inspection or audit. The other interventions detailed at 5.2.6 - 5.2.9 below should not be followed by a change in the risk rating.

#### **5.2.2.2 Initial inspection of a new establishment**

The Code of Practice requires that all food establishments must receive an initial inspection. This should take place within 28 days of registration or from when the Authority becomes aware that the establishment is in operation. This reflects the importance of ensuring new food establishments are complying with food law. This applies to both hygiene and standards inspections.

Where food standards inspections are handled by a separate authority (such as a county council) the food standards Competent Authority must be notified as soon as possible after receipt of registration or discovery of an establishment in operation without registration.

Prioritisation of initial inspections within the authority's intervention programme must be risk based. The requirement to undertake initial inspections within 28 days might in some circumstances present a conflict for resources to complete other higher priority activities or where businesses might register well in advance of opening.

#### **5.2.2.3 Determining when to undertake the initial inspection**

The following factors should be considered by the Competent Authority when determining when to undertake an initial inspection:

- Where the new establishment is believed to be undertaking high risk food activities the Competent Authority should undertake an initial inspection within 28 days of commencement of operations.
- Where the establishment is believed to be low-risk from the available information, consideration can be given to postponing the initial inspection in circumstances where it would delay planned interventions to premises involved

in, or believed to be involved in, high-risk activities as defined in Chapter 5.6 of the Code.

- Where an establishment is registered 28 days before commencement of operations, the inspection can be delayed until operations within the establishment have begun.

Where a decision has been taken to postpone an initial inspection this should be recorded on the appropriate premises file record.

#### **5.2.2.4 Factory and Fishing Vessels - Hygiene inspections**

In addition to the planned intervention programme of land based establishments, coastal Competent Authorities will need to consider the inspections of factory, freezer and fishing vessels. Such inspections will normally be carried out whilst vessels are in port.

Inspections of factory, freezer or fishing vessels whilst at sea must not normally be undertaken by officers of Competent Authorities. In the case of factory vessels, there might be circumstances when inspections can only be carried out when the factory vessels are moored offshore.

The frequency of inspections of fishing vessels must be set out in the Competent Authority's Food Service Plan or Enforcement Policy.

While a vessel can be approved by another Competent Authority, there is nothing to prevent any authorised officer of any other Competent Authority from inspecting the vessel, as long as they are satisfied that they have the appropriate legal authority to inspect and have contacted the Competent Authority that has approved the vessel and that authority considers it necessary. Where, during an inspection, contravention of the Regulations is identified, the authorised officer must notify the Competent Authority, where the vessel is normally based, of the contravention. The Competent Authority receiving details of contravention must liaise with the notifying Competent Authority and take whatever follow-up action is necessary.

#### **5.2.3 Planning and Notification of Interventions**

See 5.2.3 of the Code of Practice

#### **5.2.4 Enforcement action and revisits – food hygiene and food standards**

Food businesses that fail to comply with significant statutory requirements must be subject to appropriate enforcement action and revisit inspection(s). See section 5.2.4 of the Code.

Failure to comply with significant statutory requirements includes failure to comply with:

- a single requirement that compromises food safety, compromises public health, or prejudices consumers;
- a number of requirements that, taken together, indicate ineffective management;
- the requirements of a statutory Notice or Order

Revisit inspections should be based on the relevant inspection form, where one has been developed, for the business concerned, although the inspection may focus on the significant statutory requirements that were found to be contravened at the previous intervention.

### **5.2.5 Co-ordination of Intervention**

Where authorised officers of the various enforcement functions need to inspect the same premises, there can be advantages for food businesses, Competent Authorities and consumers in co-ordinating the inspections. This is particularly true of inspection of manufacturing premises, where co-ordination can make the whole inspection process more effective and efficient. However, there can often be practical difficulties in co-ordinating inspections. For example, premises might need to be inspected more frequently for some purposes than for others. There might be particular advantages in co-ordinating visits to consider a new process or product, or where there have been significant changes in quality control procedures.

Wherever it is practicable and appropriate to do so, Competent Authorities should co-ordinate inspections of food premises. The inspection team should include all the expertise necessary to inspect the premises in question and where appropriate further experts in particular fields of food technology<sup>16</sup>.

### **5.2.6 Verification**

The circumstances below are examples of when an intervention should be recorded as verification for that visit to the food establishment. These include:

- A visit to verify compliance with specific issue(s) identified at an earlier intervention, investigation of a complaint and/or serving of notices
- Investigation at a food establishment in response to a food poisoning incident where it is necessary to verify key aspects of the food business operation
- Verification visits to confirm that the procedures for HACCP have been implemented.
- One-to-one follow-up visit to verify compliance after participation of food business in a training seminar or completion of a business survey

### **5.2.7 Monitoring and Surveillance**

The circumstances below are examples of when an intervention should be recorded as monitoring or surveillance for that visit to the food establishment. These include:

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<sup>16</sup> The Institute of Food Science and Technology maintains a list of experts in particular fields.

- Information gathering visit if they include verification of information collected on site by an appropriately qualified officer.
- Surveillance of an establishment, for instance, the undeclared purchase of food items for verification of compliance with food law, undeclared visits to verify hygienic practices
- Visit to check the information supplied as part of an alternative enforcement strategy.

### **5.2.8 Sampling Visits**

A visit to an establishment for the purpose of obtaining a sample does not constitute a planned intervention unless the sampling activity forms a component part of a wider reaching official control that overall provides sufficient information to allow the officer to determine the level of compliance.

The circumstances below are examples of when an intervention should be recorded as sampling for that visit to the food establishment. These include:

- A visit solely to take formal sample/samples to be analysed/examined at an official laboratory. NB if samples are taken during another sort of intervention for instance, an inspection, then the visit must be recorded as an inspection not a sampling visit. Visits to take samples as part of a national, regional or local sampling programme can be included in this category, as long as the samples are analysed / examined by an official laboratory.

Also See Chapter 8 of the Code of Practice.

### **5.2.9 Other Interventions**

The following intervention types are classed as other interventions (not official controls):

- Education
- Advice
- Coaching
- Information and intelligence gathering

#### **5.2.9.1 Education and advisory work**

Providing education, advice and training delivered at the business establishment can be a key part of a Competent Authority's strategy to change behaviour and increase compliance in food businesses and should be encouraged whenever resources allow.

The circumstances below are examples of when the intervention should be recorded as advice and education for that visit to the food establishment. These include:

- Visit to premises to give advice and/or training.
- Visit to give advice on Safer Food Better Business (SFBB) or equivalent schemes.
- Visit to give advice on planning applications/building control applications.

Educational and advisory work can also be delivered away from the food establishments, for instance, through a business forum or seminar. It can be targeted at specific types of food businesses or around specific food safety topics. Details of such education and advisory work should be recorded in the free text box of the annual monitoring return sent to the FSA.

### **5.2.9.2 Information and intelligence gathering visits**

These are visits to confirm key information relating to the food establishment. They might be carried out under a scheme of information sharing between different regulatory agencies. The information or intelligence gathered should be reviewed by a competent authorised officer (See Chapter 4) who will assess whether further action is appropriate.

The circumstances below are *examples* of when the intervention should be recorded as information and intelligence gathering for that visit to the food establishment. These include:

- Visit to take sample/samples that will not be analysed/examined at an official laboratory but that do provide information on some aspect of the food business.
- Visit by a regulator other than the Competent Authority to gather intelligence/information on a food establishment.

### **5.2.9.3 Record(s) keeping**

The rationale, focus and use of alternative official controls to inspections should be documented in relevant files.

## **5.3 Frequency of Official Controls and Requirements of a Risk Based Approach**

### **5.3.1 Approach to enforcement – requirement for food safety management procedures based on HACCP principles**

Article 5 of Regulation 852/2004 requires all food businesses (except primary producers) to develop food safety management procedures based on HACCP principles. Recital 15 of the Regulation allows for a degree of flexibility in the application of these principles and implementation of such procedures, particularly in small, businesses where traditional HACCP might be difficult to apply.

#### **5.3.1.1 Enforcement approach**

Enforcement should be graduated and educative.

## **Regulation 852/2004**

Regulation 852/2004 requires food businesses to put in place, implement and maintain food safety management procedures based on HACCP principles. The FSA has produced guidance materials to help businesses comply with this legislation, which will be available through FSA's web site and competent authorities.

Food premises that present significant health risk conditions or an imminent risk of injury to public health should be subject to formal enforcement action to secure compliance and protect public health.

Where food premises do not present significant risks to public health, the aim must be to help the business improve standards of food safety and hygiene. In practice this means:

- ***Ensuring that significant hazards are understood and controlled, and where understanding and control is lacking – provide advice and guidance to FBOs adopt good practice to improve compliance with food law.***

In following an educative approach enforcers should concentrate on significant hazards to public health, ensuring that those responsible for food safety understand these hazards and know how to control and manage them.

A graduated approach should be based on the expectation that businesses improve their standards over time, taking account of the understanding they gain from the enforcement officer and other sources. Where a business does not improve – given reasonable time, after being offered guidance, hygiene improvement notices and other formal enforcement measures can be used.

### 5.3.1.2 Flexibility

Regulation 852/2004 is flexible, and requires food businesses to establish procedures in the business that control food safety hazards, and integrate these procedures with documentation and record keeping appropriate to the size and nature of the business.

Whilst larger, more complex businesses and businesses that have a high level of understanding of food safety management may choose to demonstrate compliance with the legislation by putting in place a traditional HACCP system, others may do so with simpler approaches that take account of this flexibility. This section describes this flexibility for small businesses.

Whilst some businesses will wish to follow the traditional 7-principle HACCP framework this may not be easily understood or implemented by others – particularly small businesses. There is no requirement to use this 7-principle approach as long as the same outcome is achieved – safe food being produced.

For enforcement, *in practice, compliance means:*

- *obtaining assurance that the person responsible for food safety understands significant hazards and has them under control e.g. by questioning;*
- *seeing that there are some written procedures that demonstrate how the business controls these hazards at all times;*
- *seeing some evidence that these procedures are followed, and that they are reviewed and kept up to date.*

Where a business is especially low-risk (e.g. sweet shop, greengrocer, market stall etc.) presenting only basic hygiene hazards, it may be sufficient that the business has a guide to good hygiene practice and understands and applies it. Documentation and record keeping may not be necessary.

The key points are:

- Flexibility applies to all food businesses
- The FBO or manager of a business should have the skills necessary to maintain a food safety management system proportionate to their business, and not simply be trained in HACCP principles. These skills can be gained in many ways; formal training is not the only route.
- Staff in a business should have the skills needed to undertake their duties and follow the food safety procedures in the business. Training for staff should be proportionate and reflect the flexibility guidance. Formal training may not be necessary to achieve the objective of having the required competencies. In practical terms, on the job training might be appropriate, attendance at a formal training event is not necessary.
- Monitoring key activities in the business (critical control points) need not be numeric and can be based on sensory observation, craft skills and supervision.
- Incident recording is an appropriate and proportionate form of record keeping in many businesses
- Corrective actions must supplement incident recording.



In order to help businesses develop appropriate procedures and to adopt a graduated approach to its enforcement, it is important to understand how to judge progress. The table below describes the components of the legislation and how an enforcement officer might judge progress towards complying with it in small businesses.

The table breaks down the components of the legislation into the standard 7 principles of HACCP, with some of the flexibility in the legislation identified. Although guidance materials may use this 7-principle framework, it is not necessary for this approach to be used. Provided the same outcome is achieved, safe food being produced, this can be achieved by substituting, in a simplified but effective way, some or more of the seven principles. This is clarified in Annex II of the Commission guidance on flexibility:

[http://ec.europa.eu/food/food/biosafety/hygienelegislation/guidance\\_doc\\_haccp\\_en.pdf](http://ec.europa.eu/food/food/biosafety/hygienelegislation/guidance_doc_haccp_en.pdf).

Similarly, the terminology or 'jargon' of HACCP need not be used, and may be confusing to some businesses

This breakdown is based on the FSA approach 'Safer food better business', but should be useable to identify compliance in a business using other similarly flexible tools, or where the business has devised its own procedures.

|    |  |
|----|--|
| 1. | <p><b>Identify any hazards that must be prevented eliminated or reduced;</b></p> <p>Mapping Hazard Analysis with tools such as flow-charts might not be suitable for all businesses. It is sufficient that the business has thought about its activities in a structured way. The effect of the analysis and the procedures produced should be to ensure that safe food is always produced.</p> <p>The traditional HACCP approach of controlling some hazards through prerequisite programmes of Good Hygienic Practice and others through the HACCP system might not be appropriate, particularly in small businesses where it is not readily understood. Whatever the format of the guidance, the business must be managing all significant hazards including those traditionally controlled through Good Hygienic Practice.</p> <p><b>For enforcement, in practice, this means:</b></p> <ul style="list-style-type: none"> <li>• <i>Being provided with sufficient evidence that the person responsible for food safety has thought about their business and identified significant hazards and knows how to control them – for some businesses it may be appropriate to follow standard advice from the FSA, industry guides, advice from trade bodies etc.</i></li> </ul> |
| 2. | <p><b>Identify the critical control points (CCPs) at the steps at which control is essential;</b></p>  |
| 3. | <p><b>and Establish critical limits at CCPs;</b></p>   |

|    |  |
|----|--|
|    | <p><b>Critical control points and their limits might not always be helpful ways of thinking about food safety for small businesses and they can instead identify generic controls - like thorough cooking, together with the ways of ensuring they know this has happened.</b></p> <p>The legislation is flexible in stating the requirement that establishing a critical limit does not always imply that a numerical value must be fixed. This is in particular the case where monitoring procedures are based on visual observation, for example a business might rely on sensory information such as colour change, juices running clear, stews bubbling etc. Businesses must understand how these methods control hazards and be sure they are effective. This validation can be done by the business themselves (on the basis of experience), or it might be appropriate to use pre-validated procedures that follow established best practice, produced by the FSA, trade bodies or others.</p> <p><b>For enforcement, in practice, this means:</b></p> <ul style="list-style-type: none"> <li>• <i>Being provided with sufficient evidence that the business is following procedures that include steps where the significant hazards are controlled – for many businesses it may be appropriate to follow standard advice.</i></li> </ul> |
| 4. | <p><b>Establish procedures to monitor the CCPs;</b></p> <p>Management of food safety through the procedures detailed above will need to be demonstrated. This can be shown in many ways. In some larger businesses this may be achieved by monitoring protocols and record keeping. In other businesses – particularly where the person responsible spends significant time in the food preparation areas, this can be demonstrated by their ability to supervise their operation – that their procedures are being followed. It will be important to establish that if the procedures are followed, safe food will result.</p> <p>Monitoring might in many cases be a purely sensory exercise, for example a regular visual verification of the temperature of cooked food by a colour change.</p> <p><b>For enforcement, in practice, this means:</b></p> <ul style="list-style-type: none"> <li>• <i>Being provided with sufficient evidence that the business is monitoring their procedures, either using physical checks such as noting temperatures or via sensory checks such as noting that a stew or sauce is bubbling. The person responsible for food safety should be able to explain the chosen method of monitoring.</i></li> </ul>   |
| 5. | <p><b>Establish corrective actions to be taken if a CCP is not under control;</b></p> <p>It is also important that the business knows what to do when things go wrong – the corrective action that needs to be taken.</p>  |

|    |  |
|----|--|
|    | <p><b>For enforcement, in practice, this means:</b></p> <ul style="list-style-type: none"> <li>• <i>Verifying that the person responsible for food safety management ensures that there is adequate supervision of staff and equipment so as to assure that procedures are being followed and safe food produced, and also questioning staff working in the area where the CCP exists, to provide assurance that HACCP based controls are understood, implemented and that when things go wrong appropriate action is taken.</i></li> </ul>  |
| 6. | <p><b>Establish procedures to verify whether the above procedures are working effectively;</b></p> <p>The business will need to demonstrate that its procedures are verified and reviewed and kept up to date, and that changes to menus, types of foods and cooking methods, and new equipment are reflected. In larger businesses, verification may be achieved by third parties, but for smaller businesses it is sufficient that the business carries out periodic reviews of its procedures and methods, and takes account of good practice and safe methods.</p> <p><b>For enforcement, in practice, this means:</b></p> <ul style="list-style-type: none"> <li>• <i>Seeing sufficient evidence that the procedures in a business are reviewed to ensure they continue to be appropriate and reflect changes in the business.</i></li> </ul>   |
| 7. | <p><b>Establish documents and records to demonstrate the effective application of the above measures;</b></p> <p>Documentation and record keeping are particularly onerous for smaller businesses and the legislation is clear that this should be well balanced and limited to what is essential with regard to food safety.</p> <p><b>For enforcement, in practice, this means:</b></p> <ul style="list-style-type: none"> <li>• <i>Seeing documentation that is up to date and describes the main procedures or methods used in the business to control the most important hazards;</i></li> <li>• <i>Seeing periodic records that represent evidence that these procedures were followed and that corrective action has been taken. This does not have to record every monitoring and supervisory activity and in small caterers, exception reporting will be acceptable.</i></li> <li>• <i>However for simple small businesses following good hygienic practice guides, documentation and record keeping might not be necessary.</i></li> </ul> |

### 5.3.1.3 Role of Competent Authorities

The flexibility means that all food businesses should be able to comply with the requirements of the legislation.

In accordance with the legislation, businesses are required to implement appropriate food safety management procedures. Different support models are appropriate for different types of business. Larger businesses and manufacturers may continue to develop and use traditional HACCP systems. The approach developed by the FSA, Safer food, better business (SFBB) is one approach considered suitable for use by small caterers.

Small food manufacturers represent a specific banding of businesses falling between those businesses where a SFBB type approach is suitable and those larger manufacturing business that have in-house technical competence on the traditional 7- principle HACCP approach.

In order to support small food manufacturing businesses, the FSA has developed MyHACCP, ([www.food.gov.uk/myhaccp](http://www.food.gov.uk/myhaccp)) a free interactive web tool, that guides food businesses through the process of identifying food safety hazards and controls and the production of a documented food safety management system based on HACCP principles.

Guidance for authorised officers on MyHACCP can be accessed at: <http://www.food.gov.uk/enforcement/enforcework/food-law/guidance-enforcement/myhaccp-guidance>

Proper implementation of the appropriate support model constitutes compliance with Article 5 of Regulation 852/2004.

Businesses should either have in place or be seen to be making progress toward having effective food safety management systems. Enforcement officers should try to educate and give businesses an understanding about what is required. For businesses that are not a threat to public health, it is expected that formal enforcement action should only be taken where the business has been:

- given reasonable opportunity to implement food safety management
- directed to appropriate training, if needed
- provided with appropriate guidance

The graduated approach should seek to educate businesses and improve their standards in realisable steps. Guidance material should be broken down in such a way that the enforcer and business can agree that by their next visit, so much progress should have been made. The FSA's advice, SFBB, is broken down into the 4Cs (cooking, cleaning, chilling and cross-contamination) and it may be appropriate to set a business one of these 'Cs' at a time. Other guidance material can also be divided into 'chunks' like this. Where fundamental skills are missing, enforcers should point businesses at sources of the competencies – guidance materials, books, courses etc. Enforcers should look to the business to make reasonable progress through the material and make appropriate changes in their practices

before the graduated approach progresses from education to more formal infraction methods.

A food safety management system should give assurance that the business knows how to produce safe food, has procedures in place that assure this, repeatedly does produce safe food and is capable of taking appropriate corrective actions when things go wrong. Whether a business has an effective food safety management system in place is a judgement for enforcement officers.

### **5.3.2 Alternative Enforcement Strategies**

Alternative enforcement strategies are methods by which low risk (hygiene category E and standards category C in accordance with the Food Law Code of Practice risk rating mechanism) establishments are monitored to ensure their continued compliance with food law. Alternative enforcement strategies are not appropriate for higher risk establishments or those subject to Regulation 853/2004.

Competent Authorities that decide to subject low-risk establishments to alternative enforcement strategies must set out their strategies for maintaining surveillance of such establishments in their Food Service Plan and Enforcement Policy. It is not intended to preclude inspection, partial inspection or audit at such establishments where any of these are the Competent Authority's preferred official control option, in which case the minimum frequency of intervention must be determined by the intervention rating.

An establishment must have been subject to an initial formal inspection, and have been subsequently risk rated in accordance with Chapter 5.6 of the Code of Practice, before it can be determined to be a low risk establishment and therefore appropriate for it to be included in the alternative enforcement strategy.

Low-risk establishments must be subject to an alternative enforcement strategy or other intervention, at least once during any three year period for hygiene or five year period for standards. Visits to check the information supplied, by an appropriately qualified officer, can be recorded as a verification visit.

Alternative enforcement strategies typically use questionnaires, with a sample of businesses receiving a follow up visit to verify the information provided.

Interventions might need to be carried out to establishments within the alternative enforcement strategies for various reasons. Triggers for an alternative intervention may be:

- Consumer complaint
- Planning or building regulation applications
- Infectious disease notification
- Changes in activities or management
- Non-return of questionnaire

### **5.3.2.1 Elements of an Alternative Enforcement Strategy**

An Alternative Enforcement Strategy may consist of any, all or a combination of the following options:-

- Questionnaires
- Surveys
- Project Based Inspections
- Customer Complaint Response
- Intelligence Gathering Visits
- Random % of Premises Subject to Inspection

### **5.3.3 Food Hygiene Intervention Frequency**

#### **5.3.3.1 Impact of Food Information Regulations 2014 on the Food Law Code of Practice food hygiene scoring system (and FHRS ratings)**

The purpose of the food hygiene scoring system at Chapter 5 of the Food Law Code of Practice (England) 2015 is to determine planned intervention frequencies at all food establishments on the basis of assessment of compliance with food hygiene law. 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.

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. Such consideration should not be the overriding factor but rather should contribute to the overall assessment of confidence in management.

### **5.3.4 Food Standards Intervention Frequency**

#### **5.3.4.1 Additional advice for risk rating food standards premises to take into account potential risk of chemical contamination of food**

Chapter 5.6.2 of the Food Law Code of Practice contains the Food establishment intervention rating scheme for Food Standards. Competent Authorities that are responsible for enforcing food standards law should determine the food standards intervention frequencies of food businesses within their areas using the risk assessment criteria in this Intervention Rating Scheme, in order to determine their planned food standards intervention programmes.

At present under the Food Standards Intervention Rating Scheme there is no scope for determining the risk from potentially hazardous chemical contamination in particular with respect to imported foods and food ingredients.

Therefore when considering under the Food Standards Scoring Scheme Part 1 “The Potential Risk” Table A “Risk to Consumers and/or Other Businesses”, Officers should consider allocating a top score of 30 points for:

“Food businesses including manufacturers and importers which handle imported foods or food ingredients which might be subject to increased risk of chemical contamination”.

### **5.3.5 Primary Production**

#### **5.3.5.1 Matters relating to primary production assurance schemes**

The following assurance scheme standards have been evaluated against the requirements of the hygiene legislation for primary production and are currently considered to meet those requirements. The standards are operated by Assured Food Standards (AFS), who trade as Red Tractor. They are also covered by a Memorandum of Understanding (MoU) between AFS and the FSA. The MoU enables information exchange between ASF and Competent Authorities on membership details, which can be used to inform decisions on inspection frequency. Copies of the MoU can be found on the FSA website at: <http://www.food.gov.uk/enforcement/enforcework/feedlawcop>

Red Tractor Standards:

- Beef & Lamb
- Dairy
- Crops and Sugar Beet
- Pigs
- Poultry (all schemes)
- Fresh Produce

## **5.4 Inspection of ships and aircraft**

### **5.4.1 Introduction**

This section supplements the information supplied in the corresponding section in the Code of Practice to enable authorised officers to consider additional aspects relating to the inspection of ships and aircraft. An inspection template for aircraft, which may be adapted, where appropriate, provided that the procedures outlined in the Code are not overlooked, this can be found on the Knowledge Hub (<https://khub.net/>).

### **5.4.2 General**

The types of hazards that may be present in the shipboard/aircraft environment are vastly different to those that might be found in fixed premises.

Examples include:

- Hazards resulting from the various sources of water and its storage in onboard tanks;
- The 24 hour nature of operations onboard ships and aircraft;
- The multi-cultural and international nature of crews;
- The availability of provisions only when the vessel/aircraft is in port;
- The restricted storage space available for provisions (dry, chilled and frozen);
- The age and conditions on board;
- The fixed layout of food production facilities which cannot be expanded or changed due to structural and safety issues.

The shipboard environment is essentially a closed community for long periods of time during voyages, which presents particular problems in relation to the hazards associated with food production and the potential results of contamination. In large passenger ships, for example, the presence of food contaminated by food poisoning bacteria or toxins could be devastating, amongst both passengers and crew. Even on smaller vessels, or vessels with smaller crews, an outbreak of food poisoning could have a significant impact on the ability to sail the vessel safely because critical members of the crew may be incapacitated.

The scale of food production on board vessels varies greatly, from large passenger vessels and cargo vessels with large crew and passenger numbers (e.g. some cruise liners over 3,000 passengers and 1,200 crew) to smaller vessels crewed by 10 to 15 personnel.

Aircraft meals are mainly, but not exclusively, prepared prior to departure, some of which might be for return flights.

During any inspection of a ship or an aircraft, authorised officers must be aware of their own health and safety and have regard to any requirements of the port authority and the shipping operator or airline.

In many cases it would not be necessary to inspect aircraft on a regular basis, if sufficient information has been obtained from the airline and/or relevant Home Authority (HA)/Primary Authority and has been verified.



When the service of notices is considered, it should be borne in mind that through case law, “proprietor” does not necessarily mean “owner”, as it is the person who carries on the food business. It might be the company running a shipping operator or it could be a company hired to operate the food business. Authorised officers will need to establish who the food business operator / food business proprietor is in each case.

Inspection reports should be copied to any food safety advisers employed by the shipping operator or airline.

#### **5.4.3: Catering Waste**

The disposal of [international catering waste](#) to landfill is regulated by the Animal By-Products (Enforcement) Regulations. DEFRA has identified significant risks to animal health if this waste is not dealt with effectively at landfill. Specific measures are needed to ensure that disease is not introduced into the UK from landfill sites, which receive this waste. A mechanism for suspending or amending the conditions of a landfill site approved to deal with such waste is in place, in the event that the conditions of approval are not observed.

#### **5.4.4: Other issues – aircraft**

Airlines should be encouraged to adopt, where necessary, approved codes of practice, for example, the ITCA<sup>17</sup>/IFSA World Food Safety Guidelines, and to develop in-house supplier audits and aircraft audits and to make any reports available to the authorised officer.

Such reports, where available, should form part of the authorised officer’s initial checks. Authorised officers should also give consideration, where appropriate, to these Guidelines, which can be found at the following link: <http://www.ifsanet.com/Default.aspx?tabid=236>.

Flight caterers or secondary food suppliers should be requested to make details of meal ingredients available to their airline customers. Relevant cabin crew should have access to this information and be able to pass it on for the benefit of passengers who have allergies or food intolerances.

Authorised officers should be aware that there have been reported outbreaks of foodborne illness affecting the crew of aircraft, and airline policies might include the requirement for crew members to eat at different times to the passengers and from different menus.

Inspections of aircraft may be undertaken at the maintenance base, taking account of any documentation on, for example, food supply specifications, cabin crew training and food temperature control that is supplied by the airline or HA.

When it is necessary to board an aircraft, the actual time spent on board should be as short as possible, as most of the above issues should be standard operating

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<sup>17</sup> The International Flight Caterers’ Association (IFCA) became The International Travel Catering Association (ITCA) in 2005

procedures included in the airline's documentation. However, if there are any causes of concern relating to the above, the authorised officer should notify the relevant company and HA, if designated, that increased surveillance may be undertaken, e.g. assessment of galley cleanliness, increased water sampling for analysis/examination, etc.

Delays to aircraft are costly. Aircraft operations should therefore not be interrupted unless there is an imminent risk to the health of passengers or crew. If flights are in transit, inspections should be undertaken only if absolutely necessary, based on background information relating to the specific type of aircraft, company policy, flight caterer, temperature control, etc. Authorised officers should also consider the practicalities of their inspection schedule and endeavour to work with the relevant crew/ground staff to avoid unnecessary difficulties, and bear in mind the primary objective of an airline is the safety of the aircraft, passengers and crew.

The Association of Port Health Authorities has published "*Airline Catering Guidance for Inspectors*".

#### **5.4.5: Other issues – ships**

If appointed, the HA for the shipping operator should ensure that all relevant documentation is made available to it, (see below for examples of relevant documentation), for liaison with and the information of other relevant Competent Authorities. For military ships see paragraph 5.5.4 in the Code of Practice.

Recipient Competent Authorities should use the previous inspection report to ensure that: (a) if necessary, follow-up inspections are undertaken at that time and/or (b) inspections are not carried out at a frequency of greater than annually, unless there is clear justification for doing so.

It is also good practice to send a copy of the report to the UK Competent Authority which had carried out any previous inspection, in order that they may see what action, if any, had taken place as a result of their previous inspection of the vessel.

Ships may be inspected for training purposes so long as the purpose of the inspection is made clear to the Master and they agree to such an inspection taking place.

Examples of relevant documentation:

- Food specifications/suppliers;
- Water sample results;
- Hazard analysis (HACCP);
- Food temperature records;
- Food Handler Training Records.

## **5.5 Import Controls**

### **5.5.1 Guidance for Competent authorities on import of food from third countries**

Significant volumes of food are routinely imported into the UK and it is important that effective arrangements are in place in Competent Authorities to check imported food both at points of entry and inland. Competent Authorities must have regard to the general guidance on enforcement contained in the Code of Practice in relation to their imported food enforcement control arrangements.

All Competent Authorities have responsibilities for imported food controls. The purpose of this guidance is to set out and assist competent authorities on the level and type of activity to achieve effective and consistent enforcement on imported food.

The guidance also focuses on the principal legislation relating to the import of food not of animal origin (FNAO). FNAO import controls were harmonised at EU level by Regulation (EC) No 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules. The provisions of this Regulation are directly applicable but are given effect at national level by the Official Feed and Food Controls (England) Regulations 2009 (as amended), and parallel legislation in Scotland, Wales, and Northern Ireland.

#### **5.5.1.1 Scope**

The scope of this guidance extends to imported FNAO and illegally imported products of animal origin (POAO). However this guidance does not cover control activities for POAO at Border Inspection Posts (BIPs), where central guidance produced by DEFRA is available in the BIP manual at

<https://www.gov.uk/government/publications/border-inspection-post-bip-manual>

Please note: Border Inspection Posts (BIPs) may be situated at seaports, airports or international rail links, and are designated points of entry for POAO from third countries (those outside the EU).

The guidance does however provide enforcement advice for Competent Authorities relating to illegally introduced POAO. The guidance covers imported food control only.

Except where a specific distinction is made this guidance applies to all Competent Authorities, both inland and at points of entry, including Port Health Authorities (PHAs). For the purpose of this guidance “imported food” means food imported into the UK from outside the European Union (“third countries”); and “point of entry” means a seaport, airport or international rail link at which imported food is introduced into the UK.

Competent Authorities (including PHAs) with a point of entry provide the first line of control on imported food to ensure it is safe and complies with EU and UK

requirements. However, it is important that controls are also in place at External Temporary Storage Facilities ( ETSF), ships suppliers, international rail terminals, and other premises inland, as significant amounts of FNAO are not required to undergo checks at points of entry (specifically non-restricted FNAO as all restricted FNAO would be subject to controls) and there is also the possibility that POAO may have entered the UK illegally.

Please note: External Temporary Storage Facilities (ETSFs) are Customs approved warehouse facilities whereby imported goods are held in temporary storage under Customs control. They are intended to facilitate entry of goods for Customs purposes and may be some distance from the seaport/airport, and so may therefore fall under the jurisdiction of another local authority.

Further details of the roles and responsibilities of PHAs, Competent Authorities and other Government Agencies and Departments can be found in the FSA's Resource Pack for Inland Enforcement of Imported Feed and Food Controls which can be accessed using the link:

[http://www.food.gov.uk/foodindustry/imports/enforce\\_authorities/resourcepack](http://www.food.gov.uk/foodindustry/imports/enforce_authorities/resourcepack)

This resource pack also provides guidance for inland authorities on the effective monitoring of imported food.

Guidance is also available for those authorities with points of entry through which occasional and/or low levels of imports of feed and food of non-animal origin are received. This guidance can be accessed at:

[http://www.food.gov.uk/business-industry/imports/enforce\\_authorities/smaller-seaports-and-airports/](http://www.food.gov.uk/business-industry/imports/enforce_authorities/smaller-seaports-and-airports/)

Guidance on effective imported food control for local authority food services, which draws on experience gained from FSA audits, is available at:

[http://www.food.gov.uk/business-industry/imports/enforce\\_authorities/](http://www.food.gov.uk/business-industry/imports/enforce_authorities/)

## **5.5.2 Status of this Guidance**

This document should be considered as centrally issued guidance for the purpose of the Framework Agreement on Official Feed and Food Controls by Competent Authorities which can be found at:

<http://www.food.gov.uk/enforcement/enforcework/frameagree/>

Amendments have been made to the Standard in the Framework Agreement to clarify its application to imported food control.

This guidance should also be read in conjunction with the Food Law Code of Practice which provides direction and guidance on the LA approach to enforcement generally.

### **5.5.3 Imported Food Legislation – Food Not of Animal Origin (FNAO)**

#### **5.5.3.1 Regulation (EC) No 882/2004**

This provides EU-wide harmonised rules for import controls of food from Third Countries not already covered by Directive 97/78/EC (POAO Veterinary Checks regime).

#### **5.5.3.2 The Official Feed and Food Controls (England) Regulations 2009 (as amended)**

The Official Feed and Food Controls (England) Regulations 2009 (as amended) give effect to the import provisions of Regulation 882/2004 in England only. Parallel legislation is in place in Scotland, Wales, and Northern Ireland.

The Official Feed and Food Controls (England) Regulations 2009 (as amended) include a mechanism (regulation 35) for ensuring that where there is a serious risk to animal or public health, control measures may be put in place. In particular, it may be used to ensure that Emergency Decisions made at EU level are implemented without delay. It does so by giving the FSA powers to make declarations regarding import conditions for particular products. These conditions can apply with immediate effect.

#### **5.5.3.3 Other legislation**

For certain areas, for example, contaminants, there are specific EU harmonised requirements for foods which can be applied at points of entry as well as inland. These EU requirements are implemented in the UK by separate legislation but the powers to deal with non-conforming food at import are those contained in the Official Feed and Food Controls (England) Regulations 2009 (as amended). Separate and detailed European Commission guidance on the contaminants legislation is available at:

[http://ec.europa.eu/food/food/chemicalsafety/contaminants/index\\_en.htm](http://ec.europa.eu/food/food/chemicalsafety/contaminants/index_en.htm)

#### **5.5.3.4 Food of ‘known or emerging risk’**

Regulation 882/2004 (Article 15(5)) provides that the Commission may issue a list of FNAO of ‘known or emerging risk’. This has occurred with the implementation of Regulation (EC) No 669/2009 (as amended) regarding the increased level of official controls on imports of certain feed and food of non-animal origin. These products are identified on the basis of ‘known or emerging risk’, and are subject to increased import controls at designated points of entry (DPEs). A list of current FNAO identified as being of ‘known or emerging risk’ and therefore subject to checks, can be found at:

[http://www.food.gov.uk/foodindustry/imports/banned\\_restricted/restricted\\_foodstuffs](http://www.food.gov.uk/foodindustry/imports/banned_restricted/restricted_foodstuffs)

The frequency and nature of such checks are specified by the European Commission when products with a risk from particular third countries are identified. The enhanced controls provided for by this Regulation include; prior notification by means of a Common Entry Document (CED), import through DPEs (that must have particular facilities available and be approved by the FSA), and specified documentary, identity and physical checks (which are undertaken at these points of entry).

Separate Guidance documents on this Regulation have been produced for enforcement officers and FBOs. They are available on the FSA's website at:

<http://www.food.gov.uk/multimedia/pdfs/ec6692009enforcers1003.pdf>

(Advice for enforcement officers)

<http://www.food.gov.uk/multimedia/pdfs/fbohighriskguidance1003.pdf>

(Advice for FBOs)

The Commission has also produced guidance at:

[http://ec.europa.eu/food/safety/official\\_controls/legislation/imports/non-animal/docs/food\\_official\\_control\\_guidance\\_document\\_669-2009\\_en.pdf](http://ec.europa.eu/food/safety/official_controls/legislation/imports/non-animal/docs/food_official_control_guidance_document_669-2009_en.pdf)

#### **5.5.3.5 EU Emergency Measures**

The European Commission imposes special conditions governing the import of certain FNAO from particular third countries where specific hazards are a risk to food safety. These special conditions can differ depending on the measure but may include that specified products can only enter the UK through specific ports or airports following prior notification and may require that they must be accompanied by a health certificate and results of sampling and analysis.

Further information on such measures can be found on the FSA's website at:

[http://www.food.gov.uk/business-industry/imports/banned\\_restricted](http://www.food.gov.uk/business-industry/imports/banned_restricted)

#### **5.5.3.6 Third country pre-export checks**

Regulation 882/2004 includes provisions for the Commission to grant third countries reduced import checks on imported FNAO. Such arrangements will be restricted to those countries where the Commission is satisfied that effective official controls are in place to carry out the appropriate pre-export checks immediately prior to export to the EU. Details of relevant products and third countries will be notified to Competent Authorities, as appropriate.

This status can be repealed by the Commission in the light of information or experience. Where such arrangements are in place Competent Authorities at points of entry should check relevant certification to validate such assurances. Particular consideration must be given to consignments accompanied by certification from non-accredited laboratories. Where Competent Authorities have concerns relating to any

such arrangements based on checks carried out they must notify the FSA as soon as possible.

#### **5.5.4 Service planning**

The Framework Agreement on Official Feed and Food Controls by Local Authorities includes service planning guidance. Section 2.3 (“Scope of the feed and food service”) and Section 2.4 (“Demands on the feed and food service”) provide for Competent Authorities to set out the scope of the responsibilities and service provided and to describe any external factors that might impact on their service. Competent Authorities should include in these sections imported food responsibilities and the control arrangements in place.

Competent Authorities with a point of entry should include details of resources allocated for imported food control work in their service plans.

#### **5.5.5 Documented policies and procedures**

All Competent Authorities should ensure that their written policies and procedures cover imported food having regard to the work that might reasonably be anticipated within the administrative district and jurisdiction of the authority.

Procedures relating to examination of imported food including deferred examinations under The Official Feed and Food Controls (England) Regulations 2009 (as amended) should cover both food safety and food standards issues, where applicable.

Such procedures might be audited by the FSA or the Food and Veterinary Office (FVO) of the European Commission and should be suitable and sufficient for these purposes. They should make public, information on their control activities and their effectiveness.

#### **5.5.6 Authorisation**

All Competent Authorities should ensure that at least one officer is properly authorised to undertake imported food control work and related enforcement action. One of the key issues to be considered in any review of authorisations is the identification of the specific legislation where enforcement powers originate. This will affect the content and wording of authorisation documentation.

For food safety and food standards matters this should include authorisation under the Food Safety Act 1990 and under hygiene and processing Regulations issued under it, including any relevant legislation such as The Official Feed and Food Controls (England) Regulations 2009 (as amended).

Officers should also be authorised to enforce relevant Regulations issued under the European Communities Act 1972 (e.g. The Food Safety and Hygiene (England) Regulations 2013). However, the European Communities Act does not contain the

specific enforcement powers, as its primary function is to provide a mechanism by which Regulations can be enacted. Powers of enforcement for Regulations made under the Act are usually contained in the Regulations themselves. Therefore, the FSA's view is that all Regulations relevant to imported food controls should be specifically referred to in authorisation documents, including officers' credentials. For example (note this list is not exhaustive), include:

- the Trade in Animals and Related Products (TARP) Regulations 2011
- the Official Feed and Food Controls (England) Regulations 2009 (as amended)

The FSA's view is that officers do not need to be specifically authorised to enforce declarations made under Regulation 35 of the Official Feed and Food Controls (England) Regulations 2009 (as amended) if already authorised under these Regulations.

Competent Authorities might also wish to consult their own legal advisors on this matter. See Chapter 4 of the Code and this Practice Guidance.

#### **5.5.7 Qualifications/experience of authorised officers**

Officers authorised to undertake imported food controls work and enforcement action must be appropriately qualified and competent to carry out the range of tasks and duties they are authorised to perform, in line with the relevant requirements of the Code.

For competency requirements, please see the relevant section in chapter 4 of the Code, and chapter 4 of this Practice Guidance.

#### **5.5.8 Information**

Competent Authorities with a point of entry in their territory should maintain up to date information on:

- the port operator
- access to port/Customs areas, including External Temporary Storage Facilities (ETSF)
- stakeholders, including import agents and airlines/shipping operators
- trade type (volume, nature, and trade routes)
- facilities where imported food inspection can be carried out and arrangements for storage of detained/seized goods. DEFRA have issued further specific advice on operating procedures for sharing facilities at BIPs in their BIP Manual which can be found at: <https://www.gov.uk/government/publications/border-inspection-post-bip-manual>
- equipment available for carrying out inspections and sampling of imported food.
- details of appointed and specialist laboratories for analysis and/or examination of samples who are able to provide an appropriate service in particular, in relation to the time-scale of analysis / examination and issuing of the results.
- health and safety requirements



- security requirements

See 2.3.1.3 of Food Law Code of Practice for information on the communication between Competent Authorities for Competent Authorities at Points of Entry , ETSF or international rail terminal

Contact details and information on the roles and responsibilities of relevant central government departments and other organisations can be found in the [FSA's Resource Pack for Inland Enforcement of Imported Feed and Food Controls](#)

Where relevant, Competent Authorities should ensure that their officers have access to secure areas under the Aviation and Maritime Security Act 1990. Information on this can be obtained from the port operator.

## **5.5.9 Records**

### **5.5.9.1 Identifying and recording food importers**

All Competent Authorities should ensure that food premises and traders in their district which import food are identified and recorded in premises/trader databases and included in inspection programmes as appropriate.

Completed food premises registration forms can be used to assist identification of food premises as being used for imports.

For the purposes of identifying and recording food businesses and systems falling under the official controls, Competent Authorities / PHAs should refer to the scope of Regulation (EC) No 882/2004 as detailed in Articles 14 and 15. Relevant activities should be identified on the appropriate files together with an indication of the type and origin of foods being imported.

To help identify food importers, Competent Authorities may conduct desktop exercises using such information sources as local knowledge, telephone directories or internet searches. Information from PHAs might also assist this process. Records can be refined further after visits to food premises and/or communications with food business operators and other local government departments as part of outline programmed activities.

### **5.5.9.2 Records of consignments and examinations**

Competent Authorities with a point of entry should ensure that, where available, information relating to the number and type of food consignments is maintained together with relevant information on the checks made to determine compliance with legal requirements. Where information is recorded, the level of information about food examinations (including examinations undertaken at ETSF or international rail terminals) and deferred examinations should provide consignment traceability and permit effective internal monitoring. This information should include any identifying reference for the consignment examined, country of origin, information on the nature

of the food and the checks carried out and, where any enforcement action or sampling has been undertaken, the details of the agent and/or consignor/consignee. Records of sampling checks and records relating to emergency controls should be held for up to three years.

Please note: A 'consignment' is a quantity of food or feed of the same type, class or description covered by the same document(s), conveyed by the same means of transport and coming from the same third country.

### **5.5.9.3 Arrangements for points of entry without permanent Competent Authority presence**

The Import controls at smaller seaports and airport' guidance provides further advice on imported food control at points of entry through which occasional and/or low levels of consignments of FNAO are received. This guidance can be accessed at:

[http://www.food.gov.uk/business-industry/imports/enforce\\_authorities/smaller-seaports-and-airports/](http://www.food.gov.uk/business-industry/imports/enforce_authorities/smaller-seaports-and-airports/)

Also see 5.4.2 of the Food Law Code of Practice

## **5.5.10 Reporting and notification arrangements**

### **5.5.10.1 Nominated officer for imported food controls**

See 2.3.1.6 of the Code. The details of the nominated officer or changes to the nominated officer should be notified to the FSA's Imported Food Team, who can be contacted by e-mail: [imported.food@foodstandards.gsi.gov.uk](mailto:imported.food@foodstandards.gsi.gov.uk).

### **5.5.10.2 Monitoring returns**

All Competent Authorities should provide data on imported food enforcement activity via the Local Authority Enforcement Monitoring System (LAEMS). This includes both points of entry, whether formally a PHA or not and all inland authorities. Where samples are taken of imported food, even at catering or retail level, a record should be made in the samples section of the imported food part of LAEMS. Guidance on the completion of imported food returns on LAEMS is available on the FSA website at:

<http://www.food.gov.uk/enforcement/auditandmonitoring/laems/laemsimportguide>

Competent Authorities should also supply any other information reasonably requested by the FSA. This can relate to information about the import of specific food or food products from certain countries. It might relate to information required by the European Commission in connection with emerging animal/public health issues or for inclusion in the National Control Plan or annual reports that the UK produces in accordance with the requirements of Articles 42 and 44 of Regulation 882/2004.

Commission emergency measures also normally require monitoring returns to be made to the Commission through the FSA, as does Regulation 669/2009 (as amended).

### **5.5.10.3 Notification of food hazards or incidents**

See 2.3.1.4 of the Code. The Incidents Branch can be contacted by e-mail: [foodincidents@foodstandards.gsi.gov.uk](mailto:foodincidents@foodstandards.gsi.gov.uk) or on 020 7276 8448

All Competent Authorities should notify the FSA of a serious localised incident or a wider problem under the Food Alert System as soon as a decision has been taken that one has occurred. This must be done at the earliest opportunity and by the quickest available means using the appropriate contact details and reporting arrangements set out in section 2.2.2 ('Food Alerts') of the Code and any subsequent documents.

### **5.5.10.4 Notification of illegal imports of POA**

A notification should be made to Defra ([ITAP@defra.gsi.gov.uk](mailto:ITAP@defra.gsi.gov.uk)) whenever illegally imported POAO are seized under Regulation 19 of the TARP Regulations 2011. Competent Authorities should report the seizures to Defra using the IIT1 form. The reporting of seizures by Competent Authorities/PHAs requires the completion (preferably electronically) of a common form (IIT 1 (4/08)), which is then sent by e-mail for DEFRA to record the appropriate information required. However, the option remains for the form to be completed manually, if that method is preferred, and sent to DEFRA by fax/post. Details of where to e-mail/fax/post the form is included on the form. The form is located on the secure parts of the following websites. Please note Competent Authorities will need to obtain the necessary password permission in order to access these areas from.

The Association of Port Health Authorities: <http://www.porthealthassociation.co.uk>  
CIEH: <http://www.ehcnet4.net/govt/defra/iit/iitrept.php>

The information provided in this form is also shared with the FSA's Food Fraud team (email: [foodfraud@foodstandards.gsi.gov.uk](mailto:foodfraud@foodstandards.gsi.gov.uk)).

Please note: Where illegally imported POAO is found at a point of entry, this is dealt with by the Competent Authority at the point of entry. If illegally imported POAO is found outside of the BIP it is instead referred to Border Force for their action.

### **5.5.11 Liaison/referrals**

Whenever inland Competent Authorities come across problems with imported food, where the point of entry for the goods can be ascertained and similar problems are likely to be found in other imported consignments, the Competent Authority at the point of entry should be informed as soon as possible, to help target their future surveillance activities.

In certain circumstances, it may be necessary for Competent Authorities covering points of entry to refer imported food matters to inland Competent Authorities. This

would include situations where inland supervision of consignments is required and where checks at the point of entry reveal food safety or food standards concerns that are most appropriately dealt with by the inland Competent Authority.

Examples include where:

- a consignment of FNAO, which is subject to emergency controls or other restrictions, has been illegally imported e.g. without being presented to the Competent Authority at the point of entry for the required checks to be carried out
- the Competent Authority at the point of entry is aware that illegal imports of POAO might have been distributed
- checks on imported food reveal labelling issues which cannot be enforced at time of import
- examination under The Official Feed and Food Controls (England) Regulations 2009 (as amended) has been deferred
- unsatisfactory test results are received for samples taken for routine surveillance but meanwhile the consignment has been released from the port
- analysis indicates, for example, that nuts are not suitable for human consumption but are referred for feed use

Wherever practicable, inland Competent Authorities should agree to assist with these referrals and respond as appropriate without undue delay and provide feedback to the Competent Authority at the point of entry on the outcome. Records of such referrals and details of any action taken should be maintained by all Competent Authorities involved.

It might also be necessary for the FSA to refer matters concerning illegally imported POAO to inland Competent Authorities. This information will normally be received from Border Force where they have intercepted illegal imports destined for commercial premises. Competent Authorities should respond to these referrals as soon as possible and where requested provide feedback directly to Border Force. Competent Authorities should maintain records of action taken.

### **5.5.12 Inland inspection of imported food**

See 5.4 of the Food Law Code of Practice

The Official Feed and Food Controls (England) Regulations 2009 (as amended) also cover semi-finished products, materials and articles in contact with food, pesticides, and labelling issues.

When considering specific imported food inspection programmes local Competent Authorities should not simply focus on food businesses that specialise in the supply of food to specific minority groups. They should consider food businesses within their area that routinely import food from third countries, in particular those premises that are the first destination after import. Such premises are likely to include local food manufacturers and warehouses. Any inspection programme should also be informed by food alerts and the premises compliance history.

In addition to assessing fitness for consumption, reasonable steps should be taken to check the legality of the importation of any POAO and FNAO from a third country. The FSA's Resource Pack for Inland Enforcement of Imported Feed and Food Control (see 5.4.1 of the Code) provides detailed advice on points to consider when investigating the legitimacy of food imports. For further information about imported food controls and the types of food imports and countries of origin where there are prohibitions and restrictions see: [www.food.gov.uk/imports](http://www.food.gov.uk/imports).

#### **5.5.12.1 Deferred examination of FNAO – inland controls**

See section 5.4.4 of the Code and 5.5.14.4 of this Practice Guidance. Inland LAs should ensure that any available information on imported food, which is sampled, detained, seized or destroyed, wherever practicable is recorded in relevant in-house records or databases.

### **5.5.13 Sampling of Imported Food**

#### **5.5.13.1 Considerations for sampling**

Routine imported food sampling considerations, for Competent Authority surveillance and enforcement purposes, should take account of:

- any statutory requirements for sampling laid down in European Commission Decisions or Emergency Control Regulations (usually this will occur at a point of entry)
- any agreed LGA/ FSA sampling programmes
- any sampling required following a Food Alert or RASFF notification
- information from any EU, LGA, regional liaison group, local or other sampling survey
- any imported food where there is no history or information on the product

Commodities sampled under EU Emergency measures should be detained until the enforcing Competent Authority receives the results unless otherwise stated in the implementing rules. This type of sampling occurs at the point of entry (~~BIP~~) as the products will not usually be permitted clearance for free circulation until satisfactory laboratory analysis is confirmed.

Competent Authorities should also take into account local priorities, including consumer complaints relating to imported food, and their local business profile when considering sampling, and include these in their sampling programmes. Sampling policies and programmes should be reviewed from time to time to assess the need to include national or regional imported food priorities/surveys and the UK's National Control Plan.

Competent Authorities should take into account any specific central guidance on sampling or other matters set out by the FSA or LGA.

#### **5.5.13.2 Qualifications/experience/training of officers carrying out sampling**

Samples for microbiological examination or chemical analysis should be taken by authorised officers, having been properly trained in the appropriate techniques including relevant EU protocols and FSA guidance, and being competent to carry out the duties assigned to them. Sampling should only be undertaken by officers meeting the relevant qualification and experience requirements described in the Code. See chapter 4 of this Practice Guidance for more information.

### **5.5.14 Food of Non-Animal Origin (FNAO)**

This section applies to Competent Authorities with a point of entry, checks undertaken at ETSF or international rail terminals, and deferred examinations under The Official Feed and Food Controls (England) Regulations 2009 (as amended)..

The advice in this section also applies to composite products which contain a small amount of product of animal origin and which are outside the Veterinary Checks regime covered by Directive 97/78/EC.

#### **5.5.14.1 Identification**

It is important that Competent Authorities with a point of entry are aware of the volume and nature of foods entering the port. Competent Authorities overseeing seaports where enquiries with the port operator indicate that food is imported should check 100% of ships' manifests (a document/computer file describing all cargo carried on a ship, cargo train or aircraft) for imported food. 100% checks should continue until enquiries with the port operator reveal no food imports for a continuous period of three months, and further food imports are not reasonably foreseeable. Thereafter contact should be made with the port operator at least once every three months to check the status of food imports.

Competent Authorities overseeing airports, ETSF and international rail terminals must set up, implement and maintain documented procedures on the arrangements in place to identify imported food. Where possible, airline manifest documents should be checked.

This might include:

- liaison with HMRC regarding food imported directly from third countries or via other Member States or ports under T1 arrangements (a transit declaration made to HM Revenue and Customs. T1 signifies those goods that are not in free circulation i.e. still subject to Customs control)
- liaison with transit shed operators to obtain copies of cargo manifests
- random checks of ITSF (Internal Temporary Storage Facilities – formerly known as 'transit sheds')/ETSF transit sheds/ERTS handling imported food with a view to verifying the information arrangements in place
- informal notification systems in co-operation with importers, their agents or airlines and ITSF operators.

#### **5.5.14.2 Prohibition**

It is an offence under regulation 28 as read with regulation 41 of The Official Feed and Food Controls (England) Regulations 2009 (as amended) for any person to import a product that does not comply with the food safety requirements as set out in EU Food Law Regulation (EC) No 178/2002 or with the requirements of Articles 3 to 6 of Regulation (EC) No 852/2004. This prohibition applies to products being imported either direct from a third country or from a third country through another EU Member State.

#### **5.5.14.3 Examination**

Imported food should be subjected to risk based checks. Regulation 882/2004 outlines the requirements for documentary checks, random identity checks and where appropriate physical checks. The checks that are conducted will vary slightly

depending on whether these take place at the point of entry or whether these are inland.

Checks on imported food should take into account any guidance issued by the FSA. Such guidance might cover foods for which specific documentary checking regimes have been laid down or foods with restricted points of entry and/or testing regimes laid down in Commission Decisions or Regulations. Competent Authorities with points of entry which are not designated to handle certain FNAO products subject to Emergency Control Decisions and Regulations must ensure relevant port operators, local HMRC, or agents/importers are aware of any restrictions. Arrangements must also be in place to deal with any such consignments which arrive at the point of entry.

A systematic documentary check does not imply 100% checking of documents but there must be risk based planned arrangements in place. However, documents required to accompany any consignment by food law, such as under Emergency Control measures, are likely to require 100% checking. At the point of entry the documentation that would be checked, would consist of for example, health certification and laboratory reports and analysis. However, inland, documentary checks may involve, for example, checking CEDs/CVEDs and clarifying that the consignment was imported by the correct means.

An identity check involves checking that the consignment corresponds with the documentation that is provided. At the point of entry the checks would be to ensure the product tallies up with all of the documentation provided, for example, checking batch codes for the products. An identity check conducted inland would be closely linked with the documentary check, but may include verifying the batch codes and ensuring that the identity of the product can be confirmed. This may also assist with identifying and verifying whether the product has been legally imported.

Physical checks might include: checks on the food itself, checks on the means of transport, checks on the packaging, checks on the temperature controls, organoleptic testing, and chemical or microbiological examination, or any other check necessary to verify compliance with EU food safety requirements. Such checks may also take into account any guarantees that the competent authority of the third country has given and which have been assessed by the European Commission. The arrangements and follow up actions should be set out in relevant service policies and procedures.

For physical checks conducted at both points of entry and inland, these should be carried out under appropriate conditions inclusive of standards of hygiene and at a place with access to appropriate control facilities allowing investigations to be conducted properly. Samples should be handled in such a way as to guarantee both their legal and analytical validity.

Where an authorised officer reasonably requires facilities and assistance to carry out checks on a product, the importer may be asked to provide these. The Official Feed and Food Controls (England) Regulations 2009 (as amended) also allow an authorised officer to require that physical checks and identity checks take place at a specified place, where necessary for proper examination.



Checks should be informed by:

- statutory requirements for documentary checks and associated sampling laid down in relevant Emergency Control Decisions and Emergency Control Regulations,
- the risk associated with different types of food safety issues,
- knowledge of the product e.g. new or unusual,
- any requirements following a Food Alert or RASFF notification,
- the history of compliance for the product, country of origin and exporter/importer
- the controls that the food business operator importing the food has carried out,
- any guarantees that the competent authority of the third country of origin has given under the third country pre-export checks provisions in Regulation 882/2004 (details under Section 5.5.36 below),
- any existing co-ordinated programmes e.g. at the request of or under the direction of other food control/advisory bodies,
- adequacy or sufficiency of documentation e.g. discrepancies which need further investigation
- suspicion of non-compliance

Checks might also be influenced by information received from inland Competent Authorities regarding non-compliant food or from other control authorities or the port operator who may have concerns about a consignment.

As well as the reference sample required by the Food Safety (Sampling and Qualifications) Regulations 2013, officers should give the owner, importer or importer's agent a receipt for, or a record of, all samples taken and a copy of the results in the case of non-compliance.

Competent Authorities with points of entry, ETSF or international rail terminals, should aim to establish effective holding arrangements in liaison with local stakeholders such as transit shed operators or dock companies, to ensure that consignments for which they are seeking additional information cannot be removed from the port or ETSF.

#### **5.5.14.4 Deferred examinations of FNAO**

See 5.4.4 of the Food Law Code of Practice

Deferred examinations may be considered where the Competent Authority at the point of entry has a valid reason why an examination needs to be deferred, but it is anticipated this is likely to be in exceptional circumstances only.

Either the Competent Authority covering the point of entry or the importer can request deferred examination. However, the final decision on whether to defer examination rests with the Competent Authority covering the point of entry. In coming to any decision, liaison with the receiving Competent Authority should be carried out to ensure that appropriate checks will take place and deferral should therefore be based on full co-operation and agreement between the two Competent Authorities.

Where products are subject to Emergency Control Decisions or Emergency Control Regulation measures which require designated points of entry, deferred examination is unlikely to be appropriate but there might be exceptional circumstances where there are overriding health and safety considerations. In such cases the FSA should be informed. In all cases where food is of a known or emerging risk should it be subject to relevant document and identity checks before being deferred for physical checks.

When any examination is deferred, the Official Feed and Food Controls (England) Regulations 2009 (as amended) require that the importer must provide a written undertaking that the consignment has been sealed and will not be opened until it reaches its specified destination and opening the container has been authorised by the receiving Competent Authority. The Competent Authority at the point of entry should notify the receiving Competent Authority forthwith and in writing that the food has not been examined and forward to the Competent Authority a copy of any written undertaking given by the importer.

Deferred examinations under The Official Feed and Food Controls (England) Regulations 2009 (as amended) should be carried out in accordance with Regulation 27 of the Regulations - only an outline has been provided in this practice guidance. . Please note: these arrangements are not common practice.

#### **5.5.15 Onward Transportation**

Article 8 of Regulation (EC) 669/2009 (as amended) permits the authorisation by the competent authority at a designated point of entry (DPE) for onward transportation of a consignment(s) of foods of non-animal origin that may have been sampled at the DPE pending results of tests/analysis. The competent authority at the DPE may authorise these arrangements; however where authorisation is given, the competent authority at the point of destination must be consulted. Appropriate arrangements shall be put in place to ensure that the consignment remains under the continuous control of these competent authorities (so it may not be tampered with in any manner pending the results of the tests/analysis).

Please note: the onward transportation arrangement can apply for consignments of products of non-animal origin, moving inland within the UK (i.e. from a DPE to an inland authorities remit) but may also apply to consignments of products of non-animal origin transporting between EU Member States.

#### **5.5.15 Charges**

Regulation 669/2009 provides that mandatory fees for FNAO imports of a 'known or emerging risk' are collected in accordance with the criteria laid down in Annex VI of Regulation 882/2004.

Commission Emergency measures normally provide for mandatory charges.

## **5.5.16 Enforcement at Points of Entry and Inland**

See 5.4.3 of the Food Law Code of Practice

Where there is no evidence to suggest that a deliberate attempt has been made to import non-compliant goods, and adequate control arrangements are in place, ports might consider voluntary surrender as an option for dealing with such consignments. In accordance with the Code (see 6.2.10.8), where food is voluntarily surrendered for destruction, a receipt should be issued and the description of the food should include the phrase “voluntarily surrendered for destruction” with the person surrendering the food or their representative signing the receipt.

## **5.5.17 Products of Animal Origin (POAO) – POAO Enforcement**

### **5.5.17.1 Imported Food Legislation – Products of Animal Origin**

In the UK, DEFRA is the Government Department designated as the central competent authority for controls at BIPs on products of animal origin (excluding fishery products and bivalve molluscs for which the FSA has responsibility) and live animal imports in England. Agricultural departments in the devolved administrations do have competency in these countries. Defra as the central competent authority have provided the following guidance for Competent Authorities within England that are responsible for enforcement of imported food inland to explain key elements of the Trade in Animals and Related Products Regulations 2011 SI No 1197 ('TARP') and how those Regulations are applied and fit with other existing domestic and EU legislation.

### **5.5.17.2 The Official Controls (Animals, Feed and Food) (England) Regulations 2006 SI 2006 No. 3472**

The relevant provision of these regulations is: Regulation 5. This provides that the Competent Authority is designated in relation to enforcement and execution under relevant legislation.

In this context relevant legislation means feed law and food law to which Regulation (EC) No 882/2004 applies.

### **5.5.17.3 Regulation (EC) No 882/2004**

This regulation applies to official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules. The relevant provisions of these regulations are:

Article 14 – Under this article the general rules of Articles 18-25 of Regulation 882/2004 also apply to official controls on all feed and food, including feed and food of animal origin.

Article 18 – This Article provides that in case of suspicion of non-compliance or if there is doubt as to the identity or the actual designation of the consignment, or as to the correspondence between the consignment and the certified guarantees, the competent authority shall carry out official controls in order to confirm or to eliminate the suspicion or doubt. It also provides that the competent authority may place the consignment concerned under official detention until it obtains the results of such official controls.

Article 22 – The feed or food business operator responsible for the consignment or its representative shall be liable for the costs incurred by competent authorities for the activities referred to in Articles 18, 19, 20 and 21.

Article 28 – This Article provides for the recovery of expenses arising from additional official controls when the detection of non-compliance leads to official controls that exceed the competent authority's normal control activities. The competent authority can then charge the operators responsible for the non-compliance, or may charge the operator owning or keeping the goods at the time when the additional official controls are carried out, for the expenses arising from the additional official controls.

#### **5.5.17.4 The Trade in Animals and Related Products Regulations 2011 SI No 1197**

The relevant provisions of these regulations are:

Regulation 19 – The enforcement authority must seize any consignment that is either: brought into England other than through a Border Inspection Post (BIP) approved for that animal or product, removed from a BIP without a Common Veterinary Entry Document (CVED) or the authority of the Official Veterinary Surgeon (OVS) (or official fish inspector in relation to fish and fishery products) at the BIP, or transported from a BIP to a destination other than that specified on the CVED. Regulation 20(3) – If a consignment of products is seized outside a BIP under Regulation 19 the enforcement authority must dispose of the consignment as Category 1 material in accordance with Regulation (EC) No. 1069/2009 (Animal-by products Regulation), or act in accordance with sub-paragraph (b) or (c) of paragraph (1) of Regulation 20.

#### **5.5.17.5 Illegally introduced POAO**

POAO must be imported in accordance with the relevant provisions of the Trade in Animals and Related Products (TARP) Regulations 2011. These require that POAO are imported through a designated BIP and are subject to mandatory veterinary checks. A CVED must be issued for consignments which pass the veterinary checks and this should accompany the consignment to the first premises after import, where it should be retained for a period of one year. POAO are considered to be illegally introduced (smuggled) where they have not been presented at the BIP of entry, for clearance or have not received a correctly completed CVED from the BIP.

Border Force are responsible for detecting smuggled POAO in Customs controlled areas including ETSF. However, Competent Authorities have responsibilities

relating to goods presented at BIPs and also inland where officers come across illegal POAO in the course of their routine enforcement activities.

The FSA's Operations Group are responsible for illegal POAO found at premises under their control. Where FSA Operations staffs discover meat in approved cutting plants that they suspect is illegally imported, they have the primary responsibility and enforcement powers to deal with it. The FSA has also produced Enforcement Guidance on Illegal Meat for Enforcement Officers, which can be found at:

<http://www.food.gov.uk/foodindustry/guidancenotes/meatregsguid/illegalmeatguidance>

All Competent Authorities should set up, implement and maintain arrangements to effectively deal with illegally introduced POAO. Due to the nature of the enforcement activity which might require prompt action, officers must be properly authorised, template notices should be available, and effective mechanisms for any likely sampling or examination should be in place. Consideration should be given to necessary arrangements for the transport, storage, facilities and the necessary control arrangement for the destruction of POAO by high temperature incineration.

Where an authorised officer, in the course of their duties, comes across POAO at premises under Customs control i.e. in a port area or an ETSF, which they have reason to believe has been illegally introduced, they should notify HMRC (in the absence of any local reporting arrangements, contact HMRC National Co-ordination Unit on 0845 600 4374) and if needed for adequate interim control of the consignment, issue a detention notice under Regulation 32(6) of the TARP Regulations 2011. This should be done as soon as possible.

#### **5.5.17.6 Detention/Seizure of POAO found inland at premises outside Customs control**

See 6.2.11.2 of Food Law Code of Practice

#### **5.5.17.7 Reporting**

A notification to DEFRA should be made when illegally imported POAO is seized under Regulation 19 of the TARP Regulations 2011.

The reporting of seizures requires the completion of IIT 1 (04/08) form (preferably electronically), which is located on the secure parts of APHA and CIEH websites. See paragraph 5.5.10.4 above.

## **Chapter 6 – Enforcement Sanctions and Penalties**

### **6.1 Dealing with Non-compliance**

#### **6.1.1 Introduction**

This Chapter requires Competent Authorities to take appropriate action on FSA guidance on the effective enforcement of food law. This Chapter:

- gives additional information to the material in the Code on the application of enforcement sanctions and penalties, and other measures that can be taken by authorities to secure compliance
- requires each Competent Authority to document its Food Law Enforcement Policy and keep it up-to-date; and
- lists reference materials which Competent Authorities should take account of

#### **6.1.2 The enforcement approach**

The primary objective of any enforcement action must be to achieve compliance in the most effective way and the approach should be in line with the “hierarchy of enforcement”.

The practice of giving advice, and communicating by letter about enforcement issues, are well-established approaches to enforcement that are understood by food businesses. Such procedures are therefore encouraged whenever they are likely to secure compliance with the requirements of food law within a time that is reasonable in the circumstances. See Chapter 6.1.1 of the Code of Practice for information on proportionality and consistency.

When determining the appropriate enforcement action, consideration should be given to;

- The level of risks to consumer safety resulting from the non-compliance;
- Particular consumer sensitivities around an issue, leading to loss of consumer confidence or economic loss to industry;
- The potential for non-compliant foods being distributed widely with large numbers of consumers affected;
- Previous history of compliance.
- Collaboration with Home Authority/Primary Authority (see 6.1.6 for further information)

#### **6.1.3 Enforcement Information**

In order to ensure consistent interpretation and application of food law Competent Authorities should ensure that authorised officers have up-to-date information readily available to enable them to carry out their duties competently.

For example:

- relevant legislation;
- the Code of Practice;
- EU Guidance documents
- UK Guides to Good Practice where appropriate;
- Guidance/ relevant correspondence issued by, jointly with, or on behalf the FSA; and LGA;
- FSA food alerts e.g. Food Alerts For Action (FAFA)
- relevant industry codes of practice; and
- appropriate technical literature.

#### **6.1.4 Guidance issued to Competent Authorities**

The FSA periodically issues communication to Competent Authorities on new and/or revised enforcement policies, information on food safety matters and other issues connected with the effective enforcement of food law. Annex 3 contains links to legislation and guidance.

Competent Authorities should have arrangements to determine what action is appropriate on receipt of such communications, and to bring them to the attention of their authorised officers as necessary.

#### **6.1.5 FSA's Food Law Prosecution Outcomes Database**

The FSA has created a central repository of information about successful prosecutions brought by UK competent authorities and the FSA. The database will include food standards, food safety and food hygiene related prosecution cases in the UK. Competent authorities will be able to utilise this information to support their own enforcement activities. This will be available on the '[Enforcement and Regulation → Monitoring](#)' section of food.gov.uk.

To help the FSA maintain the database, Competent Authorities should report successful prosecutions 28 days after a conviction has been obtained. Cases should be reported using the Food Law Prosecution Outcomes spreadsheet and sent to the Directorate Support Team at [prosecutionsuccess@foodstandards.gsi.gov.uk](mailto:prosecutionsuccess@foodstandards.gsi.gov.uk). The FSA will also record whether a defendant has been added to the prohibited persons register but this information will only be made available upon request.

## **6.1.6 Primary Authority Role**

Where enforcement action is being considered in relation to a business which has a Primary Authority partnership, the Competent Authority needs to make a statutory notification to the Primary Authority via the [Primary Authority Register](#). In most circumstances, this notification must be made at the stage at which the enforcement action is being considered, allowing the Primary Authority to consider whether relevant Primary Authority Advice has been given to the business. However, in certain limited circumstances, the notification may be made retrospectively. The conditions of the notification are set out in the [Primary Authority Handbook](#) which is available on the [BRDO website](#).

Primary Authority Advice provided to a business may be published on the Primary Authority Register by the Primary Authority, although this is not always the case. However, Competent Authorities are encouraged to communicate with the relevant Primary Authority during the early stages of an investigation to determine whether Primary Authority Advice has been given, and whether the business has followed it.

In Northern Ireland and Scotland the Primary Authority scheme does not extend to the devolved functions of food or feed law enforcement. Although the Primary Authority Scheme does not extend to Northern Ireland on a statutory basis, Competent Authorities in NI have agreed to apply the principles of the scheme when discharging their food law functions.

## **6.2 Formal Sanctions**

### **6.2.1 Hygiene Improvement Notices and Improvement Notices**

#### **6.2.1.1 Introduction**

This section deals with the use of:

- Hygiene Improvement Notices (HINs) under Regulation 6 of the Food Safety and Hygiene (England) Regulations 2013, and
- Improvement Notices (INs) under Section 10 of the Food Safety Act 1990 in connection with food safety issues that do not involve hygiene.

#### **6.2.1.2 Service of notices**

The Food Safety and Hygiene (England) Regulations 2013 require a HIN to be served on the food business operator by the officer that observed the breach. The Food Safety Act 1990 requires an IN to be served on the proprietor of a food business (see Paragraph 6.2.2 of the Code of Practice). HINs or INs must be served in accordance with the statutory requirements.

It is vital to identify the food business operator if possible, however Regulation 30(2) of the Food Safety and Hygiene (England) Regulations 2013 gives the capacity for a



HIN to be addressed to the “food business operator” and left at the named premises. Similarly, Section 50(2) of the Act allows an IN to be addressed to the “owner” or “occupier” and delivered to the named premises if the proprietor of the food business cannot be identified.

The officer serving a HIN or IN should ensure, wherever possible, that the person who is responsible for taking action also receives a copy, especially where the local manager is not the food business operator / food business proprietor (FBO).

### **6.2.1.3 Drafting of Notices**

It should be clear from the HIN or IN the grounds for failure to comply with a relevant provision of food law, the matters which constitute the failure to comply, and the measures (or equivalent measures) the recipient is required to take. Notices should be clear and easy to understand.

As failure to comply with the requirements of a HIN or IN within the specified period is an offence, an officer who has decided to serve a notice should consider whether a single notice with a single time limit is appropriate.

It may be possible to cite more than one non-compliance in a notice; provided the issues are of the same theme, the action required of the FBO are capable of rectifying all the failures cited on the notice, and the time frames for compliance are all the same. However, simplicity is often better; to avoid confused drafting, ensure the notice is understandable to the FBO and any time frames for compliance fit with the escalation of each issue.

Using multiple notices, each with a different time limit, may be more appropriate where multiple contraventions are concerned. Separate notices with separate time limits may also be easier to handle if there is an appeal. An appeal against a single notice concerning multiple contraventions would result in the suspension of the whole notice until the appeal had been dealt with.

In respect of HINs or INs requiring structural work to be carried out, ideally the officer will discuss the detail of any such work with the FBO, or with a person acting on the FBO’s behalf who is in a position to authorise the work, before a notice is issued, and reach agreement with them on what should be done. However, the issue of a notice should not be unduly delayed if agreement cannot be reached or a responsible person cannot be contacted.

It is the FBO’s responsibility to obtain any necessary planning permission, if they need or choose to undertake any building works to improve the structure of the establishment.

### **6.2.1.4 Time limits**

A HIN should clearly state the time limit by which the measures required by the notice must be completed. The Food Safety and Hygiene (England) Regulations

2013 and the Food Safety Act 1990 specify a minimum period of 14 days<sup>18</sup>. For time limits of INs served under FIR2014 see section 6.2.2.8

An appeal can be lodged against the time limit, so it must be realistic, justifiable, and have regard to the extent and complexity of the measures required.

Where circumstances allow, it is good practice to discuss and agree the time limit with the FBO or with a person acting on the FBO's behalf who is in a position to agree a time limit, before a notice is issued. The officer may, however, set a time limit without such agreement if agreement cannot be reached or a responsible person cannot be contacted.

The following factors should be taken into consideration in setting a time limit:

- the risk to public health
- the nature of the problem
- the availability of solutions

#### **6.2.1.5 Extension of time limits**

Although HINs and INs are to be complied with by the stipulated time limit, Competent Authorities should give due regard to any genuine difficulties that may occur in achieving compliance by that deadline. There is no specific provision in the regulations to extend the time limit for compliance with a notice, but it may be unreasonable not to allow an extension if the FBO has a genuine reason for needing more time. If the FBO requests an extension to the time limit specified in the Notice this should be made in writing and received by the competent authority prior to the expiry of the Notice.

Before issuing a new Notice the authorised officer must consider again whether the conditions prevailing at the premises still warrant the issuing of another notice. If the authorised officer is satisfied that there is a genuine reason for such an extension, they should make a note of the reasons for their decision on the relevant establishment file. The existing notice should then be withdrawn and a new notice issued reflecting the new time limit by which compliance must be achieved.

However, the officer should never issue such a notice automatically. When deliberating a request for an extension of the time limit, the officer should always consider whether the facts at that time justify such an extension, taking account of:

- the reason for the request
- the remedy involved
- the risk to public health associated with the fault if an extension was granted
- past record of co-operation of the operator / proprietor

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<sup>18</sup> See Regulation 6(1)(d) of The Food Safety and Hygiene (England) Regulations 2013 and s. 10(1)(d) of the Food Safety Act 1990.

- any temporary action which the operator / proprietor proposes to take to rectify the non-compliance
- demonstrable evidence of steps taken to address the requirements contained in the Notice

#### **6.2.1.6 Works of equivalent effect**

Notices should make clear that Regulation 6 of the Food Safety and Hygiene (England) Regulations 2013 and Section 10 of the Food Safety Act 1990, as appropriate, allow a FBO to carry out measures of at least equivalent effect to those specified in a HIN / IN and recommend that alternative measures are discussed with the officer who served the notice before starting work to avoid unnecessary expenditure or inappropriate work. Ultimately, it is for the FBO to decide how they will comply with the objectives of the legislation.

The Competent Authority should respond in writing to any request from an FBO to vary the work, and any agreed alternative measures should be confirmed in writing.

Disputes should be considered by the Competent Authority's lead officer for food safety, or by the head of service or another senior manager.

Competent Authorities should ensure that they have procedures in place to consider such matters, so that it is clear to the FBO that there is a proper review.

#### **6.2.1.7 Compliance**

The officer who served the HIN or IN should liaise with the FBO and monitor the work being undertaken and encourage the FBO to notify the officer when the work has been completed. Another authorised officer should monitor the work if the officer who served the notice is unable to do so.

The work should be checked as soon as practicable after notification has been received that it has been completed or as soon as possible following the expiry of the notice and the officer should confirm in writing to the FBO that the works have been satisfactorily completed.

#### **6.2.1.8 Compensation and Appeals**

If a HIN or IN is served in error and as a result a food business suffers, financial loss due to being unable to sell the food due to its perishable nature, they may pursue compensation through a civil negligence claim against the serving competent authority.

It should be clear to the recipient of a HIN or IN that there is a right of appeal against the notice.

The notice should therefore include details of the right of appeal and the recipient provided with the name and address of the relevant local Court.

The FBO should also be asked to notify the officer if an appeal is lodged .

#### **6.2.1.9 Other discussions with the Competent Authority**

Although an FBO has a right of appeal against a HIN or IN, the Competent Authority should be prepared to discuss the notice and its requirements informally with the FBO if they wish to do so.

The Competent Authority should also be prepared to discuss the requirements of any letter or other enforcement action.

If an FBO indicates that the requirements of a notice are inconsistent with the interpretation or practice of other Competent Authorities, the Competent Authority should have regard to the views of the “primary authority” and/or “home authority” for the business, where one exists as defined by BRDO/Local Government Association (LGA).

Competent Authorities should have internal arrangements to consider such requests for further discussion and consider how they make these arrangements known to FBOs.

Any disputes that arise should be referred to the lead officer for food safety, or an appropriate senior manager nominated by the lead food officer to come to a decision.

#### **6.2.1.10 Other guidance**

Further guidance on the drafting and use of HINs has been issued by LGA and can be found on the Knowledge Hub: <https://khub.net/>

The Competent Authority may want to discuss enforcement issues on a regional level or via the '[knowledge hub](#)' with other Competent Authorities to see if there is other established practice that should be taken into account. An opinion may be sought from the National Food Hygiene Focus Group or the Food Standards and Labelling Focus Group with cases submitted via the Regional Liaison Groups. Officers from 2 tier District Councils requiring advice should access opinions of the Food Standards and Labelling Focus Group via their Trading Standards colleagues.

### **6.2.2 Food Information Regulations Improvement Notices**

#### **6.2.2.1 Introduction**

This section is for food enforcement officers issuing INs under section 10 of the Food Safety Act 1990 as applied and modified by Regulation 12 of the Food Information Regulations 2014

Regulation 12 of the [Food Information Regulations 2014](#) (FIR 2014) applies the provisions in section 10 of the Food Safety Act 1990 to enable INs to be served for a contravention of certain provisions of [Regulation \(EU\) No 1169/2011](#) on the provision of food information to consumers (EU FIC) and other provisions of FIR 2014. For these purposes, section 10 of the Food Safety Act 1990 has been modified by FIR 2014 (SI 1855). Please see Part 1 of Schedule 4 of FIR 2014 for details of the modifications.

#### **6.2.2.2 When to use Food Information Regulations INs**

An IN may be served on a person (FBO) requiring the person to comply with the provisions listed in subsection (1A) of the modified version of section 10 of the Food Safety Act 1990 set out in Part 1 of Schedule 4 to FIR 2014. These are:

- the EU FIC provisions listed in Schedule 5, (the main provisions of 1169/2011), except insofar as they relate to net quantity (section 10(1A)(a) to (c)); and
- the provisions in FIR 2014 listed in section 10(1A)(d). These relate to:
  - the national requirements for non-prepacked foods requiring meat QUID labelling for foods containing meat (regulation 7(1), (4) and (5)); and
  - food irradiation labelling (the provisions of regulation 8(1) and (3)).
  - The national requirements under Regulation 6 to provide the name of food for non-prepacked foods.

#### **6.2.2.3 Food Authorities (Competent Authorities)**

'Food authorities' are under a duty to enforce the Regulations within their areas. Regulation 2(1) of FIR 2014 contains a definition of 'food authority'. It covers county councils, metropolitan district councils, non-metropolitan councils for areas where there is no county council (unitary authorities), London borough councils, the Common Council of the City of London and the Council of the Isles of Scilly.

Port Health Authorities are under a duty to enforce FIR 2014 within their districts.

Non-metropolitan district councils for an area for which there is a county council have a power to enforce certain provisions of EU FIC and FIR 2014 (regulation 9(2)) and may issue an IN for the allergen labelling requirements for non-pre-packed foods (, Article 44(1)(a) and regulation 5(3), (4) and (5) of FIR 2014). It is expected that these Competent Authorities will carry out these checks of mainly catering premises as part of their routine inspections.

#### **6.2.2.4 Food Business Operators**

The use of the term "food business operator" has the meaning given in point 3 of Article 3 of [Regulation \(EC\) 178/2002](#) of the European Parliament and of the Council (regulation 2(1) of FIR 2014 as read with Article 2 (1)(a) of EU FIC).

FBOs are responsible for complying with the Regulations by ensuring that consumers are provided with accurate and up to date information and the requirements are set out in EU FIC (Article 8). The Regulations apply to FBOs at all stages of the food chain from production to wholesalers, retail and caterers. It includes food delivered by mass caterers, and food intended for supply to mass caterers, as well as foods offered for sale by means of distance communication – this includes foods sold over the internet or telephone orders.

The requirements for the presentation of mandatory food information are set out in EU FIC. (Chapter 4: Articles 9 to 35)

Communication of mandatory food information can be by a number of means depending on where in the supply chain the transaction occurs.

#### **6.2.2.5 Allergenic Ingredients**

The information accompanying the sale of non-prepacked allergenic foods and foods containing allergens sold to consumers or mass caterers, can be provided by verbal communication, and writing on a board or menu at point of purchase, as permitted by regulation 5 of FIR 2014 as read with Article 9(1)(c) of EU FIC.

Where a FBO intends to make allergens information available verbally, the FBO must indicate to consumers that details of those allergens can be obtained by asking a member of staff. This indication must be given in one of the ways specified in regulation 5(4) of FIR 2014.

#### **6.2.2.6 Issuing Notices and carrying out enforcement in a proportionate manner**

Food Information Regulations INs should be used in line with the Competent Authority's enforcement policy and must be considered as part of the escalation of enforcement action in line with the hierarchy of enforcement.

If the authorised officer has reason to believe that an informal approach will not result in a successful outcome then a more formal approach should be considered

Since breach of a Notice is a criminal offence, Competent Authorities should carefully consider whether they are appropriate in the circumstances and in line with the hierarchy of enforcement and their own enforcement policy. A Notice once served may be appealed to the First-tier Tribunal (or Magistrates Court in Wales & Northern Ireland), if the business doesn't agree with the conditions of the Notice. Care should be taken to make sure that evidence of the non-compliance is obtained and its continuity maintained and the relevant procedures have been followed when issuing a Notice.

For information on the drafting and service of notices please see 6.2.1.3 of this Practice Guidance.

### **6.2.2.7 Breaches of Allergens Labelling Provisions**

In the case of a failure to comply with any of the allergen-related provisions specified in regulation 10 of FIR 2014, officers will have the choice of taking a criminal prosecution in relation to the contravention or serving an IN.

It will be possible, in serious cases, for an enforcement officer to take a criminal prosecution for the basic contravention as well as issuing an IN to require measures to be taken by the food business to remedy the contravention within a specified time period .

Decisions on whether to issue a Notice, take a criminal prosecution for an offence under regulation 10 of FIR or (in serious cases) doing both, should take into account the public health risk and the evidence and circumstances, and what they believe is the most effective enforcement strategy.

### **6.2.2.8 Time Limits**

The modification to section 10 of the Food Safety Act 1990 by FIR 2014 included the removal of the minimum 14 day requirement for compliance. This will allow the notice to require immediate rectification to ensure that consumers are safeguarded where public safety is at risk through poor or incorrect labelling i.e. through the absence of or wrongly applied date marking. Criminal sanctions are also retained for failure to comply with certain allergen labelling / information requirements – see section 6.2.2.7. INs should therefore, be used in accordance with statutory guidance and the Competent Authority's enforcement policy, and must be considered as part of an escalation of enforcement action.

For additional information on time limits see 6.2.1.4 of this Practice Guidance. For information on the extension of time limits see section 6.2.1.5 of this Practice Guidance.

### **6.2.2.9 Works of equivalent effect and Compliance**

See section 6.2.1.6 of this Practice Guidance

### **6.2.2.10 Appeals**

In the case of INs issued under the FIR 2014 INs must make it clear that there is a right of appeal against the Notice to the First-tier Tribunal or the Magistrates Court (Wales and NI). (For INs issued under the Food Safety Act 1990 – see section 6.2.1 of this Practice Guidance) The recipient should be provided with further information on how to appeal via the First-tier Tribunal system (<http://www.justice.gov.uk/tribunals/the-general-regulatory-chamber/making-an-appeal>).

The FBO should also be asked to notify the officer if an appeal is lodged.

The First-tier Tribunal General Regulatory Chamber (“the GRC”) is governed by the Tribunal Procedure (First-tier Tribunal) (General Regulatory Chamber) Rules 2009 (SI 2009/1976).

The FBO has 28 days from the date on which the IN was served to appeal to the correct tribunal office.

As soon as an appeal is lodged with the tribunal, the time limit set out in the IN for carrying out the stated measures is suspended, until the appeal has been decided in accordance with the Food Safety Act 1990, s.39(2). Time limits imposed by the Rules can be extended (Rule 5(3)(a) of SI 2009/1976).

The powers of the GRC are contained in the new s.39(1) of the Food Safety Act 1990 which states that “the First-tier Tribunal may either cancel or affirm the notice and, if it affirms it, may do so either in its original form or with such modifications as the First-tier Tribunal may in the circumstances see fit.”

If the IN remains as originally imposed or is altered, the enforcing authority may enforce the IN, respectively in its original or altered form

While an appeal is pending, Section 39(2) of the Food Safety Act 1990 effectively stops the clock in terms of the time period for compliance with an IN. This will mean that during and up to the appeal the FBO will be able to continue selling the product.

Further information on appeals can be found at <https://www.gov.uk/appeal-against-a-food-labelling-decision-or-improvement-notice>

#### **6.2.2.11 Compensation**

There is no provision for compensation in the FIR 2014 or in the First-tier Tribunal Rules. If an IN is served in error and as a result a food business suffers, financial loss due to being unable to sell the food due to its perishable nature, they may pursue compensation through a civil negligence claim against the serving competent authority.

#### **6.2.2.12 Responsibilities and Enforcement**

Article 8 sets out responsibilities under FIC and the FBO responsible for the food information is the operator under whose name or business name the food is marketed. Which business in the food supply chain is responsible for the food information will affect which enforcement authority to involve where breaches are found. Below is some general guidance for how this applies in practice but this will vary case by case and officers should discuss with other members of the enforcement community if they have any concerns relating to a particular case they are dealing with. The principles apply to issuing INs and pursuing criminal sanctions.

For ‘branded’ pre-packed foods the brand owner would generally be responsible for the information on the label. For ‘own branded’ products, the retailer group selling the goods will be responsible for the information.



Under Article 8(3) of EU FIC retailers have a responsibility not to sell items they know or presume, on the basis of information available to them as professionals to breach the provisions of the FIC.

Where the contravention is the responsibility of the brand owner which is sold across many retail outlets the competent authority should inform the seller of the contravention and notify the brand owner and their relevant Primary Authority of the contravention. See section 6.1.6 for information on the Primary Authority role. For retailers where the Competent Authority has reason to believe the retailer are or should have been aware of the contravention, the details should be referred to the Primary/Home Authority for pre enforcement discussions and decisions as to enforcement action

The approach to enforcement action should be subject to a dialogue and agreement between the various authorities and businesses involved. *For example*, an agreement may have been made by the Home Authority or Primary Authority to allow the 'selling on' of goods with labels in breach of labelling provisions, on condition that changes are made to future batches. In these instances the enforcing authority would be expected to adopt a flexible approach.

An IN can be served on a FBO outside of the Competent Authority area provided there is contravention inside the Competent Authority area.

Depending on the circumstance, food businesses may choose to take action with their suppliers direct in order to avoid reputational damage associated with the sale of non-compliant goods.

#### **6.2.2.13 Authorisation of Officers**

The authorisation of officers to serve INs will be as described in the Code which applies to the serving of INs for Regulations made under the Food Safety Act 1990. Section 6(6) of the Act allows competent authorities to authorise officers to act "in matters arising" under Regulations made under the Act such as the FIR 2014. The Food Safety Act 1990 allows for the authorisation of officers, in writing, either generally or specifically to act in matters arising under the Act or Regulations made under the Act.

INs served under section 10 of the Food Safety Act 1990 may only be signed by officers who have been authorised to do so by the Competent Authority. See Chapter 4 of this Practice Guidance.

#### **6.2.2.14 Resources available**

- A model form of an IN for the purposes of FIR 2014 can be found in Section 6.3
- Links to EU and FSA allergens guidance can be found in Annex 3

## **6.2.3 Prohibition Procedures**

### **6.2.3.1 Introduction**

This section deals first with:

- the use of hygiene prohibition procedures, hygiene emergency prohibition orders, remedial action notices and detention notice procedures under Regulations 7, 8, 9 and 10 respectively of the Food Safety and Hygiene (England) Regulations 2013 and the associated voluntary closure procedures; and
- the prohibition procedures of Section 11 and Section 12 of the Food Safety Act 1990, the associated voluntary closure procedures and the prohibition of persons from participating in the management of any food business, or any food business of a class or description specified in the order under Section 11 of the Act, in connection with general food safety issues.

### **6.2.3.2 Food Safety and Hygiene (England) Regulations 2013- Regulation 7 - Hygiene Prohibition Procedures**

Hygiene Prohibition orders (HPOs) are made by a magistrates' court following the conviction of an FBO under Regulation 7 of the Food Safety and Hygiene (England) Regulations 2013 to either to:

- prohibit the use of a process or treatment for the purposes of the business if the health risk condition is fulfilled
- prohibit the use of the premises or equipment for the purposes of the food business or any similar food business if the construction of the premises or use of any equipment fulfils the health risk condition
- prohibit the use of the premises or equipment for the purposes of any food business if the state or condition thereof fulfils the health risk condition

The Competent Authority must first successfully prosecute the FBO for an offence under the Food Safety and Hygiene (England) Regulations 2013. If the authorised officer may bring to the attention of the Court to Regulation 7 of Food Safety and Hygiene (England) Regulations 2013 so that a HPO against a FBO may be considered,

The Court will make an order if it is satisfied that the premises, equipment, treatment and/or process fulfil the health risk condition as per Regulation 7(2).

The Court may also make an order prohibiting a FBO from managing any food business, or a particular type of food business as per regulation 7(4) where the health risk condition has not been fulfilled, provided the FBO has been convicted of an offence under these Regulations and the Court thinks it appropriate in the circumstances of the case.

### **6.2.3.3 Food Safety and Hygiene (England) Regulations 2013 - Regulation 8 - Hygiene Emergency Prohibition Procedures**

An authorised officer may serve a HEPN on the FBO under Regulation 8 of the Food Safety and Hygiene (England) Regulations 2013, if the health risk condition is fulfilled in respect of a food business and there is an imminent risk of injury to health. The effect of the notice is to immediately close the premises, or prevent the use of equipment, or the use of a process or treatment.

The authorised officer must apply to a magistrates' court for a HEPO within three days of a HEPN being served, the day of service of the notice being Day 1. The FBO must be given at least one day (24 hours) notice of the officer's intention to apply to the court for a HEPO. Although there is no legal requirement for the application to be heard within the three days, the Court should be asked to list the application for hearing at the earliest opportunity, given that compensation may be payable for loss of business if the court refuses to grant the Order. Once made, a HEPO supersedes a HEPN.

### **6.2.3.4 The Food Safety Act 1990 - Section 11 - Prohibition Procedures**

**It should be noted that prohibition procedures under the Food Safety Act 1990 are rarely used and in general only in cases where the food safety risk is not related to food hygiene.**

A magistrates' court can make a prohibition order under Section 11 of the Act after a FBO has been convicted of an offence to:

- close food premises
- prohibit premises from being used for particular kinds of food business
- prevent the use of a piece of equipment for any food business, or a particular food business
- prohibit a particular process;
- prohibit the proprietor from managing any food business

The Competent Authority must first successfully prosecute the proprietor of the business for a breach of relevant food law.

The Court can make an order if it considers that the premises, equipment or process pose a risk of injury to health. The authorised officer may bring the attention of the court to Section 11 of the Food Safety Act so that a prohibition order against a food business proprietor may be considered,

The Court can also make an order prohibiting a proprietor or manager from managing a food business.

### **6.2.3.5 The Food Safety Act 1990 - Section 12 - Emergency Prohibition Procedures**

An authorised officer can, serve an emergency prohibition notice (EPN) under Section 12 of the Act, if there is an imminent risk of injury to health in food premises. The effect of the notice is to immediately close the premises, or prevent the use of the equipment or process.

The authorised officer must apply to a magistrates' court for an emergency prohibition order (EPO) within three days of an EPN being served, the day of service of the notice being Day 1.

Although there is no legal requirement for the application to be heard within the three days, the Court should be asked to list the application for hearing at the earliest opportunity.

The authorised officer must serve notice on the FBO at least one complete day (24 hours) before the day upon which the authorised officer intends to make the application to the court.

Once made, an EPO supersedes an EPN.

#### **6.2.3.6 "Health risk condition" / "(imminent) risk of injury to health"**

Regulations 7 and 8 of the Food Safety and Hygiene (England) Regulations 2013 can only be used if the "health risk condition" is fulfilled. In respect of Regulation 7, there must be a risk of injury to health and in respect of Regulation 8 there must be an imminent risk of injury to health. Section 11 of the Food Safety Act 1990 can only be used if the "health risk condition" is fulfilled and Section 12 can only be used if there is an "imminent risk" of injury to health.

In respect of Regulation 8 of the Food Safety and Hygiene (England) Regulations 2013 and Section 12 of the Food Safety Act 1990, the word "imminent" qualifies the word "risk". There must always be an imminent risk of injury to health before a HEPN or EPN can be served. The injury itself may occur sometime in the future, but it is essential to show that it could occur for the action to succeed. Not everyone exposed to the risk of injury would need to suffer the injury for there to be considered an imminent risk. It is the exposure to the risk of injury that enables action to be taken.

#### **6.2.3.7 "Health risk condition" –Food Safety and Hygiene (England) Regulations 2013**

In relation to food hygiene, the health risk condition under the Food Safety and Hygiene (England) Regulations 2013 may exist if, for example, conditions in premises, or a defective process or treatment, carry a high risk of causing food borne infection.

Foods containing potentially harmful levels of pathogenic micro-organisms represent an imminent risk and should be seized or detained under Regulation 25 of the Food Safety and Hygiene (England) Regulations 2013 by using the powers in Section 9 of the Food Safety Act 1990 (see also Regulation 10 of the Food Safety and Hygiene (England) Regulations 2013 in this regard). However, the process or treatment which

exposed the food to this microbiological contamination should be dealt with under Regulation 8 of the Food Safety and Hygiene (England) Regulations 2013 where appropriate.

#### **6.2.3.8 “Health risk condition” – Food Safety Act 1990**

The “health risk condition” applies specifically in the context of seeking either a prohibition order under Section 11 of the Food Safety Act 1990 or an EPN/EPO for the purposes of Section 12 of the Act. The health risk condition under the Food Safety Act 1990 can exist if, for example:

- a process or treatment introduces a teratogenic chemical (one that injures a developing foetus in the womb) into food, but the damage will not be apparent until the baby is born
- a process or treatment introduces a genotoxic chemical (one that damages genes or chromosomes) into food, the effects of which may not manifest themselves until the affected child develops or a malignant tumour occur sometime in the future

Foods containing potentially damaging levels of such chemicals represent an imminent risk and should be seized or detained under Section 9 of the Food Safety Act 1990. However, the process or treatment which exposed the food to this chemical contamination should be dealt with under Section 12 of the Food Safety Act 1990.

#### **6.2.3.9 Criteria for Action - Hygiene Prohibition Procedures / Prohibition Procedures**

The FBO must have been convicted of an offence before the Court considers any prohibition order. The criteria for action depend on the conditions in Regulation 7(2) of the Food Safety and Hygiene (England) Regulations 2013 and Section 11(2) of the Food Safety Act 1990 being met, i.e. that either the construction or condition of the premises, or any equipment or the use of any process or treatment involves a risk of injury to health.

An authorised officer should use professional judgement to decide whether premises, process, treatment or piece of equipment or its use involves a risk of injury to health.

The following paragraphs provide examples of circumstances that may show that the health risk condition exists as defined by regulation 7(2)/regulation 8(4) i.e. there is an imminent risk of injury to health, and where an authorised officer may therefore consider the use of such prohibition powers. **These examples are in no way prescriptive or exhaustive and are for illustrative purposes only.**

#### **6.2.3.10 Health risk conditions where prohibition of premises may be appropriate**

- Infestation by rats, mice, cockroaches, birds or other vermin, serious enough to result in the actual contamination of food or a significant risk of contamination.
- Very poor structural condition and poor equipment and/or poor maintenance, or routine cleaning and/or serious accumulations of refuse, filth or other extraneous matter, resulting in the actual contamination of food or a significant risk of food contamination.
- Drainage defects or flooding of the establishment, serious enough to result in the actual contamination of food, or a significant risk of food contamination.
- Premises or practices which seriously contravene food law and have been, or are implicated, in an outbreak of food poisoning.
- Any combination of the above, or the cumulative effect of contraventions which, taken together, represent the fulfilment of the health risk condition.

#### **6.2.3.11 Health risk conditions where the prohibition of equipment may be appropriate**

- Use of equipment for the processing of high-risk foods that has been inadequately cleaned or disinfected or which is grossly contaminated and can no longer be properly cleaned.
- Dual use of complex equipment, such as vacuum packers for raw and ready-to-eat foods. However, dual use of less complex equipment such as weighing scales may be appropriate subject to the business being able to demonstrate that such equipment will be effectively cleaned and disinfected between use for raw and ready-to-eat foods.
- Use of storage facilities or transport vehicles for primary produce where the storage facilities or transport vehicles have been inadequately cleaned or disinfected.

#### **6.2.3.12 Health risk conditions where prohibition of a process may be appropriate**

- Serious risk of cross contamination.
- Failure to achieve sufficiently high processing temperatures.
- Operation outside critical control criteria, for example, incorrect pH of a product which may allow *Clostridium botulinum* to multiply.
- The use of a process for a product for which it is inappropriate.

#### **6.2.3.13 Hygiene Emergency Prohibition Procedures / Emergency Prohibition Procedures**

In the case of Regulation 8(2) of the Food Safety and Hygiene (England) Regulations 2013 and Section 12(2) of the Food Safety Act 1990, the application is made by the Competent Authority and hence it bears the burden of proof. The necessary evidential requirements are respectively set out in Regulation 7(2) and

7(4) and Regulation 8(1) and 8(4) of the Food Safety and Hygiene (England) Regulations 2013, and Section 11(2) and 11(4) and Section 12(1) and (4) of the Food Safety Act 1990.

An authorised officer should use professional judgement to decide whether premises, process, treatment or piece of equipment or its use involves an **imminent risk** of injury to health.

#### **6.2.3.14 Seeking additional advice**

Authorised officers should seek expert medical or other professional advice if a process or treatment is producing food that appears to contain chemicals or other substances that might pose an imminent risk of injury to health, or where the process or treatment in question itself requires other specialist knowledge or expertise<sup>19</sup>.

An authorised officer exercising a right of entry under Regulation 16 of the Food Safety and Hygiene (England) Regulations 2013 or Section 32 of the Food Safety Act 1990 can be accompanied by any other necessary persons, including experts.

It is, however, the authorised officer who must be satisfied that the health risk condition is fulfilled with respect to the food business.

#### **6.2.3.15 Deferring immediate action**

There may be circumstances where immediate closure may be unnecessary, even though there might be an imminent risk to health. For example, the condition of a retail food premises that might pose an imminent risk, would not necessarily warrant immediate closure if the condition was only discovered at the end of trading hours.

In such a case, the authorised officer might decide not to impose an emergency prohibition if the FBO undertook the necessary measures to clean the premises overnight.

The risk in such circumstances might be minimal, as the premises would not be open to the public. The authorised officer would be free to decide on the following morning whether the imminent risk still existed or had been removed.

#### **6.2.3.16 Serving a prohibition order**

A HPO, a HEPO, a prohibition order or an EPO – all of which are made by the Courts – need not necessarily be served by the authorised officer who initiated the action. It should, however, be served by an authorised officer who is competent to explain the purpose of the Order or deal with obstruction.

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<sup>19</sup> The Institute of Food Science and Technology maintains a list of experts in particular fields.

If a HPO, a HEPO, a prohibition order or an EPO cannot be handed to the FBO in person, a copy of the document should be handed to whoever is responsible for complying with immediate closure or prohibition action, e.g. the manager.

The authorised officer should ensure that the FBO is aware of the matters that constitute an imminent risk. Although this is included in the model HEPN in this Practice Guidance and the prescribed EPN, the FBO may not understand what steps need to be taken to remove the imminent risk and further explanation may be necessary.

#### **6.2.3.17 Methods of serving the notice or order**

Every effort should be made to serve a HPO, a HEPO, a prohibition order or an EPO by delivering it by hand to the FBO, or each of the operators/proprietors in the case of a partnership etc.

The authorised officer can, if necessary, consult with the Justices' Clerk to see if it would be possible to serve an order before the operator/proprietor leaves the Court, where the operator/proprietor is present.

The service of the notice or order on a number of partners can present difficulties, particularly where a partner is not in the United Kingdom at the time. As soon as the notice or order is properly served on any one of the partners it takes effect.

If it is not possible to serve the document by hand then the authorised officer should serve the document by a postal or courier service that includes proof of posting or despatch and, ideally, proof of delivery.

The document can be faxed to the operator / proprietor for information in advance of its formal service, but a hard copy must follow for it to be properly served.

It is useful to record the time of service, even when the postal service is used.

Immediately the document has been legally served by one of the methods mentioned in Regulation 30 of the Food Safety and Hygiene (England) Regulations 2013 or Section 50 of the Food Safety Act 1990, the prohibition on the use of the premises, or equipment for the purposes of any food business, or a particular type of food business, or prohibition on a process or treatment, becomes effective under the order and the HEPN or EPN ceases to have effect.

#### **6.2.3.18 Evidence required**

The authorised officer should collect sufficient evidence to produce to the Court to substantiate any proceedings.

It is important that contemporaneous notes, including sketches and photographs, are taken during an inspection as they may be used in evidence to a Court. Samples of insects, dirt or other contaminants may also be useful.



Although authorised officers need not be accompanied by a witness, there may be occasions when visual reports are of particular relevance and there would be benefits in matters being witnessed. An authorised officer's notes made during or at the end of a visit to an establishment should be accurate and factual, so that they may rely on it in Court.

### **6.2.3.19 Prohibition of a person**

When an FBO has been convicted of a relevant offence, the authorised officer may feel that it is appropriate to ask the Court to consider making a prohibition order in relation to that FBO.

Circumstances where such action may be appropriate include repeated offences such as failure to clean, failure to maintain equipment, blatant disregard for health risks, or putting health at risk by knowingly using unsafe food.

### **6.2.3.20 Application to the Court**

Some Competent Authorities have authorised officers under Section 223 of the Local Government Act 1972 to represent the Competent Authority in proceedings before the magistrates' court as prosecutors.

Where such an arrangement does not exist, the Competent Authority should try to agree procedures. The Competent Authority should discuss a detailed programme of formal action with its litigation solicitor and with the clerk of the local magistrates' court and should clarify details of local Court practice to try and resolve potential difficulties of obtaining Court time at short notice. This can be initiated by informal contact with the Magistrates' Clerk's Office to ensure that, if at all possible, applications for EPOs and HEPOs are expedited.

The FBO must be notified that the authorised officer intends to apply for an HEPO or EPO. A notice of application for the order must be served on the FBO at the latest on the day before the date of the application, giving details of the Court appearance.

### **6.2.3.21 Action to be taken prior to the hearing**

The authorised officer should organise monitoring of the premises between the service of the notice and the Court hearing. The officer who served the notice need not necessarily carry out the monitoring but should fully brief the relevant colleague of the risks and evidence gathered, that gave rise to the service of the notice.

The premises should be re-inspected shortly before the hearing (preferably the day before or on the day of the hearing itself) by the officer who served the notice.

If this is not possible, an authorised officer with relevant experience should carry out the re-inspection. This should also be the case if any contravention was found during the monitoring.

The purpose of the re-inspection is to gather evidence as to the current condition of the premises or equipment for the Court hearing. . The authorised officer must note any changes that have taken place since the notice was served. For example, the circumstances which led to the service of the notice might have worsened, or other circumstances not present originally might now also pose a risk to health.

If the authorised officer is considering bringing the attention of the Court to Regulation 7 of Food Safety and Hygiene (England) Regulations 2013 or Section 11 of the Food Safety Act so that a HPO or prohibition order against a FBO is to be considered, it is important that suitable evidence is gathered to produce to the Court.

It is important that the authorised officers brief their legal advisers fully on the public health aspect of the case in hand, including the public health basis for the legal requirements which have been breached, so that they can, in turn, impress upon the Court the seriousness of the charges.

#### **6.2.3.22 Information to be given to the Court**

Information that the Court may require includes:

- the state of the premises or equipment, both at the time of the offence and at the time the premises were re-inspected prior to the hearing
- any evidence that the FBO had been involved in the commission of offences elsewhere, which tended to show weaknesses in management (the authorised officer may have to investigate to ascertain whether the operator / proprietor has been convicted of offences at previous food premises and what these convictions were for)

It is usual practice for those prosecuting to ascertain whether there have been any previous convictions or cautions and to obtain details for presentation to the Court in the event of the prosecution being successful. They may also be used in evidence if the requirements of Section 101 of the Criminal Justice Act 2003 are met.

#### **6.2.3.23 Affixing the notice or order on the premises**

Regulations 7 and 8 of the Food Safety and Hygiene (England) Regulations 2013 and Sections 11 and 12 of the Food Safety Act 1990 direct that as soon as practicable after the making of an order or the service of a notice, a copy of the order or notice should be affixed in a conspicuous position on the premises by the Competent Authority.

The purpose of this is to inform the public, which includes anyone who may use the premises or equipment, that the premises have been closed or a process or piece of equipment prohibited from being used.

An authorised officer, who is competent to explain the meaning and importance of the notice, should take this action. A witness need only accompany the officer if required by the Competent Authority. The authorised officer who initiated the action need not necessarily be involved.

The authorised officer must, firmly affix the document inside the premises, but in a position where it can clearly be seen and read from the outside, preferably on the inside of the glass of a front display window.

If such a position is unavailable the officer should use professional judgement as to the best place available and if necessary affix a second copy of the document to the outside of the premises, making sure, as far as possible, that it is protected from the weather and possible vandalism. The Competent Authority should arrange for periodic checks to be made on the document to establish that it is still there.

#### **6.2.3.24      Unauthorised removal or defacement of notices or orders**

Neither the Food Safety and Hygiene (England) Regulations 2013 nor The Food Safety Act 1990 make any reference to defacing or removing a HPO, a HEPN, a HEPO, a prohibition order, an EPN, or an EPO. Such action should be considered as obstruction under Regulation 17 of Food Safety and Hygiene (England) Regulations 2013, as removing or defacing a notice or order can be considered an act that "intentionally obstructs any person acting in the execution of the Hygiene Regulations". Similarly, section 33 of the Food Safety Act 1990 makes it an offence to intentionally obstruct any person acting in the execution of this Act.

#### **6.2.3.25      Lifting a notice or order**

The FBO must apply in writing to the Competent Authority for a certificate lifting a HPO, a HEPN or HEPO, a prohibition order or an EPN or EPO. On receiving such a request, the authorised officer should re-inspect the premises as soon as possible and determine as soon as is reasonably practicable, or in any event within 14 days, whether the notice or order can be lifted.

The decision on whether to issue the certificate or not should be made by the officer who initiated the action if this is possible or, if it is not, by another authorised officer with the relevant qualifications and experience.

If the Competent Authority is of the opinion that the health risk condition has been removed, arrangements should be made for the certificate under Regulation 7(7) or 8(8) of the Food Safety and Hygiene (England) Regulations 2013, or Section 11(6) or 12(8) of the Food Safety Act 1990 as appropriate to be issued as quickly as possible, and in any case within 3 days. The certificate can be sent by fax, although the proprietor can also be informed of the decision verbally, thus allowing the premises to re-open immediately.

If the authorised officer is of the opinion that the health risk condition has not been removed, arrangements should be made under Regulation 7(7) (b) or 8(9) (b) of the Food Safety and Hygiene (England) Regulations 2013, or Section 11(7) (b) or Section 12(9) (b) of the Food Safety Act 1990 as appropriate for the Competent Authority to issue a notification of continuing risk to health as quickly as possible. The Competent Authority must give reasons why it is not satisfied that the health risk condition has been removed.

Although a certificate lifting a HEPN or EPN can be issued before the application for a HEPO or EPO can be heard, the operator / proprietor can still be prosecuted for the offence(s) against the Food Safety and Hygiene (England) Regulations 2013 or the Food Safety Act 1990 as appropriate.

The Competent Authority should ensure that the court is informed in this situation.

A HPO or prohibition order on the FBO / food business proprietor can only be lifted on application by the operator / proprietor to the Court that made the order.

#### **6.2.3.26 Lifting of Hygiene Emergency Prohibition Notice (HEPN) before court hearing**

Where a **delay** occurs between the inspection/ service of the HEPN and the hearing of the HEPO application by the Court, a further inspection should take place prior to the hearing to ensure evidence of any current risk to public health is available. Failure to gather such evidence may prevent the Court in making an informed decision on whether the health risk condition still exists.

If an officer conducts a further inspection before the Court hearing and they are satisfied that the health risk condition no longer exists, under Regulation 8(9) of the Food Safety and Hygiene (England) Regulations 2013 they must issue a certificate within three days to this effect. The authorised officer may still wish to continue with the application to request the HEPO – the officer should make clear the distinction between making of the application for the HEPO and the hearing to request the HEPO, the latter of which may lessen the possibilities of a claim for compensation by the FBO. Regulation 8(10) gives the Court discretion to issue a declaration that they are satisfied the health risk condition was fulfilled on the date of service of the HEPN. If the FBO has sought a certificate that the health risk condition no longer exists the competent authority must determine within 14 days whether that this condition is fulfilled or not.

#### **6.2.3.27 Breach of a notice or order**

A person who fails to comply with a HIN is guilty of an offence under Regulation 6(2) of the Food Safety and Hygiene (England) Regulations 2013

A person who knowingly contravenes a HPO or a prohibition order is guilty of an offence under Regulation 7(5) of the Food Safety and Hygiene (England) Regulations 2013 or Section 11(5) of the Food Safety Act 1990, respectively.

A person who knowingly contravenes a HEPN or HEPO or an EPN or EPO is guilty of an offence under Regulation 8(5) or (6) of the Food Safety and Hygiene (England) Regulations 2013 or Section 12(5) or (6) of the Food Safety Act 1990, respectively.

A person who fails to comply with a Remedial Action Notice (RAN) is guilty of an offence under Regulation 9(5) of the Food Safety and Hygiene (England) Regulations 2013.

A person who fails to comply with a Detention Notice (DN) is guilty of an offence under Regulation 10(3) of the Food Safety and Hygiene (England) Regulations 2013.

Where a Notice is breached, there are several offences, the breach of the Regulations and the breach of the notice requiring the non-compliance to be addressed. Both are offences and should be referred for prosecution.

The authorised officer should start proceedings for the offence under the appropriate legislation by laying a draft summons before the Magistrates' Court which is subsequently served on the Defendant requiring them to attend a first hearing to enter a plea.

If the authorised officer believes that there is sufficient evidence to show that the proprietor is unlikely to respond to a summons, application should be made for a warrant rather than a summons. The Court will decide if the circumstances justify this action and can ask the authorised officer for their view as to whether to endorse the warrant with bail. The authorised officer should use their professional judgement and take into account all relevant circumstances in their decision.

The Competent Authority should make contingency arrangements with its legal department, so that in the event of the breach of a notice or order, there is no delay in making an application before the Court. Competent Authorities should refer to their internal enforcement policy when deciding what action to take regarding the breach of regulations and or notices.

#### **6.2.3.28 Appeals: Refusal of a Competent Authority to issue a certificate that the health risk condition no longer exists**

Regulation 22(1) of the Food Safety and Hygiene (England) Regulations 2013 and Section 37 of the Food Safety Act 1990 allow anybody who is aggrieved by a decision of a Competent Authority to refuse to issue a certificate that there is no longer a risk to health to appeal by way of a complaint to the Magistrates' Court. The time limit for such an appeal is one month from the date when the Competent Authority served the notice of their refusal to lift the prohibition.

The recipient of a notice of refusal should clearly understand their right of appeal. The notice should therefore include, or be accompanied by, details of the right of appeal and the name and address of the relevant Magistrates' Court.

#### **6.2.3.29 Compensation**

Regulation 8(10) of the Food Safety and Hygiene (England) Regulations 2013 and Section 12(10) of the Food Safety Act 1990 provide for the Competent Authority to compensate the FBO for losses arising from the service of a HEPN or EPN if a HEPO or EPO as appropriate is not applied for to the Court within three days and the Court is not satisfied that the health risk condition was fulfilled at the time the notice was served.

Compensation is payable in respect of “any loss” which is directly attributable to the wrongful service of the notice.

The Competent Authority can assess the amount of compensation due taking into account (among other things) the following aspects where applicable:

- the length of time the process or treatment was halted, or the use of premises or equipment was prohibited and for what purpose
- loss of trade
- value of spoiled food
- loss of goodwill
- loss of wages
- how much of the damage to trade is repairable
- obligation of the operator / proprietor to mitigate their own loss

or, if the operator / proprietor of the business is agreeable, a loss adjuster can be called in.

## **6.2.4 Seizure and Detention**

### **6.2.4.1 Introduction**

This section concerns the use of the detention and seizure powers under Regulation 29 of the Food Safety and Hygiene (England) Regulations 2013 and / or Section 9 of the Food Safety Act 1990, as amended.

#### **6.2.4.2 General**

It is presumed under food law that all food is intended for human consumption until it is proved to the contrary.

Detention powers should not be used in relation to food that has already been clearly identified by a food business as not being intended for human consumption.

An officer may assist or advise the person in charge of the food as appropriate. If there is any doubt about the food being used for human consumption, it must be presumed that it is. If an FBO wished to argue for a contrary intention then it is for the FBO to prove this. .

#### **6.2.4.3 Regulation 29 Food Safety and Hygiene (England) Regulations 2013 - Food not produced, processed or distributed in compliance with the hygiene regulations**

Under Regulation 29 of the Food Safety & Hygiene (England) Regulations 2013, an authorised officer of a Competent Authority may, on an inspection of any food, certify that it has not been produced, processed or distributed in compliance with the Hygiene Regulations as defined in Regulation 2 of the same Regulations. A model certificate for this purpose can be found at 6.3 below. The food must then be treated

for the purposes of Section 9 of the Food Safety Act 1990 as failing to comply with food safety requirements. Competent Authorities must continue to use the forms set out in the Detention of Food (Prescribed Forms) Regulations 1990<sup>20</sup> when using powers under Section 9 of the Food Safety Act 1990 following the issue of a certificate as mentioned above.

#### **6.2.4.4 Food which does not satisfy food safety requirements - Food Safety Act 1990, Section 9 as amended**

If food does not satisfy food safety requirements for other than hygiene reasons, Section 9 of the Food Safety Act 1990 should be used. Section 9 of the Act permits the service of a detention of food notice to prevent the use of the food for human consumption. Competent Authorities must continue to use the forms set out in the Detention of Food (Prescribed Forms) Regulations 1990 when using powers under Section 9 of the Food Safety Act 1990.

#### **6.2.4.5 Specific powers of seizure and detention for County Council Competent Authorities**

The following legislation, gives powers of seizure and detention to Competent Authorities carrying out food standards controls.

- Contaminants in Food (England) Regulations 2013
- Eggs & Chicks Regulations (England) 2009
- Food Irradiation (England) Regulations 2009
- Genetically Modified Food (England) Regulations 2004
- Tryptophan in Food (England) Regulations 2005
- Scotch Whisky Regulations 2009
- Spirit Drinks Regulations 2008
- The Food Additives, Flavourings, Enzymes and Extraction Solvents (England) Regulations 2013

#### **6.2.4.6 Detention of food**

Authorised officers need to exercise careful judgement, and might need to seek expert advice, before using their powers to detain food pending further investigation.

Food that is suspected of causing food poisoning can often be readily identified, and the decision to detain can therefore be taken relatively easily.

The notice can specify that the food is either to be held where it is, or moved to a place specified by the officer, pending further investigations.

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<sup>20</sup> SI 1990 No. 2614

Food that requires special storage conditions, such as refrigeration, might need to be moved elsewhere, in which case the decision to require the food to be moved should be discussed with the owner of the food.

The decision to detain a whole batch, lot, or consignment needs careful consideration before a notice is served (see paragraph 6.2.4.10).

#### **6.2.4.7 Seizure of food**

The officer might be required to prove that the food produced before the Justice of the Peace is the food that was seized. The food should only be left if the officer is confident that it will not be moved, used for human consumption, or the evidence destroyed.

#### **6.2.4.8 Food condemnation warning**

A food condemnation notification giving details of the time and place of the appearance before a Justice of the Peace should be given to the person in charge of the food once the decision to seize food has been taken. This notification is purely administrative and can therefore be signed by any authorised officer.

The officer delivering the notification does not need to hold the same qualifications as the officer who took the decision to detain or seize the food, but must be sufficiently competent to explain the purpose of the notification and to deal with any obstruction.

Notification to the owner of the food can be by personal delivery, fax, telephone, e-mail, or other rapid means of communication.

This is especially important in cases of seizure, because of the right conferred by Section 9(5) of the Food Safety Act 1990, as amended, on any person who might be liable to prosecution for selling or producing unsafe food to attend before a Justice of the Peace, to be heard and to call witnesses.

#### **6.2.4.9 Taking action without inspecting**

The provisions of Section 9 of the Food Safety Act 1990 also apply to food that has not been inspected (Section 9(2)).

This could apply when the officer has reasonable grounds to suspect that consumption of the food would be likely to cause foodborne or other communicable disease, or that it was otherwise so contaminated that it would not be reasonable for it to be consumed in that condition.

Information from another reliable source, e.g. another Competent Authority, the HPA, the CCDC, or the FSA etc. can be sufficient to enable an authorised officer to act without inspecting.



Although an inspection of the food is not legally necessary in such situations, it might nonetheless be prudent, if only for identification purposes.

#### **6.2.4.10 Dealing with batches, lots or consignments of food**

Article 14(2) of Regulation 178/2002<sup>21</sup> defines unsafe food and is relevant to both the Food Safety and Hygiene (England) Regulations 2013 and the Food Safety Act 1990.

Article 14(6) of Regulation 178/2002 covers situations where food is part of a larger batch, lot or consignment of food of the same class or description. In such circumstances it is presumed, until the contrary is proved, that all of the food in the batch, lot or consignment fails to comply with food safety requirements.

The authorised officer should use professional judgement to decide whether to detain or seize the whole of the batch, lot or consignment. Appropriate expert advice should be sought if necessary.

If a whole batch, lot or consignment is detained and it subsequently becomes clear that only part of the detained food is affected and needs to be seized, the remainder of the batch etc. may be released. The compensation provisions under Section 9(7) of the Food Safety Act 1990, as amended, should always be borne in mind if this course of action is taken.

#### **6.2.4.11 Voluntary procedures**

It should also be borne in mind that the use of voluntary procedures might contribute to a defence in any subsequent prosecution. It could, for example, be argued that the food was not so contaminated that it had to be seized.

The fact that food had been condemned by a Justice of the Peace would be persuasive in any prosecution, but would not in itself necessarily establish an offence. It would still be necessary for a case to be proved beyond reasonable doubt. In this respect certificates of analysis or examination are of particular value.

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<sup>21</sup> Regulation (EC) No. 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety

## 6.2.5 Remedial Action Notices and Detention Notices

### 6.2.5.1 Regulation 9 and 10– Food Safety and Hygiene (England) Regulations 2013 - Remedial Action Notices / Detention Notices

All relevant information is contained in Chapter 6.2.12 of the Code of Practice.

## 6.3 Documentation

Model forms which can be used by authorised officers in connection with the Food Safety and Hygiene (England) Regulations 2013 (FSHR 2013) and Food Information Regulations 2014 are provided as summarised in the following table.

| Practice Guidance Reference | Model form   | For use In connection with:   |
|-----------------------------|--|---|
| 6.3.1                       | <a href="#">Hygiene Improvement Notice</a>   | regulation 6, FSHR 2013   |
| 6.3.2                       | Hygiene Emergency Prohibition Notice   | regulation 8, FSHR 2013   |
| 6.3.3                       | Notice of Intention to apply for a Hygiene Emergency Prohibition Order   | regulation 8, FSHR 2013   |
| 6.3.4                       | Certificate that health risk condition no longer exists  | regulation 7 and regulation 8, FSHR 2013  |
| 6.3.5                       | Notice of determination that health risk condition remains in existence  | regulation 7 and regulation 8   |
| 6.3.6                       | Certificate that food has not been produced, processed or distributed in compliance with the Hygiene Regulations | regulation 27, FSHR 2013  |
| 6.3.7<br>6.3.8              | Suggested wording with use of FIR 2014 INs<br>A model form of an IN for the purposes of FIR 2014                 | Regulation (EU) No 1169/2011 of the European Parliament and of the Council or the Food Information Regulations (SI 2014/1855) |
| 6.3.9                       | Remedial Action Notice   | regulation 9, FSHR 2013   |
| 6.3.10                      | Detention Notice   | regulation 9, FSHR 2013   |
| 6.3.11                      | Notice of withdrawal of Remedial Action Notice/Detention Notice  | regulation 9, FSHR 2013   |

**6.3.1 Model form - Hygiene Improvement Notice**

Authority: \_\_\_\_\_  
**The Food Safety and Hygiene (England) Regulations 2013 –  
Regulation 6  
HYGIENE IMPROVEMENT NOTICE**

Reference  
Number: \_\_\_\_\_

1. To: \_\_\_\_\_ (Food Business  
Operator)

At: \_\_\_\_\_  
\_\_\_\_\_  
(Address of Food Business  
Operator)

2. I have reasonable grounds for believing that you are failing to comply with the  
Hygiene Regulations because:

\_\_\_\_\_  
\_\_\_\_\_  
[Officer to insert grounds for believing that the Hygiene Regulations are being  
breached]  
in connection with your food business \_\_\_\_\_

\_\_\_\_\_  
(Name of Food  
Business)

at: \_\_\_\_\_  
\_\_\_\_\_  
(Address of Food  
Business)

The matters which constitute your failure to comply are:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
[Officer to insert provision(s) of the Hygiene Regulations which is/are being  
breached and why]

3. In my opinion, the following measure(s) are needed for you to comply with the  
Hygiene Regulations:

\_\_\_\_\_

4. The measure or measures that will achieve the same effect must be taken by:  
\_\_\_\_\_ (date)

5. It is an offence not to comply with this hygiene improvement notice by the date  
stated.

Signed: \_\_\_\_\_ (Authorised Officer)

Name in capitals: \_\_\_\_\_

Date: \_\_\_\_\_

Address: \_\_\_\_\_

Tel: \_\_\_\_\_ Fax: \_\_\_\_\_

E-mail: \_\_\_\_\_

**Please read the notes overleaf carefully. If you are not sure of your rights or  
the implications of this notice, you may want to seek legal advice.**

## **Model form - Hygiene Improvement Notice (reverse)**

### NOTES

In the opinion of the authorised officer you are not complying with the Hygiene Regulations as described in paragraph 2 of the notice. The work needed in the officer's opinion to put matters right is described and it must be finished by the date set.

You are responsible for ensuring that the work is carried out within the period specified, which must be at least 14 days from the date of the notice.

You have a right to carry out work that will achieve the same effect as that described in the notice. If you think that there is another equally effective way of complying with the law, you should first discuss it with the officer.

### YOUR RIGHT OF APPEAL

In accordance with Regulation 22 of the Food Safety and Hygiene (England) Regulations 2013, if you disagree with all or part of this notice, you can appeal to the Magistrates' Court. You must appeal within one calendar month of the date of the notice or the period ending with the date stated in paragraph 4 of the notice, whichever ends earlier.

If you decide to appeal, the time set out in the notice is suspended and you do not have to carry out the work described until the appeal is heard. However, if you are not complying with the Regulations mentioned in the notice, you may still be prosecuted for failure to comply with those Regulations.

When the appeal is heard, the Magistrates' Court may confirm, cancel or vary the notice.

**WARNING**

**FAILURE TO COMPLY WITH THIS NOTICE IS AN OFFENCE**

Offenders are liable to be fined and/or imprisoned for up to 2 years.

**6.3.2 Model form - Hygiene Emergency Prohibition Notice**

Authority: \_\_\_\_\_  
**The Food Safety and Hygiene (England) Regulations 2013 –  
Regulation 8  
HYGIENE EMERGENCY PROHIBITION NOTICE**

Reference  
Number:

1. To: \_\_\_\_\_ (Food Business  
Operator)

At: \_\_\_\_\_  
\_\_\_\_\_  
(Address of Food Business  
Operator)

2.\* I am satisfied that the health risk condition is fulfilled with respect to:  
\_\_\_\_\_  
(Name of Food  
Business)

at: \_\_\_\_\_  
\_\_\_\_\_  
(Address of Food  
Business)

Because: \_\_\_\_\_  
\_\_\_\_\_

(\* See Note 1 overleaf)  
YOU MUST NOT USE IT FOR THE PURPOSES OF [THIS] [ANY] [THIS OR  
ANY SIMILAR]† FOOD BUSINESS.  
[† Officer to delete as appropriate]

Signed: \_\_\_\_\_ (Authorised Officer)

Name in capitals: \_\_\_\_\_

Date: \_\_\_\_\_

Address: \_\_\_\_\_  
\_\_\_\_\_

Tel: \_\_\_\_\_ Fax: \_\_\_\_\_

E-mail: \_\_\_\_\_

**Please read the notes overleaf carefully. If you are not sure of your rights or  
the implications of this notice, you may want to seek legal advice.**

## **Model form 2 - Hygiene Emergency Prohibition Notice (reverse)**

### **NOTES**

When you receive this notice you must IMMEDIATELY stop using the premises, process, treatment or equipment described by the officer in paragraph 2 of the notice and located at the address stated.

Within 3 days of service of this notice, the authority must apply to a Magistrates' Court for an order confirming the prohibition. You will be told the date of the hearing which you are entitled to attend and at which you may call witnesses if you wish.

If you believe that you have acted to remove the health risk condition, you may apply in writing to the authority for a certificate of satisfaction which, if granted, would allow you to use the premises, process, treatment or equipment again. You can do this even if the court hearing has not taken place.

You are not allowed to use the premises, process, treatment or equipment for the purpose specified in paragraph 2 of the notice (see Regulation 7(3) of the Food Safety and Hygiene (England) Regulations 2013) as applied by Regulation 8(4)) until a court decides you may do so; or the authority issues you with a certificate as in paragraph 3 above; or 3 days have passed since the service of the notice and the authority has not applied to the court as in paragraph 2 above; or the authority abandons the application.

A copy of this notice must, by law, be fixed on the premises. It is an offence (under Section 1 of the Criminal Damage Act 1971) to deface it.

**COMPENSATION:** If the authority does not apply to the Magistrates' Court, for an order confirming its action within 3 days of the date of service of this notice, you will be entitled to compensation for any losses you have suffered because you could not use the premises, process, treatment or equipment because you were complying with this notice. You will also be entitled to such compensation if the Magistrates' Court, decide at the hearing that the health risk condition was not fulfilled with respect to the food business at the time when the notice was served.

**WARNING**

**ANYONE WHO CONTRAVENES THIS NOTICE IS GUILTY OF AN OFFENCE**

Offenders are liable to be fined and/or imprisoned for up to 2 years.

**6.3.3 Model form – Notice of intention to apply for a Hygiene Emergency Prohibition Order**

Authority: \_\_\_\_\_

**The Food Safety and Hygiene (England) Regulations 2013 –  
Regulation 8**

**NOTICE OF INTENTION TO APPLY FOR HYGIENE EMERGENCY PROHIBITION  
ORDER**

Reference

Number: \_\_\_\_\_

1. To: \_\_\_\_\_ (Food Business Operator)

At: \_\_\_\_\_  
\_\_\_\_\_  
(Address of Food Business Operator)

2. You are the food business operator of the food business at:

\_\_\_\_\_  
\_\_\_\_\_

3. I give notice that I shall be applying to the Magistrates' Court sitting at

on: \_\_\_\_\_ (Date)\*

at: \_\_\_\_\_ (Time)\*

[\*Officer to insert if known]

for a Hygiene Emergency Prohibition Order

because: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

[Officer to state reason why the order is being sought in respect of the premises, process, treatment or equipment]

4. If an order is made by the court you will not be able to use the [premises] [process] [treatment] [equipment]† described:

\_\_\_\_\_  
\_\_\_\_\_

for the purpose of [this] [any] [this or any similar]† food business.

[† Officer to delete as appropriate]

Signed: \_\_\_\_\_ (Authorised Officer)

Name in capitals: \_\_\_\_\_

Date: \_\_\_\_\_

Address: \_\_\_\_\_  
\_\_\_\_\_

Tel: \_\_\_\_\_ Fax: \_\_\_\_\_

E-mail: \_\_\_\_\_  
\_\_\_\_\_

**Please read the notes overleaf carefully. If you are not sure of your rights or the implications of this notice, you may want to seek legal advice.**

## **Model form - Notice of intention to apply for a Hygiene Emergency Prohibition Order (reverse)**

### **NOTES**

This notice tells you that the authority intends to apply to the Magistrates' Court for a Hygiene Emergency Prohibition Order which, if granted, would mean that you could not use the premises, process, treatment or equipment described for the purposes specified in paragraph 3 of the notice (see Regulation 7(3) of the Food Safety and Hygiene (England) Regulations 2013 as applied by Regulation 8(4)).

The court will consider the evidence from the authority as to why they believe the health risk condition is fulfilled from the operation of your food business or part of it. You may bring your own evidence and witnesses to put before the court and you may choose to be represented by a lawyer.

If the court is satisfied by the authority's evidence that the health risk condition is fulfilled, then an order will be made stating what you may not do. The order will be served on you by the authority. A copy of it must be fixed by the authority in a conspicuous position on your premises and it is an offence to deface it (section 1 of the Criminal Damage Act 1971).

In accordance with Regulation 23 of the Food Safety and Hygiene (England) Regulations 2013, you have the right to appeal to the Crown Court against the decision of the Magistrates' Court if you think that it is wrong.

The making of an order does not mean you are guilty of an offence but the authority may seek to prosecute you for offences under the Food Safety and Hygiene (England) Regulations 2013 or associated Regulations.

If you have been issued with a Hygiene Emergency Prohibition Notice from the authority, you will know what steps should be taken to remove the health risk condition.

If the court is not satisfied by the authority's evidence and an order is not issued, then you will be entitled to continue your business. If the authority has already issued you with a Hygiene Emergency Prohibition Notice and you have suffered loss because you have complied with it, then you will also be entitled to compensation from the authority.



**6.3.4 Model form - Certificate that health risk condition no longer exists**

Authority: \_\_\_\_\_

**The Food Safety and Hygiene (England) Regulations 2013 –  
Regulations 7 and 8**

**CERTIFICATE THAT THE HEALTH RISK CONDITION NO LONGER EXISTS**

1. To: \_\_\_\_\_ (Food Business Operator)

At: \_\_\_\_\_  
\_\_\_\_\_  
(Address of Food Business Operator)

Name of food business: \_\_\_\_\_

Address of food business: \_\_\_\_\_

2. The enforcement authority certifies that it is satisfied that you have taken sufficient measures to secure that the health risk condition described in the:  
Hygiene Prohibition Order\*  
Hygiene Emergency Prohibition Notice\*  
Hygiene Emergency Prohibition Order\*  
[\* Officer to delete as appropriate]  
served \_\_\_\_\_ on \_\_\_\_\_ you \_\_\_\_\_ on \_\_\_\_\_  
..... (date) is no longer fulfilled with respect to the food business.

Signed: \_\_\_\_\_ (Authorised Officer)

Name in capitals: \_\_\_\_\_

Date: \_\_\_\_\_

Address: \_\_\_\_\_  
\_\_\_\_\_

Tel: \_\_\_\_\_ Fax: \_\_\_\_\_

E-mail: \_\_\_\_\_

**THIS CERTIFICATE MEANS THAT YOU MAY NOW USE THE PREMISES,  
PROCESS, TREATMENT OR EQUIPMENT AGAIN.**

**Please read the notes overleaf carefully. If you are not sure of your rights or the implications of this certificate, you may want to seek legal advice.**

**Model form - Certificate that health risk condition no longer exists (reverse)**

**NOTES**

The enforcement authority is now satisfied that the health risk condition no longer exists in respect of the circumstances that caused the enforcement authority to issue you with a Hygiene Emergency Prohibition Notice or the court to impose a Hygiene Prohibition Order or Hygiene Emergency Prohibition Order.

The relevant notice or order is now lifted and you may use the premises, process, treatment or equipment again.

**6.3.5 Model form – Notice of determination that health risk condition remains in existence**

Authority: \_\_\_\_\_  
**The Food Safety and Hygiene (England) Regulations 2013 –  
Regulations 7 and 8**

**NOTICE OF DETERMINATION THAT THE HEALTH RISK CONDITION REMAINS  
IN EXISTENCE**

1. To: \_\_\_\_\_ (Food Business Operator)  
At: \_\_\_\_\_  
\_\_\_\_\_ (Address of Food Business Operator)

Name of food business: \_\_\_\_\_  
Address of food business: \_\_\_\_\_

2. The enforcement authority has determined that it is **NOT** satisfied that you have taken sufficient measures to remove the health risk condition described in the:  
Hygiene Prohibition Order\*  
Hygiene Emergency Prohibition Notice\*  
Hygiene Emergency Prohibition Order\*  
[\* Officer to delete as appropriate]  
served on you on \_\_\_\_\_ (date) and is satisfied that the health risk condition remains fulfilled with respect to the food business.
3. The enforcement authority is not satisfied because

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
Signed: \_\_\_\_\_ (Authorised Officer)  
Name in capitals: \_\_\_\_\_  
Date: \_\_\_\_\_  
Address: \_\_\_\_\_  
Tel: \_\_\_\_\_ Fax: \_\_\_\_\_  
E-mail: \_\_\_\_\_

**THIS NOTICE MEANS THAT YOU MAY NOT USE THE PREMISES, PROCESS,  
TREATMENT OR EQUIPMENT UNTIL THE ENFORCEMENT AUTHORITY  
NOTIFIES THAT YOU MAY DO SO.**

**Please read the notes overleaf carefully. If you are not sure of your rights or the implications of this notice, you may want to seek legal advice.**

Model form - Notice of determination that health risk condition remains in existence (reverse)

## NOTES

The enforcement authority is not satisfied that the health risk condition no longer exists in respect of the circumstances that caused the enforcement authority to issue you with a Hygiene Emergency Prohibition Notice or the court to impose a Hygiene Prohibition Order or Hygiene Emergency Prohibition Order.

You still cannot use the premises, process, treatment or equipment in question for the purposes described in the Hygiene Emergency Prohibition Notice, Hygiene Prohibition Order or Hygiene Emergency Prohibition Order even if you are appealing against the terms of this notice.

In accordance with Regulation 22 of the Food Safety and Hygiene (England) Regulations 2013, you are entitled to appeal against the decision of the authority to refuse to issue a certificate of satisfaction under Regulation 7(6) or Regulation 8(8). If you want to do so, you should apply to the Magistrates' Court, within one calendar month of the date on which this notice is served on you.

As soon as you think that the health risk condition has been removed because of actions you have taken, you may apply in writing to the authority for a certificate of satisfaction which, if granted, would allow you to use the premises, process, treatment or equipment again. If a Hygiene Emergency Prohibition Notice has been issued, you can do this even if the court hearing has not taken place.

WARNING

FAILURE TO COMPLY WITH THE ORIGINAL NOTICE OR ORDER IS AN  
OFFENCE

Offenders are liable to be fined and/or imprisonment for up to 2 years.

**6.3.6 Model form - Certificate that food has not been produced, processed or distributed in compliance with the Hygiene Regulations**

Authority: \_\_\_\_\_

**The Food Safety and Hygiene (England) Regulations 2013 –  
Regulation 29**

**CERTIFICATE THAT FOOD HAS NOT BEEN PRODUCED, PROCESSED OR  
DISTRIBUTED IN COMPLIANCE WITH THE HYGIENE REGULATIONS**

1. To: \_\_\_\_\_ (Food Business Operator)

At: \_\_\_\_\_  
\_\_\_\_\_  
(Address of Food Business Operator)

Name of food business: \_\_\_\_\_

Address of food business: \_\_\_\_\_

2. Following an inspection, authorised officer certifies that the following food:

\_\_\_\_\_  
\_\_\_\_\_

\_\_\_\_\_ has not been produced, processed or distributed in compliance with the Hygiene Regulations, as outlined below:

\_\_\_\_\_  
\_\_\_\_\_

\_\_\_\_\_ The above food shall therefore be treated for the purposes of section 9 of the Food Safety Act 1990 as failing to comply with food safety requirements.

Signed: \_\_\_\_\_ (Authorised Officer)

Name in capitals: \_\_\_\_\_

Date: \_\_\_\_\_

Address: \_\_\_\_\_  
\_\_\_\_\_

Tel: \_\_\_\_\_ Fax: \_\_\_\_\_

E-mail: \_\_\_\_\_

**Please read the notes overleaf carefully. If you are not sure of your rights or the implications of this certificate, you may want to seek legal advice.**

**Model form – Certificate that food has not been produced, processed or distributed in compliance with the Hygiene Regulations (reverse)**

**NOTES**

**The authorised officer has certified that the food detailed has not been produced, processed, or distributed in compliance with the Hygiene Regulations for the reasons given.**

The food shall therefore be treated for the purposes of section 9 of the Food Safety Act 1990 as failing to comply with food safety requirements.

### 6.3.7 Food Information Regulations 2014 – Wording of Notices

Regulation 12 of the FIR 2014 applies, with modifications, Section 10 of the Food Safety Act 1990 so that IN's can be served in respect of breaches of Regulation (EU) No. 1169/2011 as well as in respect of breaches of the Food Information Regulations 2014

Schedule 5 of the Food Information Regulations 2014 specifies those provisions of Regulation (EU) No. 1169/2011 which, if breached, engage an enforcement authority's power to issue an IN.

Some suggested wording for use with INs is set out, below:

#### **Schedule 5 part 1: For matters relating to the sale / supply of non-complaint "minced meat"**

Description of the breach.....

Contrary to Article 17(5) of Regulation (EU) No. 1169/2011 on the provision of food information to consumers, a product was named as .....when its composition failed to meet the criteria for the use of that name.

#### **Schedule 5 Part 2: For all other breaches of Regulation (EU) No. 1169/2011**

Description of the breach .....

This is a breach of the provisions of Article .....of Regulation (EU) No. 1169/2011 on the provision of food information to consumers, which is specified as entry number .... of Part 2 of Schedule 5 to the Food Information Regulations 2014.

#### **Regulation 5: Allergenic ingredients - where required information is given orally**

Description of the breach .....

5(3) *No Notice indicating that the allergenic ingredient information is available orally*

"Contrary to Regulation 5 (3) of the Food Information Regulations 2014, the Food Business Operator failed to provide an indication in the required manner that allergenic ingredient information required by Article 9(1)(c) of Regulation (EU) No. 1169/2011 on the provision of food information to consumers was available by asking a member of staff"

5(4) *The Notice was incorrectly displayed*

"The Food Business operator failed to display a notice, indicating that allergenic ingredient information was available, that was readily discernable by the intended purchaser contrary to Regulation 5 (4) of the Food Information Regulations 2014"

5(5) *No name or incorrect name of allergenic substance*

"Contrary to Regulation 5 (5) of the Food Information Regulations 2014, the Food Business Operator failed to make available a clear reference to the name of the allergenic substance listed in Annex II of Regulation (EU) No. 1169/2011 on the provision of food information to consumers"

#### **Regulation 6: Name of the Food . loose food or foods broken from bulk**

6(1) *Loose food required to be named*

“Contrary to Regulation 6 (1) of the Food Information Regulations 2014, the Food Business Operator offered food for sale and failed to provide the name of the food as required by Article 9(1)(a) of Regulation (EU) No. 1169/2011 on the provision of food information to consumers.”

6(4) *Where the name of the food shall appear*

“Contrary to Regulation 6 (4) of the Food Information Regulations 2014, the Food Business Operator failed to provide the name of the food in the manner required.”

### **Regulation 7: Non Pre-packed food that contain meat**

• *No QUID Declaration*

“Contrary to Regulation 7(1) of the Food information Regulations 2014, the Food Business Operator offered for sale a food that contained meat, namely ....., and failed to provide particulars of the quantity of the meat content as required by Article 9(1) (d ) of Regulation (EU) No. 1169/2011 on the provision of food information to consumers.”

4 *Incorrect meat content declaration*

“Contrary to Regulation 7(4) of the Food information Regulations 2014, the Food Business Operator offered for sale a food that contained meat, namely ..... with an indication of the quantity of meat content which was incorrect due to excess fat and connective tissue.”

5 *Where the meat content declaration should appear*

“Contrary to Regulation 7 (5) of the Food Information Regulations 2014, the Food Business Operator failed to provide the quantity of the meat content of a food that contained meat, namely..... in the manner required.””

### **Regulation 8: Irradiated food or foods containing irradiated ingredients**

1 *Bulk food products sold loose to labelled “Irradiated” together with the name of the food*

“Contrary to Regulation 8 of the Food Information Regulations 2014, being a person who placed on the market, in bulk, a food that has been treated with, or a food containing an ingredient that has been treated with, ionising radiation and failed to ensure that the relevant indication appeared together with the name of the food in the manner required.”

3 *“Irradiated” does not appear in the ingredients list*

“Contrary to regulation 8 (3) of the Food Information Regulations 2014, being a person who placed on the market a food which contained an ingredient which has been treated with ionising radiation and failed to ensure that the relevant indication appeared in the ingredients list of the food.”





.....  
.....  
.....

[Authorised officer to insert why there is a failure to comply]

3. In order to comply with the provision specified above, you must take the following measure(s) (or measures that are at least equivalent to them)

.....  
.....  
.....  
.....  
.....

You are required to take these measures by..... (date)

5. *It is an offence not to comply with this notice.*

Signed: ..... Authorised Officer)

Name in capitals: .....

Date: .....

Address: .....  
.....  
.....  
.....

Tel: .....

Fax: .....

E-mail: .....

**Please read the notes overleaf carefully. If you are not sure of your rights or the implications of this notice, you may want to seek legal advice.**

## Model Form – Food Information Regulation 2014 Improvement Notice (reverse)

### NOTES

1. In the opinion of the authorised officer you are not complying with the provision of Regulation (EU) No 1169/2011 of the European Parliament and of the Council or the Food Information Regulations (SI 2014/1855) specified in paragraph 2 of the notice. The measures needed to put matters right are described in paragraph 3 of the notice and those measures (or equivalent measures) must be completed within the stated period.
2. You are responsible for ensuring that the measures are carried out within the period specified in the notice.
3. You have a right to take measures that are at least equivalent to the stated measures i.e. that will achieve the same effect as the measures described in the notice. If you think that there is another equally effective way of complying with the law, we would recommend that you first discuss it with the officer who issued this notice or another officer to make sure that they agree.

### YOUR RIGHT OF APPEAL

4. If you disagree with all or part of this notice, you can appeal against the notice to the First-tier Tribunal, in accordance with section 37(1) of the Food Safety Act 1990, as applied and modified by regulation 12(3) and (4) of, and Schedule 4 to, the Food Information Regulations 2014. Further information can be found here: <http://www.justice.gov.uk/tribunals/the-general-regulatory-chamber/making-an-appeal>.

5. You have 28 days from the the date of the notice was sent to you in which to send an appeal to the First-tier Tribunal. It should be sent to the First-tier Tribunal at:

General Regulatory Chamber,

HMCTS,

PO Box 9300,

Leicester, LE1 8DJ

Telephone - 0300 123 4504

Fax - 0870 739 4114

Opening times 8:30am - 5.00pm, Monday to Friday.

By email: [grc@hmcts.gsi.gov.uk](mailto:grc@hmcts.gsi.gov.uk)

6. If you decide to appeal, then the period from when you have lodged your appeal until the appeal has been decided will not count in the computation of the time period specified in the notice for carrying out the specified measures. If the notice is affirmed by the First-tier Tribunal then you will have the remainder of the period in which to carry out those measures.
7. In dealing with the appeal, the First-tier Tribunal may affirm the notice (with or without modifications) or cancel the notice.
8. You should notify the officer serving the notice if an appeal is lodged.

**WARNING**  
**FAILURE TO COMPLY WITH THIS NOTICE IS AN OFFENCE<sup>22</sup>**

<sup>22</sup> The Legal Aid, Sentencing and Punishment of Offenders Act 2012 (LASPO<sup>22</sup>) Regulation will create reforms to the justice system and these changes came into effect on 12<sup>th</sup> March 2015. These changes affects any primary and secondary legislation in England and Wales which gives magistrates courts the power to impose a fine for a criminal offence and removes the upper limit to magistrates powers when imposing fines for both summary and either way offences and will highlight that 'Offenders are liable to a fine. There is no maximum. The amount will be determined by the court'.

**6.3.9 Model form - Remedial Action Notice**

Authority: \_\_\_\_\_  
**The Food Safety and Hygiene (England) Regulations 2013 –  
Regulation 9  
REMEDIAL ACTION NOTICE  
(Establishments subject to approval under Article 4(2) of Regulation (EC) No.  
853/2004)**

Reference

Number: \_\_\_\_\_

1. To: \_\_\_\_\_  
(Food Business Operator or a Duly Authorised Representative)

At: \_\_\_\_\_  
\_\_\_\_\_  
(Address of Food Business Operator or a Duly Authorised Representative)

Name of food business: \_\_\_\_\_

Address of food business: \_\_\_\_\_

2. In my opinion:  
The Hygiene Regulations are being breached\*  
Inspection under the Hygiene Regulations is being hampered\*  
because: \_\_\_\_\_

\_\_\_\_\_  
[Officer to insert which provision(s) of the Hygiene Regulations is/are being breached and why]

[\* Officer to delete as appropriate]

3. This notice requires you to:  
Cease use of the following rooms/areas/items of equipment\*  
Observe the conditions imposed on the following process\*  
Cease the following process\*  
Reduce the rate of operation to the rate stated\*  
Stop the following operation(s) completely\*  
[\* Officer to delete as appropriate]

4. The action required to remedy the situation is as follows:  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Signed: \_\_\_\_\_ (Authorised Officer)  
Name in capitals: \_\_\_\_\_  
Date: \_\_\_\_\_  
Address: \_\_\_\_\_  
Tel: \_\_\_\_\_ Fax: \_\_\_\_\_  
E-mail: \_\_\_\_\_

It is an offence under Regulation 9(5) not to comply with this notice.

**Please read the notes overleaf carefully. If you are not sure of your rights or the implications of this notice, you may want to seek legal advice.**

## NOTES

**The authorised officer is satisfied that the requirements of the Hygiene Regulations are not being met and/or that an inspection under the Hygiene Regulations is being hampered for the reasons given.**

When an authorised officer is satisfied that relevant action has been taken or any inspection by an authorised officer will not be hampered this notice will be withdrawn by means of a further notice in writing.

## YOUR RIGHT OF APPEAL

In accordance with Regulation 22 of the Food Safety and Hygiene (England) Regulations 2013, you are entitled to appeal against this notice. If you want to do so, you should apply to the Magistrates' Court, within one calendar month of the date on which this notice is served on you.

This notice remains in effect even if you are appealing against the terms of this notice.

WARNING

FAILURE TO COMPLY WITH THIS NOTICE IS AN OFFENCE

Offenders are liable to be fined and/or imprisonment for up to 2 years.

**6.3.10 Model form - Detention Notice**

Authority: \_\_\_\_\_  
**The Food Safety and Hygiene (England) Regulations 2013 – Regulation 10**

**DETENTION NOTICE**  
**(Establishments subject to approval under Article 4(2) of Regulation (EC) No. 853/2004)**

1. To: \_\_\_\_\_  
(Food Business Operator or a Duly Authorised Representative)  
At: \_\_\_\_\_  
\_\_\_\_\_  
(Address of Food Business Operator or a Duly Authorised Representative)  
Name of food business: \_\_\_\_\_  
Address of food business: \_\_\_\_\_

2. The following food is being detained for the purposes of examination:  
Description: \_\_\_\_\_  
\_\_\_\_\_  
Quantity: \_\_\_\_\_  
\_\_\_\_\_  
Identification Marks/Health Marks: \_\_\_\_\_  
\_\_\_\_\_

3. This food is not to be used.  
4. The food is being detained for the purposes of examination.  
5. The food must not be removed from: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
(Name/address of food business where food is to remain)

6. You will be informed in writing as soon as the Authorised Officer is satisfied as to the result of the examination. The notice will then either be withdrawn and the food released, or the food will be seized to be dealt with by a Justice of the Peace, who may condemn the food and order its destruction. You may choose to voluntarily surrender the food at any time.

Signed: \_\_\_\_\_ (Authorised Officer)  
Name in capitals: \_\_\_\_\_  
Date: \_\_\_\_\_  
Address: \_\_\_\_\_  
\_\_\_\_\_  
Tel: \_\_\_\_\_ Fax: \_\_\_\_\_  
E-mail: \_\_\_\_\_

**Please read the notes overleaf carefully. If you are not sure of your rights or the implications of this notice, you may want to seek legal advice.**

## **Model form 5 - Detention Notice (Reverse)**

### **NOTES**

The authorised officer has, by means of this notice, required the detention of the food specified for the purposes of examination.

The food must remain where it is. If it is moved it may only be moved to the place stated in paragraph 5 of this notice.

If an authorised officer is satisfied that the food need no longer be detained this notice will be withdrawn by means of a further notice in writing.

If, for some reason, you need to move the food after receiving this notice, you should contact the officer at the address given.

|         |
|---------|
| WARNING |
|---------|

**FAILURE TO COMPLY WITH THIS NOTICE IS AN OFFENCE**

Offenders are liable to be fined and/or imprisonment for up to 2 years.



**6.3.11 Model form – Notice of withdrawal of Remedial Action  
Notice/Detention Notice**

Authority: \_\_\_\_\_

**The Food Safety and Hygiene (England) Regulations 2013 -  
Regulation 9 or 10**

**NOTICE OF WITHDRAWAL OF A  
REMEDIAL ACTION NOTICE/DETENTION NOTICE\*  
(Establishments subject to approval under Article 4(2) of Regulation (EC) No.  
853/2004)**

1. To: \_\_\_\_\_  
(Food Business Operator or a Duly Authorised Representative)

At: \_\_\_\_\_  
\_\_\_\_\_  
(Address of Food Business Operator or a Duly Authorised  
Representative)

Name of food business: \_\_\_\_\_  
Address of food business: \_\_\_\_\_

2. The authorised officer is satisfied that the action specified in the Remedial  
Action Notice reference number ..... served on  
you on .....(date) has been taken. That  
Remedial Action Notice is hereby withdrawn.\*

3. The authorised officer is satisfied that the food specified in the Detention Notice  
reference number ..... served on you on  
.....(date) need no longer be detained. That  
Detention Notice is hereby withdrawn.\*

[\* Officer to delete as appropriate]

Signed: \_\_\_\_\_ (Authorised Officer)

Name in capitals: \_\_\_\_\_

Date: \_\_\_\_\_

Address: \_\_\_\_\_

\_\_\_\_\_

Tel: \_\_\_\_\_ Fax: \_\_\_\_\_

E-mail: \_\_\_\_\_

**Please read the notes overleaf carefully. If you are not sure of your rights or  
the implications of this notice, you may want to seek legal advice.**

**Model form - Notice of withdrawal of a Remedial Action Notice/Detention Notice (reverse)**

**NOTES**

The authorised officer is now satisfied that the action specified in the Remedial Action Notice has been taken and/or that the food specified in the Detention Notice need no longer be detained.

The relevant notice/notices is/are now withdrawn.

## Chapter 7 - Subject Specific Guidance

### 7.1 Matters relating to live bivalve molluscs

#### 7.1.1 Introduction

This Chapter provides specific guidance to Competent Authorities on the application and enforcement of the Live Bivalve Mollusc (LBM) aspects of Regulations 852/2004, 853/2004 and 854/2004. In line with Annex III, Section VII (1) of Regulation 853/2004 (as amended), provisions relating to LBMs in this section also includes live echinoderms, tunicates and marine gastropods, with the exception of the provisions on purification. The classification requirements of Chapter II Part A: Requirements for Production areas do not apply to marine gastropods which are not filter feeders

Under EU Regulation 854/2004 the Competent Authority must classify production areas from which it authorises the harvesting of live bivalve molluscs. Production and relay areas are classified as being of one of three categories according to the level of faecal contamination. They are routinely monitored to ensure microbiological quality, to assess accumulation of toxin in the flesh and phytoplankton in the water and for the presence of chemical contamination in accordance with EU Regulations 852/2004, 853/2004 and 1881/2006.

#### 7.1.2 The Local Market Exemption (Small Quantities)

Regulation 853/2004 does not apply to the direct supply of small quantities of LBMs to the final consumer or to local retail establishments directly supplying the final consumer. For LBMs, a small quantity equates to a total amount of not more than 25 tonnes harvested in a calendar year. The maximum harvested in a year can be made up of different species as long as neither the total allowance for each species nor the overall total is exceeded. Allowances are detailed below:

##### 7.1.2.1 Allowances for small quantities of LBMs

| Species                     | Annual Maximum amount |
|-----------------------------|-----------------------|
| Cockles                     | 25.0 tonnes           |
| Oysters                     | 5.0 tonnes            |
| King Scallops               | 5.0 tonnes            |
| Queen Scallops              | 10.0 tonnes           |
| Mussels                     | 20.0 tonnes           |
| Other Live Bivalve Molluscs | 10.0 tonnes           |
| Marine Gastropods           | 20.0 tonnes           |

Although exempt from the detailed requirements of EU Regulation 853/2004, harvesters supplying small quantities are required to comply with the food safety and

traceability requirements set out in Articles 14 and 18 of EU Regulation 178/2002. The general traceability requirements for POAO in Regulation 931/2011 also apply.

In order for harvesters of small quantities to meet the food safety requirements of EU Regulation 178/2002, FBOs should consider the risks associated with LBMs such as microbiological contamination, viral contamination, marine biotoxins and chemical contamination and ensure that such risks are controlled.

These requirements do not apply to LBMs gathered for private domestic use and Competent Authorities may consider it reasonable to assume that individuals gathering small amounts of LBMs totalling less than 5kg in a day are exempt from the small quantity requirements. These levels are for 'whole' LBMs and include the weight of the shell. This should not however detract authorities from pursuing instances where there is a suspicion of fraudulent activity or where public health could be at risk.

### **7.1.3 Pectinidae (scallops) and non - filter feeding gastropods harvested from outside classified production areas**

Competent Authorities will wish to note the specific exemption for scallops ('pectinidae') and non-filter feeding gastropods, which may be harvested from outside classified areas providing the requirements in Annex III, Chapter VII, and Section IX of EU Regulation 853/2004 are met. Food Business Operators (FBO) are required to ensure that product placed on the market meets the required health standard and should have a system of 'own checks' in place to verify this. Competent Authorities can carry out verification checks in accordance with Annex II, Chapter III of regulation 854/2004 to ensure these requirements have been observed.

### **7.1.4 Heat treatment**

LBMs which are to undergo an approved heat treatment process or other processing, e.g. freezing, are subject to the requirements of Regulation 853/2004 that relate to ILBMs up to the point where processing begins in an approved establishment. After that point they are considered to be fishery products (see section 7.2).

The controls that must be exercised over any heat treatment process for bivalve molluscs from Class B or Class C areas are set out in Annex II, Section VII, Chapter II(5) of Regulation 853/2004 and, if appropriate Annex II, Chapter XI of Regulation 852/2004.

### **7.1.5 Shellfish liaison arrangements**

The Competent Authority's shellfish liaison officer will be the FSA's first point of contact in relation to non-routine matters concerning the enforcement of the Regulations.

It is essential for the effective enforcement of the Regulations that adjoining Competent Authorities; including Port Health Authorities, in England and Wales maintain effective liaison arrangements.

All Competent Authorities in England and Wales in areas in which there are commercial LBM harvesting activities should maintain, participate in, and be represented at a local shellfish liaison group.

Each local shellfish liaison group should also include representatives of other relevant local and national organisations, including the Chief Fishery Officer of the Inshore Fisheries and Conservation Authority (formerly local Sea Fisheries Committee), the Environment Agency, the DEFRA Sea Fisheries Inspectorate, Public Health England Laboratories and other OC laboratories utilised for shellfish monitoring

Local shellfish liaison groups should consider holding periodic meetings with members of the local shellfish industry, particularly if there are difficulties over enforcement or interpretation of the Regulations.

The liaison group's functions should include:

- the identification of local LBM relaying areas (if any) (working with the industry)
- joint sampling plans to monitor the quality of LBMs from classified areas
- arrangements for the issue of registration documents
- arrangements for the making of Closure Notices covering waters from more than one Competent Authority area
- arrangements for the detention/recall of bivalve molluscs affected by any Closure Notice
- effective local notification procedures to advise interested parties of action taken under the Regulations (where such notification is required by the Regulations)
- Arrangements for effective communication and sharing of information between various agencies and organisations to assist with identify/anticipating potential problems. Spills etc.

#### **7.1.6 Notification of classified live bivalve mollusc (LBM) production and relaying areas**

The FSA analyse official control monitoring results for all classified shellfish production areas to ensure compliance with EU legislative requirements. For Class B shellfish beds 90% of samples must be less than or equal to 4,600 *E.coli*/100g of flesh and intravalvular liquid. Class B beds that are marginally compliant (within 5% of legislative requirements) are held on a marginal compliance list and monitored closely.

An annual review of all shellfish bed classifications is carried out in August to ensure the correct classification category is awarded. A review of 12 month and 3 year datasets is carried out for annual classifications and 12 month and 5 years datasets for long-term classifications. Classifications may also be reviewed in year and re-classifications carried out when necessary. A list of classified LBM production and

relaying areas is published on the Central Competent Authorities website at: <http://www.food.gov.uk/enforcement/monitoring/shellfish/shellharvestareas> .

Any changes or additions to shellfish classifications that occur during the year are notified through the Interim update process where details of the amendments are sent to the relevant contacts. These will include Upgrades, downgrades, new classifications, re-classification, declassifications and prohibitions. Relevant Competent Authorities will be informed by the FSA whenever this is done, Competent Authorities should forward all public information concerning the classification status of production areas to members of the local shellfish industry including harvesters, handlers, operators of dispatch and purification centres and other individuals and organisations likely to be substantially affected by the classification of LBM production and relaying areas. The main classification list is updated accordingly.

#### **7.1.7 Relay areas**

Relaying areas that have been approved for classification by the FSA can be classified as Class A or Class B areas. Relaying areas are routinely monitored in the same way as production areas to monitor microbiological quality, to assess accumulation of toxin in the flesh and phytoplankton in the water and for the presence of chemical contamination in accordance with EU Regulations 852/2004, 853/2004, 854/2004 and 1881/2006.

Requirements for relaying LBMs are outlined in Regulation (EC) No. 853/2004. LBMs are required to be relayed for a minimum period of 2 months after which they must be treated in accordance with the classification status of the relaying area – i.e. following relaying, LBMs harvested from a Class A relaying area can go directly to market. LBMs harvested from a Class B relaying area must undergo purification **or** an EC approved heat treatment process prior to being placed on the market.”

#### **7.1.8 Monitoring of registration documents**

Competent Authorities must carry out regular examinations of the use and completion of registration documents. Examination of the documents should be carried out as part of the inspection of dispatch, purification centres or processing establishments (see section 7.3 of the Code of Practice) however checks can be made at any part of the traceability chain.

Under Regulation 853/2004, food businesses placing LBMs on the market are required to complete a registration document (unless issued with a permanent transport authorisation) to identify each batch harvested from production and relaying areas and each batch leaving dispatch centres and processing establishments. The registration document must accompany each batch up to and including the arrival of the shellfish at a dispatch centre or processing establishment. The date of receipt must be recorded on the registration document (can be date stamped) when the batch is received at a dispatch centre, purification centre, relaying area, or processing establishment by the operator of the establishment or relaying area. Operators are required to retain registration documents for at least 12

months. Gatherers are also obliged to keep a copy of completed registration documents for the same period.

The same requirements apply to batches of scallops (pectinidae) and non -filter feeding gastropods harvested from outside classified production areas. Although the classification status of the production area (i.e. Class A, B or C) is not appropriate, the location of the production area must be described in as precise detail as is practicable or by a code number (e.g. ICES coordinates, OS grid references etc.).

Competent Authorities must be aware of the commercial advantages of abusing the registration document procedure, e.g. by suggesting that live bivalve molluscs have been taken from waters with a superior microbiological quality or from an area that demands a premium priced product.

An appropriate system of verifying batches described as being from class A, B and C areas is to analyse samples of shellfish to assess the microbiological standard against that of the classified area it came from. On a cautionary note, it must be recognised that shellfish *E. coli* monitoring from any one production area might show significantly variable results, both temporally and spatially, due to environmental and other factors e.g. class C areas might occasionally yield single results <230 *E.coli*/100g (for this reason classifications are based on a time series of data rather than single results). Therefore a batch sample returning a single result that meets the requirements of a particular classification category must not be considered conclusive proof that the batch originated from the same class of production area. Competent Authorities should refer to the classification status of the relevant production/relaying area and the official control monitoring data which is available on the FSA/Cefas websites.

It is not possible for Competent Authorities to monitor every landing in their area, or to detect abuses in the use of registration documents by concentrating resources on sampling only. However, authorities must familiarise themselves with the commercial activities within ports in their local area and implement some degree of monitoring of landings of LBMs and other shellfish (e.g. pectinidae). This can be achieved through effective and periodic liaison with other statutory inspectorates e.g. the Sea Fisheries Inspectorate and the Inshore Fisheries and Conservation Authorities (IFCAs) (former local Sea Fisheries Committees). It is within the remit of IFCAs to track the movement of fishing vessels in their local waters and provide other vital information to help verify the information contained in registration documents and the activities of harvesters e.g. the seasonality of the harvesting season, minimum landings size, checks on whether shellfish were harvested under the appropriate permissions/IFCA licences.

Competent Authorities responsible for establishments receiving batches of LBMs should ensure that establishments are only receiving shellfish with the appropriate registration document. Those receiving shellfish from outside their local area are encouraged to contact the issuing Competent Authority when inspecting registration documents. In order to ensure efficiency in this verification process, Competent Authorities are advised to keep a log of all registration documents that have been issued by them in accordance with the retention period specified in the framework,

including details of the harvesters to whom they have been issued and the production areas which the harvester requires the registration documents for.

In addition to local liaison, Competent Authorities are also encouraged to have in place procedures to assist tracking and verifying the authenticity of registration documents they have issued. For example, the use of one or a combination of coloured carbon tear offs, embossed local authority stamps in conjunction with unique reference numbers on documents might be used when trying to ensure registration documents might not be easily falsified. It may be prudent, in some circumstances, to limit the number of documents issued to each harvester or ask for sight of previously completed documents to assist in effectively monitoring/tracking of product for traceability and verification purposes.

Competent Authorities must be aware that registration documents might be completed on behalf of the gatherer, for example, by an “agent” providing all required information relating to the batch is appropriately completed. The supplying harvester(s) must be able to support the declaration made on the registration document by the “agent”. Competent authorities might wish to consider amending their forms to reflect this activity.

#### **7.1.9 Sampling of Live Bivalve Molluscs by Operators**

Operators of approved processing establishments, auction halls and purification / dispatch centres must have adequate systems of own checks in place, including laboratory and commercial testing arrangements, to ensure that the LBMs comply with the microbiological food safety criteria set for LBMs in Annex I, Chapter I of [Regulation 2073/2005](#) and the health standards referred to in Annex III, Section VII, Chapter V of Regulation 853/2004.

Officers must be aware that the Regulations do not prescribe a frequency for these tests (to detect microbiological and marine biotoxin contamination) but they must be in line with the businesses’ food safety management system. As part of the system of own checks, operators should have arrangements for the use of commercial kits for the detection of marine biotoxins.

In determining what level of sampling and testing is appropriate, the Competent Authority must have regard to HACCP principles and any advice issued by the FSA or Local Government Association or contained in voluntary guidelines produced by relevant trade associations.

#### **7.1.10 Laboratories used in connection with dispatch, purification and processing establishments**

There is no requirement for laboratories carrying out testing for food businesses to be accredited, however, FBOs must ensure that the results of testing are robust in order to accurately validate and verify their food safety management procedures. Accredited laboratories have been subject to comprehensive quality control so use of an accredited laboratory can give the FBO more confidence in the test results and reduce the checks that the FBO will have to carry out themselves. FBOs must be able to demonstrate to the Competent Authority how they ensure that test results are



reliable and robust and this should be evidenced and documented in their food safety management system. FBOs and Competent Authorities should also consider whether the laboratory is also accredited for the relevant method(s) and participates in proficiency testing as part of a recognised external quality assurance scheme. Alternative methods may also be used if they are validated against the reference method in accordance with the criteria in EN/ISO 16140.

The current recognised method for microbiological testing of live bivalve molluscs is appended to the paper entitled “Modification of the standard method used in the United Kingdom for counting *Escherichia coli* in live bivalve molluscs”, published in Volume 1 of Communicable Disease and Public Health of 3 September 1998. The current reference method for analysis of *E.coli* specified in the Regulation is the detection and Most Probable Number (MPN) technique specified in ISO 16649-3. The Impedance method is also an accepted and validated alternative to the MPN method for detecting *E.coli* in live bivalve molluscs.

### 7.1.11 Marine Biotoxins

The regulatory limits and current recognised methods for the detection of marine biotoxins are included in the table below:

| <b>Toxin group and Regulatory Limit (Reg. 853/2004)</b>   | <b>EU Reference method (Reg. 2074/2005)</b>       | <b>Method of analysis in England</b>   |
|---|---|--|
| <b>ASP</b><br>20 mg of domoic acid/kg shellfish flesh   | HPLC  | HPLC – all species   |
| <b>PSP</b><br>800 µg of saxitoxin/kg shellfish flesh  | Biological method<br>HPLC – validated alternative | HPLC - all species   |
| <b>Lipophilic toxins (LT)</b> <ul style="list-style-type: none"> <li>• 160 µg okadaic acid eq/kg</li> <li>• 3.75mg yessotoxin eq/kg</li> <li>• 160 µg azaspiracids eq/kg</li> </ul> | LCMS  | LCMS – oysters, cockles, hard/razor clams, mussels and scallops<br><br>Biological method to continue for remaining species |

Biotoxin and Phytoplankton results are reported by the laboratory directly to the FSA for publication weekly on the FSA website.<sup>23</sup>

### 7.1.12 Sampling of Live Bivalve Molluscs by Competent Authorities

<sup>23</sup> <http://www.food.gov.uk/enforcement/monitoring/shellfish/ewbiotoxin>

Competent Authorities are required to verify food safety management plans at dispatch, purification and processing establishments. Part of this process may include the taking of samples to be analysed at an accredited official control laboratory. Any results that show breaches of the end product standard should be investigated by the FBO in the first instance and corrective action taken which could include follow up sampling, withdrawals/recalls. The CA should follow up any investigation to verify that corrective actions have been taken.

Where necessary, Competent Authorities should communicate test results which do not comply with the end product standard to neighbouring Competent Authorities responsible for the relevant harvesting area, relaying area, or purification centre.

Competent Authorities must also communicate the results of any samples of LBMs to the operator of the establishment from where the samples were procured and notify the FSA of any sample results that exceed the required health standard for the particular production or relay area..

Sampling by Competent Authorities must be aimed at verifying FBOs compliance with the requirements for end product at all stages of production, processing and distribution. Results that are inconsistent with the food business operators' own records must be followed up by further investigations and tests by the FBO.

#### **7.1.13 Information on standards to be applied in purification centres**

Regulation (EC) No, 853/2004 outlines the structural and hygiene requirements for purification plants. Information on the required standards of purification systems may be found in a series of operating manuals for the different types of purification system used in the UK and a further guidance document "Procedures to Minimise Risks to Food Safety in Bivalve Mollusc Purification" published by the Sea Fish Industry Authority (Sea-fish). These documents contain recommendations designed to help shellfish processors achieve high quality standards, as well as to comply with the requirements of the EU Hygiene Regulations. In some instances the guidance makes recommendations for good industry practice, which go beyond the requirements of legislation. These documents are available on the Sea-fish Website [www.seafish.org](http://www.seafish.org) .

Competent Authorities might refer to the guidance document to establish a consistent approach to the requirements of the Regulations but must avoid using, in support of formal enforcement action, those parts that are directed towards the achievement of good industry practice and high quality standards. A further guide to assist Competent Authority inspections of purification establishments is available at:

<http://cefas.defra.gov.uk/media/549257/d024%20v3%20lea%20guidance%20notes.pdf>

#### **7.1.14 Molluscs and other shellfish which fail to satisfy requirements**

In accordance with Regulation 29 of the Food Hygiene (England) Regulations 2013, any LBM or other shellfish that have not been produced, processed or distributed in

accordance with the Regulations should be treated, for the purposes of Section 9 of the Food Safety Act 1990 as failing to comply with food safety requirements and should be seized and taken before a Justice of the Peace to be condemned, implementing Directive 91/67/EEC on the animal health conditions governing the placing on the market of aquaculture animals and products.

#### **7.1.15 Transfer of seed molluscs to classified production areas**

Seed bivalve molluscs might be transferred from areas that are not classified as production areas for “growing on” within a production area of any class. Such molluscs must be genuine “seed shellfish” (juvenile shellfish too small to be marketed). In fisheries regulated for conservation purposes under the Seafish (Conservation) Act 1967, transfers might only be carried out on approval of the holder of the Regulating Order for that fishery.

Transfers of “seed bivalve molluscan shellfish”, (juvenile shellfish too small to be marketed) taken from an unclassified area, to be used for onward growth in a classified production area are permitted, provided that they remain in the classified production area for a period of not less than six months before they are harvested for human consumption. This does not permit the movement of adult or partially developed bivalve molluscan shellfish from an unclassified area for further short-term growth before marketing. It is restricted to the seeding of new areas or the re-seeding of existing classified production areas. If new areas are seeded they must be classified before harvesting can take place. Harvesters must inform the relevant Competent Authority if any such movements are contemplated.

#### **7.1.16 Closure Notices (temporarily closing harvesting areas)**

(See also Chapter 7.6 of the Code of Practice)

When a high shellfish result is recorded the Competent Authority must determine, in conjunction with the Local Action Group (LAG) if the result warrants the area to be closed. The Competent Authority should instigate a closure, either by a Temporary Closure Notice (TCN) or by voluntary agreement (where applicable) as soon as is practically possible and notify interested parties that sample results show that health standards for LBMS have not been met and that there may be a risk to human health. A Closure Notice must be considered where, for example, a result of >18,000 *E.coli* per 100gm had been recorded or the classified mollusc production area was subject to sudden or accidental pollution which affected the quality of the production area. The use of a Closure Notice would also be appropriate where there is a local problem with environmental pollution caused by microbiological or chemical contamination, and is compulsory following a regulatory breach for *E.coli*, marine biotoxins and chemical contamination.

There might also be circumstances when it would be appropriate for the Competent Authority to consider seeking the opinion of appropriate experts such as the consultant in communicable disease control and consultant microbiologist at the PHE.

A model Closure Notice can be found at [7.1.19](#) below.

### **7.1.17 Reporting of illegal harvesting activity**

It is an offence to place LBMs on the market that have been harvested from areas that are not classified, or which are unsuitable for health reasons. Similarly, it is also illegal for food businesses to place on the market scallops and non - filter feeding gastropods from outside classified areas that do not meet the microbiological end product standard or which contain harmful levels of marine biotoxins.

Competent Authorities should monitor harvesting areas within their remit, including areas affected by Temporary Closure Notices (as described above) to ensure this practice does not occur. Where authorities become aware of these instances, they will need to consider appropriate surveillance and follow up enforcement. Authorities are encouraged to establish close working relationships with other local inspectorates, such as IFCA's who might be able to assist in combating this practice e.g. through surveillance, notification of fishing activity in waters under restrictions, assistance in the verification of information in registration documents etc.

All cases of illegal harvesting must be reported on the Food Standards FSA's Food Fraud database, which can be accessed using the following link:

<http://www.food.gov.uk/enforcement/the-national-food-crime-unit/foodfraud/foodfrauddatabase>

Competent Authorities can contact the FSA's Food Fraud team for further advice on surveillance and enforcement [foodfraud@foodstandards.gsi.gov.uk](mailto:foodfraud@foodstandards.gsi.gov.uk)

### **7.1.18 Shellfish Identification Marks**

As part of the monitoring of the use of shellfish identification marks, Competent Authorities must, periodically, select a batch or consignment from a retail outlet or restaurant and seek to trace the batch or consignment back through an auction hall, dispatch centre or processing establishment, to the original gatherers to establish that records relating to the traceability of the batch and the identification mark are in order. Competent Authorities must co-operate with other Competent Authorities in any random check through the production and distribution chain.

Note: retailers are to retain identification tags for 60 days to assist in tracing product in the event of a report of illness.

If any checks suggest that registration documents, identification marks or records are not in order the Competent Authority must carry out an investigation to establish where the procedures have not been properly observed. In such cases they must also consider increasing the frequency of random checks through the distribution chain until they are satisfied that the appropriate procedures are being followed.

### 7.1.19 Documentation

The following template forms are available:

| <b>Practice Guidance Reference</b> | <b>Template Form</b>  |
|------------------------------------|---|
| <b>7.1.19.1</b>                    | Live Bivalve Molluscs/Live Shellfish Registration Document                                |
| <b>7.1.19.2</b>                    | Model notice of temporary closure of production area(s) (live bivalve molluscs/shellfish) |

**7.1.19.1 LIVE BIVALVE MOLLUSCS / LIVE SHELLFISH  
REGISTRATION DOCUMENT**

(Regulation (EC) No. 853/2004 – Article 7 / Annex III, Section VII, Chapter I)  
^including pectinidae and non-filter feeding gastropods harvested from unclassified areas (Regulation (EC) No. 853/2004 – Annex III, Section VII, Chapter IX)

---

Registration Document No: .....

Issued by: .....

Date of Issue: .....

Name of gatherer ..... Signature of gatherer .....

Competent Authority where shellfish landed ..... Address of gatherer .....

LBM's harvested within classified production areas

Location of production area (Name, Code or Grid ref) Class of production area. (A, B\* or C\*)  
.....

Pectinidae and non-filter feeding gastropods harvested from outside classified production areas

Location of production area (ICES area):  
.....

Date of gathering  
.....

Name of LBM species being moved ..... Destination (country, establishment and approval number)  
(common and scientific name) and quantity of shellfish being moved

\*When shellfish originate from a production area classified as B or C:  
Relaying area: .....

Duration of relaying: .....  
or Address of Purification Centre: .....

Duration of purification.....

Date batch entered Purification Centre ..... Date batch left Purification Centre: .....

Checks to verify health standards have not been carried out and have been deferred to the approved establishment stated above.

Date of Receipt .....

Place of Receipt .....

[Date of Signature] .....

**REMINDER – This document is to be kept by the person receiving the shellfish for a period of not less than 12 months and the gatherer is to keep a copy for the same period.**

### 7.1.19.2 Model notice of temporary closure of production area(s) (live bivalve molluscs/shellfish)

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#### NOTICE OF TEMPORARY CLOSURE OF PRODUCTION AREA(S)

**Regulation (EC) No. 854/2004** of the European Parliament and of the Council laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption

Pursuant to the power conferred on it by Article 6 of, and paragraph C of Chapter II of Annex II to the above EC Regulation, being satisfied that [the results of sampling show that the health standards for molluscs are exceeded] [there might be a risk to human health]<sup>24</sup> –

As Competent Authority for the purposes of the above EC provision by virtue of regulation 4 of the Food Safety and Hygiene (England) Regulations 2013 S.I. 2013 No

[Insert authority] has temporarily closed the production area identified in the Schedule to this notice for the production of [insert list of all affected species] by FBOs until further notice.<sup>25</sup>

Signed:

Dated this [ ] day of [ ] 200[ ]

---

[Insert official position of signatory]  
On behalf of the [insert authority]

#### SCHEDULE

Area[s] in which the production of [insert list of all species affected] by food business operators is prohibited by reason of this order:-

- (a) [Insert area]
- (b) [Insert area]

Food business operators must not collect the affected animals from this area by any method; it is unsuitable for their production for health reasons and has been temporarily closed. For a food business operator to collect affected animals from the area that is temporarily closed amounts to the commission of a criminal offence under regulation 19 of the Food Safety and Hygiene (England) Regulations 2013 S.I. 2013 No 2996. On conviction a fine or imprisonment for a term of up to two years or both might be imposed.

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<sup>24</sup> Recent analysis of samples taken by [insert authority] from the affected area has shown that [insert animals] are affected by [insert problem].

<sup>25</sup> [insert authority] will continue to take samples for analysis and keep its decision to close the area under review. To check the current status of the area you may contact [insert authority] by [insert preferred method of contact, e.g. telephone no.]



[PRIVATE INDIVIDUALS ARE STRONGLY ADVISED NOT TO GATHER [insert description of affected animals] FOR THEIR OWN CONSUMPTION FROM THE AFFECTED PRODUCTION AREA. THERE MIGHT BE A RISK TO HUMAN HEALTH IN DOING SO.]

## **7.2 Matters relating to Fishery Products**

### **7.2.1 Introduction**

This section provides specific guidance to Competent Authorities on the application and enforcement of the fishery products aspects of Regulations (EC) No. 852/2004, 853/2004 and 854/2004.

### **7.2.2 Competent Authority**

The FSA is the UK central Competent Authority with lead responsibility for these Regulations. Competent Authorities are responsible for enforcement of the EU food hygiene regulations at their local level, and therefore approve fishery products establishments, register certain markets and fishing vessels, and otherwise enforce the EU food hygiene Regulations.

### **7.2.3 Scope of approval**

The Regulations do not apply to retail unless expressly indicated. They apply however when operations are carried out to supply fishery products to other establishments.

Factory and freezer vessels, and auctions and wholesale markets are required to have approval and must be inspected at regular intervals to check for compliance with hygiene and temperature requirements and subject to Regulation (EC) No. 853/2004 Annex III Section VIII Chapters 1 and II, respectively

### **7.2.4 Direct supply of small quantity of fish**

The Regulations do not apply to the direct supply of small quantities of fishery products (i.e. primary products) to the final consumer or to local retail establishments directly supplying the final consumer. For the purposes of fishery products (not including live bivalve molluscs) a small amount is a total amount of not more than 25 tonnes of fishery products in a calendar year. While the Regulations do not apply to this allowance it is still the responsibility of the harvester to ensure that these products meet the end product standards set down for placing these fishery products on the market. Any amount of the catch which includes live bivalve molluscs must have originated from a class 'A' area, which designates the product as suitable for placing on the market with no further treatment required.

### **7.2.5 Conditions during and after landing**

One of the public health and quality measures in the Regulations is periodic inspection and checks on the fitness for human consumption of fish at the time of landing or before the first sale. Where fishery products are sold at a market associated with the landings, these inspections must take place in that auction hall or wholesale market. It is not normally necessary for any inspections to be carried

out at the time of landing. An organoleptic examination of the fishery products normally satisfies this requirement.

A Competent Authority can authorise the transfer of fishery products from the landing (ex-quay) into containers for immediate delivery to an approved establishment or auction or wholesale market for the checks to be carried out there. Deferring the checks to be carried out later in an auction or wholesale market normally does not require any special arrangements with the receiving Competent Authority.

Deferring checks to an approved establishment must, however, be subject to liaison and agreement with the receiving Competent Authority, and have regard to the compliance record of the receiving establishment and confidence in its management. Authorisation of such deferred checks must be withdrawn if there is any suspicion of non-compliance with the requirements of the Regulations. If an organoleptic examination of any product raises doubt as to the freshness of the product, the Competent Authority can consider submitting the product for chemical analysis or microbiological examination.

With respect to the landing of fresh fish, checks required under the Regulations are without prejudice to other checks that are required under EC marketing standards regulations by other statutory agencies. Authorised officers must, where necessary, liaise with other statutory inspectors, e.g. the DEFRA Sea Fisheries Inspectorate, or the Scottish Fish Protection Agency (SFPA) to ensure that any enforcement action taken is appropriate.

## **7.2.6 Information on standards to be applied**

Guidance on the requirements of the Regulations can be obtained from the Sea Fish Industry Authority (Seafish). Competent Authorities can use the guidance as a reference in establishing a consistent approach to the requirements of the Regulations. Competent Authorities should, however, exercise caution and avoid using, in support of formal enforcement action, those parts of the Seafish guidance that is directed towards the achievement of good industry practice and high quality standards.

## **7.2.7 Documentation**

The following Checklists are available:

| <b>Practice Guidance Reference</b> | <b>Checklist</b>          |
|------------------------------------|---------------------------|
| <b>7.2.7.1</b>                     | Fishing Vessel Check List |
| <b>7.2.7.2</b>                     | Freezer Vessel Check List |
| <b>7.2.7.3</b>                     | Factory Vessel Check List |

Although the content of these documents is regarded as the minimum required, Competent Authorities may adapt them as necessary to meet local requirements.

### 7.2.7.1 Fishing vessel check list

Vessel name: \_\_\_\_\_

Inspecting officer: \_\_\_\_\_

Registration number: \_\_\_\_\_

Inspection date: \_\_\_\_\_

Person seen: \_\_\_\_\_

| <b>A. Vessel and Fish Handling Equipment</b>  | yes                      | no                       | n/a*                     |
|---|--------------------------|--------------------------|--------------------------|
| 1. Is the vessel designed to avoid contamination of the catch with bilge water, fuel, oil, grease or other objectionable substances?        | <input type="checkbox"/> | <input type="checkbox"/> |                          |
| 2. Are surfaces and equipment that fish come into contact with corrosion resistant, smooth and easy to clean? Are surface coatings durable? | <input type="checkbox"/> | <input type="checkbox"/> |                          |
| 3. Are the engine room and any crew quarters separated from fish handling and fish storage areas?   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. If you pump seawater for use on your catch, is the water intake positioned to avoid contamination of the water from exhaust etc.?        | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 5. If ice is used, is it made from potable water or clean seawater?   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

| <b>B. Fish Handling</b>   | yes                      | no                       | n/a                      |
|---|--------------------------|--------------------------|--------------------------|
| 1. Once the catch is brought on board, is it protected from contamination?                                  | <input type="checkbox"/> | <input type="checkbox"/> |                          |
| 2. Is the catch protected from the sun and any source of heat?  | <input type="checkbox"/> | <input type="checkbox"/> |                          |
| 3. When handling the catch, whether manually or mechanically, is your system designed to minimise bruising? | <input type="checkbox"/> | <input type="checkbox"/> |                          |
| 4. Is the catch gutted and washed quickly and efficiently?  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 5. Is the catch chilled quickly?  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 6. Is fish stored at a temperature approaching that of melting ice?   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 7. Can melt water drain away from the stored fish?  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

| <b>C. General Hygiene Requirements</b>   | yes                      | no                       | n/a                      |
|--|--------------------------|--------------------------|--------------------------|
| 1. Are the crew aware of the health risks associated with fish handling?   | <input type="checkbox"/> | <input type="checkbox"/> |                          |
| 2. Is the vessel and equipment kept clean and, where necessary, disinfected?   | <input type="checkbox"/> | <input type="checkbox"/> |                          |
| 3. Is the fish storage area and fish storage containers kept clean, in a good state of repair and free of contaminants?  | <input type="checkbox"/> | <input type="checkbox"/> |                          |
| 4. Is the vessel kept free of pests? *valid ships sanitation certificate seen/issued? Any issues noted from certificate? | <input type="checkbox"/> | <input type="checkbox"/> |                          |
| 5. Following the last vessel check, if there was a request for remedial action, has the appropriate action been taken?   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 6. Applicable only to some vessels: Do you keep records relating to the control of hazards?                              | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

\* N/A: not applicable. Further explanation required in the comments box below.

\* Ships Sanitation Certificate- where issued/valid port/ in date?

|          |
|----------|
| Comments |
|----------|

### 7.2.7.2 Freezer vessel check list

Vessel name: \_\_\_\_\_  
 Registration number: \_\_\_\_\_  
 Person seen: \_\_\_\_\_

Inspecting officer: \_\_\_\_\_  
 Inspection date: \_\_\_\_\_

| <b>A. Vessel and Fish Handling Equipment</b>   | yes                      | no                       | n/a*                     |
|--|--------------------------|--------------------------|--------------------------|
| 1. Is the vessel designed and constructed to prevent contamination of the products from bilge-water, smoke, fuel, sewage, oil, grease or other objectionable substances, and to permit pest control? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. Are storage containers and holds kept clean and in good repair?   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. Are all fish contact surfaces made of a material that is corrosion-resistant, smooth, and easy to clean, durable and non-toxic?   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. Is all equipment and material used for handling fishery products corrosion-resistant and easy to clean and disinfect?   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 5. Are water intakes situated in a position to avoid contamination of the water supply used for fish/processing?   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 6. Does the vessel freezing equipment to rapidly achieve a core temperature of -18 °C or below?  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 7. Does the vessel have storage facilities to hold product at -18 °C or below?   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 8. Does the cold store have a temperature recording device located where it is easy to read?   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 9. Does it record the temperature at the point where it would be expected to be highest?   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

| <b>B. Fish Handling</b>   | yes                      | no                       | n/a                      |
|---|--------------------------|--------------------------|--------------------------|
| 1. Are fish protected from sun or other sources of heat soon after being taken on board?                | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. Is clean water used for washing the fish?  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. Are fishery products handled and stored to minimise bruising or damage to the flesh?                 | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. Are fishery products kept chilled or frozen?   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 5. Is ice that is used to chill fishery products made from clean water?                                 | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 6. Are fish headed or gutted on board? If yes:  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 6(a) Is this carried out as soon as possible after capture?   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 6(b) Are the fishery products washed with clean water?  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 6(c) Are any viscera not intended for human consumption kept apart from products for human consumption? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 6(d) Are any livers and roes for human consumption kept chilled or frozen?                              | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

**C. General Hygiene Requirements**

|  | yes                      | no                       | n/a                      |
|--|--------------------------|--------------------------|--------------------------|
| 1. Does the vessel have an adequate number of flush lavatories for the number of crew?   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. Do all the lavatories open directly into non-food/non-fish rooms?   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. Is there adequate ventilation to the lavatories?  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. Is there an adequate number of washbasins for hand washing?   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 5. Are basins located to facilitate hand washing during fish handling?   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 6. Are washbasins provided with hot and cold water and materials for cleaning hands and hygienic drying?   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 7. Are all food-washing facilities separate from all hand-washing facilities (or in use at different times, with effective cleaning between any changes of use)? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 8. Is there adequate ventilation to the fish preparation areas and sanitary conveniences?  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 9. Do fish preparation rooms have adequate lighting?   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 10. Are drainage facilities in the fish preparation areas adequate?  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 11. If open drains are used (such as gullies) do they flow from the cleaner areas to the more contaminated area?   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 12. Are adequate changing facilities provided for staff where needed?  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 13. Are cleaning materials stored away from areas where fish are handled or stored?  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 14. Pest control? Is there a valid ships sanitation certificate? If so where issued from and date?   |                          |                          |                          |

**D. Food Preparation Areas**

|  | yes                      | no                       | n/a                      |
|--|--------------------------|--------------------------|--------------------------|
| 1. Are floor surfaces made of a non-toxic material that is easy to clean?                                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. Do floors in wet rooms allow adequate drainage of water?  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. Are walls made of a non-toxic material that is easy to clean?   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. Are the walls, ceilings, windows etc. constructed so that dirt cannot accumulate and fall onto the product? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 5. Are the fittings on walls and ceiling securely attached so they cannot fall into the product?               | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 6. Are all doors made of a smooth material that is easy to clean and disinfect?                                | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 7. Are all food contact surfaces made of smooth, non-corrosive material that is non toxic?                     | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 8. Are food contact surfaces maintained so that surface material cannot come loose and contaminate the food?   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 9. Are adequate facilities provided for washing equipment?   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 10. Is hot and cold water supplied to equipment-washing facilities?  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 11. Are there adequate facilities for any fish washing?  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 12. Is clean water supplied to these facilities?   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

|  |                          |                          |                          |
|--|--------------------------|--------------------------|--------------------------|
| 13. Have all staff received training in food hygiene to enable them to carry out their duties?                   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 14. Do they have suitable work wear to prevent contamination of the food?  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 15. Do you have a reporting and exclusion policy for staff sickness?   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 16. Are wrapping and packaging materials stored to protect them from contamination?                              | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 17. Are wrapping and packing carried out in a way that prevents contamination of the product?                    | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 18. Is any packaging stored separately from food processing and preparation areas?                               | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 19. Are there members of staff responsible for HACCP and have they been adequately trained in HACCP application? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 20. Are hand-washing facilities in the work rooms designed to prevent the spread of contamination?               | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

\*n/a: not applicable. Explain further in the box below.

|          |
|----------|
| Comments |
|----------|

### 7.2.7.3 Factory vessel check list

Vessel name: \_\_\_\_\_

Inspecting officer: \_\_\_\_\_

Registration number: \_\_\_\_\_

Inspection date: \_\_\_\_\_

Person seen: \_\_\_\_\_

#### A. Vessel and Fish Handling Equipment

yes no n/a\*

|  | yes                      | no                       | n/a*                     |
|--|--------------------------|--------------------------|--------------------------|
| 1. Is the vessel designed and constructed to prevent contamination from bilge-water, smoke, fuel, sewage, oil, grease or other objectionable substances, and to permit pest control? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. Are storage containers and holds kept clean and in good repair?   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. Are all fish handling contact surfaces made of a material that is corrosion-resistant, smooth, easy to clean, durable and non-toxic?  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. Is all equipment and material used for handling fishery products corrosion-resistant and easy to clean and disinfect?   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 5. Are water intakes situated in a position to avoid contamination of the water supply used for fish handling/processing?  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 6. Do you have an area reserved for taking the catch on board?   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 7. Can each successive catch be separated?   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 8. Is the receiving area easy to clean?  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 9. Is it protected from the sun and any potential source of contamination?   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 10. Do you have a system to transport the catch from the receiving area to any processing areas in a hygienic way?   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 11. Are work areas of sufficient size and design to allow work to be carried out hygienically and for cleaning to be easy and efficient?   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 12. Are areas for finished product large enough and easy to clean?   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 13. Is waste stored separately to fishery products for human consumption?  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 13 (a) If a waste processing unit operates on board is there a separate hold for its storage?  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 14. Do you have special equipment for disposing of processing waste directly into the sea or into a watertight tank for that purpose?  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 15. Is the vessel designed to prevent pests from causing contamination?  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

#### B. Fish Handling

yes no n/a

|  | yes                      | no                       | n/a                      |
|--|--------------------------|--------------------------|--------------------------|
| 1. Are fish protected from sun or other sources of heat soon after being taken on board? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. Is clean water used for washing the fish?   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. Are fishery products handled and stored to minimise bruising or damage to the flesh?  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. Are fishery products kept chilled?  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 5. Is any ice that is used to chill fishery products made from clean                     | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |



|   |                          |                          |                          |
|---|--------------------------|--------------------------|--------------------------|
| water?  |                          |                          |                          |
| 6. Are fish headed or gutted on board?  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 7. Is this carried out as soon as possible after capture?   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 8. Are the fishery products washed with clean water?  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 9. Are any viscera not intended for human consumption kept apart from products for human consumption? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 10. Are any livers and roes for human consumption kept chilled or frozen?                             | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

### C. General Hygiene Requirements

yes no n/a

|   | yes                      | no                       | n/a                      |
|---|--------------------------|--------------------------|--------------------------|
| 11. Does the vessel have an adequate number of flush lavatories for the number of crew?   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 12. Do all the lavatories open directly into <u>non-food/non-fish</u> rooms?  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 13. Is there adequate ventilation to the lavatories?  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 14. Are there an adequate number of washbasins for hand washing?  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 15. Are basins located to facilitate hand washing during fish handling?   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 16. Are washbasins provided with hot and cold water and materials for cleaning hands and hygienic drying?   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 17. Are any fish washing facilities separate from the hand washing facilities (or in use at different times, with effective cleaning between any changes of use)? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 18. Is there adequate ventilation to the fish preparation areas and sanitary conveniences?  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 19. Do fish preparation rooms have adequate lighting?   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 20. Are drainage facilities in the fish preparation areas adequate?   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 21. If open drains are used (such as gullies) do they flow from the cleaner areas to the more contaminated area?  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 22. Are adequate changing facilities provided for staff where needed?   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 23. Are cleaning materials stored away from areas where fish is handled or stored?  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

### D. Fish Preparation Areas

yes no n/a

|   | yes                      | no                       | n/a                      |
|---|--------------------------|--------------------------|--------------------------|
| 24. Are floor surfaces made of a non-toxic material that is easy to clean?                                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 25. Do floors in wet rooms allow adequate drainage of water?  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 26. Are walls made of a non-toxic material that is easy to clean?   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 27. Are the walls, ceilings, windows etc. constructed so that dirt cannot accumulate and fall onto the product? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 28. Are the fittings on walls and ceiling securely attached so they cannot fall into the product?               | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 29. Are all doors made of a smooth material that is easy to clean and disinfect?                                | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 30. Are all food contact surfaces made of smooth, non-corrosive   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

|   |                          |                          |                          |
|---|--------------------------|--------------------------|--------------------------|
| material that is non-toxic?   |                          |                          |                          |
| 31. Are all food contact surfaces maintained so that surface material cannot come loose and contaminate the food? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 32. Are adequate facilities provided for washing equipment?   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 33. Is hot and cold water supplied to equipment washing facilities?   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 34. Are there adequate facilities for any fish washing?   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 35. Is clean water supplied to these facilities?  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 36. Have all staff received training in food hygiene to enable them to carry out their duties?                    | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 37. Do they have suitable work wear to prevent contamination of the food?   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 38. Do you have a reporting and exclusion policy for staff sickness?  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 39. Are wrapping and packaging materials stored to protect them from contamination?                               | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 40. Are wrapping and packing carried out in a way that prevents contamination of the product?                     | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 41. Are there members of staff responsible for HACCP and have they been adequately trained in HACCP application?  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 42. Is any packaging stored separately from food processing and preparation areas?                                | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 43. Are hand-washing facilities in the work rooms designed to prevent the spread of contamination?                | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 44. Pest control- is there a valid Ships sanitation certificate? Where and when issued?                           | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

\*n/a: not applicable. Further explanation required in the comments box below.

|         |
|---------|
| Comment |
|---------|

## **7.3 Matters relating to Meat**

### **7.3.1 Meat - Guidance**

A Guide to the Food Hygiene and other Regulations for the Meat Industry has been produced for UK meat plant operators, particularly for those whose premises require approval and veterinary control.

This Guide can be found on the FSA's website at:

<http://www.food.gov.uk/foodindustry/meat/guidehygienemeat>

A Food Safety Management Diary for meat producers has been produced for voluntary use and can be found at:

<http://www.food.gov.uk/multimedia/pdfs/foodmandiary2006.pdf>

For guidance on Halal food issues see [Annex 2](#).

### **7.3.2 Meat - Approval of Establishments**

Details of FSA approved establishments, and guidance on approval of establishments, can be found on the FSA's website at:

<http://www.food.gov.uk/enforcement/sectorrules>

The FSA is responsible for approving establishments subject to veterinary control (i.e. slaughterhouses, cutting plants placing fresh meat on the market and game handling establishments) as well as any cold stores, meat products, minced meat, meat preparations, mechanically separated meat premises and edible co-products plants that are co-located with approved slaughterhouses, cutting plants, or game handling establishments.

Competent Authorities (Food authorities) are responsible for approving all other food premises handling products of animal origin (except for co-located premises described above) and for registering establishments that are exempt from approval.

### **7.3.3 Enforcement in Meat Establishments**

The FSA is responsible for enforcement in meat establishments that require veterinary control (see above).

#### **7.3.3.1 Co-located establishments**

The FSA is responsible for enforcement in meat products, minced meat, meat preparations, mechanically separated meat plants, cold stores or edible co-products plants that are co-located with an approved slaughterhouse, cutting plant or game handling establishment. When a co-located meat establishment does not require approval e.g. a retail butcher, dual Competent Authority/FSA enforcement continues to apply.

### **7.3.3.2 Stand-alone establishments**

Competent authorities are responsible for enforcement in stand-alone establishments that produce meat products, minced meat, meat preparations and mechanically separated meat, and in establishments exempted from approval under Regulation 853/2004.

### **7.3.3.3 Cold stores**

Cold stores supplying the final consumer (see definition in 7.3.4.1) exclusively or supplying other establishments (including caterers) on a “marginal, localised and restricted” basis (see 7.3.4.2) are not subject to approval and must be registered under Regulation 852/2004.

European Commission guidance advises that wholesale meat cold stores require approval on the basis that they are used in relation to activities for which Annex III of Regulation 853/2004 lays down requirements. It has been decided to follow this guidance. There is no requirement for veterinary control of cold stores and Competent Authorities are therefore responsible for approving cold stores and for enforcement in cold stores, except where they are co-located with approved slaughterhouses, cutting plants or game handling establishments.

Additional advice on the approval of stand-alone cold stores which are not co-located with FSA approved establishments can be found in the FSA Guidance for LAs on the approval of establishments.

### **7.3.3.4 Wild Game**

There are exemptions from the scope of Regulation 853/2004 for the supply of wild game by primary producers or by hunters. Such supply can be in-fur or in-feather but must only be supplies of small quantities directly to the final consumer or to retail outlets directly supplying the final consumer – see 7.3.4 below. Additionally, hunters can supply small quantities of game meat. However, game supplied under the hunter exemption to a retail outlet cannot be supplied to another retail outlet under the retail to retail exemption. The retail to retail (wholesale) exemption must also be on a marginal, localised and restricted basis

Primary Producers whose onward supply is limited to small quantities of primary product (i.e. in-fur or in-feather wild game) directly to the final consumer or to retail outlets directly supplying the final consumer are exempt from the scope of both Regulation 853/2004 and Regulation 852/2004. However, they are responsible for supplying safe food under Regulation 178/2002.

Premises used for the supply of small quantities of prepared wild game to the final consumer or to retail outlets directly supplying the final consumer must meet the hygiene requirements of Regulation 852/2004 and are subject to enforcement by Competent Authorities.

Establishments that process wild game and do not qualify under the Wild Game exemptions to supply in-fur/in-feather carcasses or small quantities of wild game meat to the final consumer only or to local retail establishments that directly supply meat to the final consumer must be approved by the FSA as an approved game handling establishment (AGHE). AGHEs are subject to official veterinary controls and they need to comply with both the general hygiene requirements of Regulation 852/2004 and specific provisions for the initial handling of large/small wild game in Regulation 853/2004. They must have in place a food safety management procedure based on HACCP principles and must only accept game that has been examined by a trained person. In certain circumstances, where the trained person is unexpectedly unavailable, certain viscera such as the head (except for antlers and horns) and the heart, lungs, and liver but not the stomach and intestines of the deer, must accompany the body for post mortem inspection. AGHEs must also ensure that animal by-products are handled and disposed of according to Regulation 1069/2009.

#### **7.3.3.5 Edible co-products**

Competent Authorities are responsible for enforcement in stand-alone establishments producing edible co-products i.e. treated stomachs, bladders and intestines, rendered animal fats and greaves, gelatine and collagen.

Separate guidance on these products can be found on the FSA's website at:

<http://www.food.gov.uk/foodindustry/guidancenotes/meatregsguid/coproductbyproductguide>

#### **7.3.4 Exemptions from approval**

Also see approvals guidance at:

<https://www.food.gov.uk/enforcement/sectorrules/approvalsguidance>

##### **7.3.4.1 Retail establishments (Regulation 853/2004, Article 1(5) (b) (ii))**

The exemption is for retail establishments that supply products of animal origin to the final consumer, or that supply other establishments (including caterers) on a marginal, localised and restricted basis.

*“Final consumer” is defined as “the ultimate consumer of a foodstuff who will not use the food as part of any food business operation or activity”, i.e. the public.*

The Regulations require establishments that cut meat that is placed on the market (i.e. rather than supplied for further processing.) to be approved as cutting plants and subject to veterinary control, unless that supply is on a marginal, localised and restricted basis. Catering butchers who supply all or most of their production to the catering trade will therefore in principle be subject to approval, as well as retail butchers supplying caterers and/or other establishments in excess of the marginal threshold.

##### **7.3.4.2 Retail Establishments - “marginal, localised and restricted” supply to other establishments**

In respect of fresh or processed meat including meat products, the terms 'marginal', 'localised' and 'restricted' should be interpreted as:

**'Marginal':**

Recital 13 of Regulation 853/2004 interprets "marginal" as 'a small part of the establishment's business', but European Commission guidance provides that it may also be interpreted as 'a small amount of food of animal origin in absolute terms'.

Thus:

- (i) "a small part of the establishment's business" means **"up to a quarter of the business in terms of food"** ; or
- (ii) "a small amount of food of animal origin" means, in relation to meat (fresh or processed, excluding wild game and wild game meat) **up to two tonnes per week, (which could be averaged over any 12 month period)** subject to the establishment having a genuine retail element to its operation supplying the final consumer with part of its production of meat.
- (iii) If either (i) or (ii) applies, the establishment is exempt from the requirements of Regulation 853/2004. Provided, in relation to meat, the "localised" criteria below is also met.

**and**

**"Local"/"localised"** is within the supplying establishment's own county plus the **greater** of **either** the neighbouring county or counties or 50km/30miles from the boundary of the supplying establishment's **county**, but never beyond the UK except supply from Northern Ireland to the Republic of Ireland. When the supplying establishment is located in the Scottish islands, local is interpreted as anywhere within Scotland.

**and**

**"Restricted"**

This only applies to the supply of wild game. Supply is subject to the game having been examined by a trained person and carcasses of large wild game animals must be accompanied by a trained person's declaration stating that no abnormalities were observed either before or after shooting. For all other meat, the restrictions relate to the amount of meat supplied.

**7.3.4.3 Guidance on the cutting of meat for direct sale by farmers (e.g. at farmers' markets)**

The "marginal, localised and restricted" exemption allow a butcher to cut meat on a farmer's behalf and return it to that farmer for onward sale; provided this is a marginal part of that butcher's business and the farmer being supplied is local.

**7.3.4.4 Wild game (primary producers/hunters)**

The Regulation 853/2004 Article 1(3) (e) exemption repeats the one at Regulation 852/2004 Article 1(2) (c) allowing primary producers to supply small quantities of wild game carcasses (i.e. in-fur/in-feather) either direct to the final consumer or to local retail establishments directly who can then supply the final consumer only. Primary producers, whether individual hunters or shooting estates, are exempt from both Regulation 852/2004 and Regulation 853/2004.

The Regulation 853/2004 Article 1(3) (e) exemption applies only to individual hunters who prepare wild game meat from carcasses they have shot themselves. Only small quantities of this meat may be sold either direct to the final consumer or to local retailers directly who can then supply the final consumer only. However, because the meat is not a primary product, the hunter is exempt only from Regulation 853/2004, not from Regulation 852/2004.

For these exemptions, the UK is interpreting supply of "small quantities" as self-defining because the demand for in-fur/in-feather carcasses from local consumers and local retailers is limited. In the case of the hunter claiming a Regulation 853/2004 Article 1(3) (e) exemption, this is separate from the primary producer exemption as it allows the hunter to supply wild game meat in small quantities. The meat that is supplied would have to be part of this amount, rather than in addition to it. Supply direct to a final consumer can be via mail order or internet sales as well as by delivery/collection. The interpretation of "local" is the same as for "localised" (see Paragraph 7.3.4.2).

The summary table at 7.3.7 below provides information on what elements of the various regulations apply to the hunting of wild game and its placing on the market.

Separate guidance on the supply of wild game outside approved premises can be found on the FSA website at:

<https://www.food.gov.uk/business-industry/farmingfood/wildgameguidance>

#### **7.3.4.5 On-farm slaughter and cutting of small quantities of poultry and lagomorphs**

Regulation 853/2004 does not apply to the direct supply, by the producer, of small quantities of meat from poultry (i.e. farmed birds except ratites) or lagomorphs (i.e. rabbits, hares and rodents) slaughtered on the farm to the final consumer or to local retail establishments directly supplying such meat to the final consumer (Article 1(3)(d))<sup>26</sup>. Article 1(4) goes on to say that the rules governing the persons and activities benefiting from this exemption (in addition to those in Regulation 852/2004) will be set out in national law. These national rules are set out in Schedule 5 to the Food Safety Hygiene (England) Regulations 2013.

#### **Which producers benefit from this exemption?**

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<sup>26</sup> As amended by Article 3 of Regulation (EC) 2076/2005 (Transitional and Implementing Measures)

The exemption applies to producers of poultry or lagomorphs who slaughter their own animals on the farm of production, as long as only *small quantities* of meat are supplied.

The UK is interpreting 'small quantities' as:

- producers annually slaughtering under 10,000 birds or lagomorphs;
- or**
- producers annually slaughtering over 10,000 birds or lagomorphs who are members of an appropriate assurance scheme and who either (a) dry pluck by hand or (b) slaughter for 40 days per year or less.

The limit of 10,000 birds or lagomorphs in the first category should allow for some fluctuation in annual throughput around that level provided that it does not habitually exceed a combined limit of 10,000 a year.

Although there is no limit to the number of birds or lagomorphs that producers in the second category may slaughter, the FSA anticipates that the restrictions will limit production to relatively small quantities. In judging whether an assurance scheme is appropriate, regard should be had as to whether the scheme has requirements that go beyond minimum legal requirements in relation to food safety and hygiene and whether it has independent verification arrangements. The FSA can advise in cases of doubt.

### **Where can the meat be sold?**

Meat produced under this exemption may be supplied:

- direct to the final consumer,
- or**
- direct to local retail establishments directly supplying such meat to the final consumer.

In the first category, direct supply to the final consumer includes mail order or internet sales, as long as the supply is *direct* to the consumer. Such supplies are not necessarily limited to meat in the form of fresh meat. They could be in the form of meat products or preparations.

In the second category, the supply must be direct to local retail establishments (in the form of fresh meat, meat preparations or meat products), and could include the supply by the producer to restaurants or other catering establishments. The retail establishments supplied must be *local*. 'Local' supply is interpreted as being the same as 'localised' and, in addition, anywhere within the UK in the two weeks preceding Christmas and Easter and (for geese) Michaelmas (*late September*).

### **What rules apply?**

Regulation 852/2004 applies to producers who benefit from this exemption. This includes, among other things, the requirement to register the establishment with the local Competent Authority, to maintain procedures based on HACCP principles and



to comply with general hygiene and training requirements. The national rules in Schedule 5 to the Food Safety and Hygiene (England) Regulations 2013 regarding labelling and record keeping also apply.

The labelling rules require that the meat bear a label or other marking clearly indicating the name and address of the farm where the bird or animal was slaughtered. This is in addition to any labelling required by the Food Information Regulations 2014. .

The record keeping rule requires the producer to keep a record in adequate form to show the number of birds and the number of lagomorphs received into, and the amounts of meat despatched from, the premises during each week. Such records, in order to be adequate, should at least record this information by species of animal slaughtered. The records should be retained for one year and be made available to an authorised officer of the local Competent Authority on request.

### **7.3.5 Meat products, minced meat and meat preparations – Cutting of meat**

Paragraph 2 of Section VI of Annex III to Regulation 853/2004 has the effect that premises that cut meat exclusively for the manufacture of meat products, minced meat, meat preparations or mechanically separated meat need to comply with the relevant requirements of Annex III of Regulation 853/2004 for red or white meat cutting plants, but will not need approval as cutting plants.

### **7.3.6 Home Slaughter of Livestock: A Guide to the Law in England**

Where slaughter of a livestock animal is carried out by its owner on their property for their own personal consumption or that of immediate members of their family living there and the meat is not placed on the market (whether free of charge or not) such activity falls out of the scope of both Regulation 852/2004 and Regulation 853/2004. However, the EU TSE Regulations apply wherever a TSE susceptible animal is slaughtered (including home slaughter). This means that after slaughter of cattle, sheep or goats, specified risk material (SRM) must be removed, stained and disposed of in accordance with both the EU TSE Regulation 999/2001 (as amended) and the EU Animal By-Products Regulation 1069/2009. A more detailed guide on home slaughter is available at the web link below:

<http://www.food.gov.uk/business-industry/guidancenotes/meatregsguid/home-slaughter-livestock/livestockguidance/>

### 7.3.7 The wild game sector - which regulations apply to which activities

| ACTIVITY   | Regulation (EC) No. 852/2004  | Regulation (EC) No. 853/2004  | Regulation (EC) No. 854/2004  |
|--|---|---|---|
| Shooting for own consumption   | No<br>Art 1.2a exemption  | No<br>Art 1.3a exemption  | No  |
| <u>Supply direct to final consumer or to local retailers (directly supplying final consumer) of small quantities of:</u>                                       |   |   |   |
| <i>a) whole carcasses by primary producer (hunter or estate)</i>   | No<br>Art 1.2c exemption<br>National rules apply <sup>27</sup>                                | No<br>Art 1.3c exemption  | No  |
| <i>b) meat from carcasses (produced by hunter from own shooting)</i>   | Yes<br>Premises to be registered as food business <sup>28</sup> and to operate under Annex II | No<br>Art 1.3e exemption<br>National rules apply  | No  |
| 1. <u>Supply of whole carcasses to approved game handling establishments (AGHEs) either direct from shoot or from game larder operated by primary producer</u> | Yes<br>Premises to be registered as food business <sup>20</sup> and to operate under Annex I  | Parts relating to primary producer (“trained person <sup>29</sup> ” requirements and hygiene practices e.g. initial handling, temperature controls and transport) | Parts relating to primary producer’s documentation and hygiene practices, including OV <sup>30</sup> examination of “trained person <sup>23</sup> ” information |
| 2. <u>Supply of whole carcasses to approved game handling</u>  | Yes<br>Premises to be registered  | Parts relevant to documentation originally  | Parts relevant to supplier’s hygiene  |

<sup>27</sup> Food Safety Act 1990 (as amended by General Food Regulations 2004).

<sup>28</sup> By the Competent Authority (Local Authority)

<sup>29</sup> Either the gamekeeper or game manager on the hunting party/in the immediate vicinity or a hunter who has completed training provided to the satisfaction of the Competent Authority (see Regulation 853/2004, Annex III, Section IV, Chapter I)

<sup>30</sup> Official Veterinarian

|  |   |   |   |
|--|---|---|---|
| <u>establishments (AGHEs)</u><br><i>not by the primary producer</i>  | as food business <sup>20</sup> and to<br>operate under Annex II<br>(including any game larders<br>and vehicles) | supplied by “trained<br>person <sup>23</sup> ”, plus<br>temperature controls,<br>hygienic handling and<br>transport | practices, plus OV <sup>24</sup><br>to check supply of<br>documentation from<br>“trained person <sup>23</sup> ” |
| 3. <u>All other (non-retail) establishments<br/> preparing wild game meat for placing<br/> on the UK domestic or export market</u><br>• These are approved game handling<br>establishments (AGHEs) | Yes   | Yes<br>Premises to be approved<br>by FSA  | Yes   |

## **7.4 Matters relating to Raw Milk and Dairy Products**

### **7.4.1 Introduction**

This section provides specific guidance to Competent Authorities with regard to Raw Milk and Dairy Products and clarifies enforcement responsibilities between Competent Authorities (Local Authorities) and the Central Competent Authority (FSA).

### **7.4.2 Enforcement**

Competent Authorities approve dairy establishments, and otherwise enforce the Regulations except in the cases listed below:

Requirements in Regulation 5(1)(a) of the Food Safety and Hygiene (England) Regulations 2013 relating to milk production holdings and the subsequent supervision and inspection of production holdings (apart from animal health checks - see below). These are dealt with by the FSA Dairy Hygiene Inspectors<sup>31</sup> insofar as cattle herds are concerned. For other species, responsibility lies with Competent Authorities.

Controls under Regulation 34/Schedule 6 of the Food Safety and Hygiene (England) Regulations 2013 on the sales restrictions of raw cows' drinking milk, i.e. ensuring that raw cows' drinking milk is supplied only from farms direct to consumers, temporary guests or distributors, ensuring compliance with the appropriate RDM labelling requirements, and the management of the sampling programme to ensure adherence to standards for such milk set down in Schedule 6. These are also dealt with by the FSA Dairy Hygiene Inspectors. The Department for Environment, Food and Rural Affairs (Defra), working with Animal and Plant Health Agency (APHA), is responsible for carrying out official tests of dairy cattle herds for bovine tuberculosis (TB) and brucellosis where appropriate, including annual TB testing of cattle herds that produce raw drinking milk for direct human consumption.

Food business operators whose operations are both as a milk production holding and a processing establishment are registered with the FSA as a production holding, and approved by the Competent Authority as a dairy establishment for processing activities.

### **7.4.3 Food business operators selling raw drinking milk and cream**

Article 10(8) of Regulation 853/2004 allows member states to establish national rules on the sale of raw milk and cream intended for direct human consumption.

As explained above, the restrictions on sales of raw cows' drinking milk are set out in Regulation 34/Schedule 6 of the Food Safety and Hygiene (England) Regulations

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<sup>31</sup> With effect from April 2012

2013 and are enforced by the FSA Dairy Hygiene Inspectors. The FSA also manages the sampling programme under those regulations. However, if Competent Authorities have concerns about the microbiological standard of raw cows' drinking milk either at the bottling stage or when it is offered for sale (i.e. via a milk round or in a farm shop), they can carry out their own testing for specific pathogens and take action under the Food Safety Act if appropriate. Competent Authorities should also alert the FSA as soon as possible if they become aware of sales of raw cows' drinking milk other than from the farm or via a distributor as permitted under the Food Hygiene Regulations.

Apart from being officially TB free, cattle herds that produce raw drinking milk for direct human consumption must also be subject to annual testing for TB. Therefore, it is essential that Competent Authorities liaise closely with the FSA and the regional APHA offices to maintain an up-to-date list of local food business operators selling raw drinking milk and raw milk products.

Competent Authorities are responsible for enforcing the requirements of Schedule 6 of the Food Safety and Hygiene (England) Regulations 2013 in respect of sales of raw drinking milk intended for direct human consumption, from species other than cows' milk – specifically paragraph 5.

#### **7.4.4 Reusable Containers**

The requirements for equipment to be clean and to disinfect reusable containers mechanically can be difficult to comply with, particularly for some smaller establishments. Dairies that obtain clean bottles from central units will not normally require mechanical bottle washing facilities, providing the clean bottles are not exposed to any risk of contamination during storage and before being filled at the dairy. Bottle washing and storage can take place in the same room where products are handled, but at different times or in a separate area - providing hygiene is not compromised.

#### **7.4.5 Health requirements for raw milk production**

Food business operators are responsible for ensuring that the requirements of Regulation 853/2004, Annex III, Section IX, Chapter 1 are met through private veterinary inspections at regular intervals. The frequency of such inspections will be dependent on the individual circumstances. Such inspections can take place when a farmer's private veterinary surgeon is present for other purposes. Food business operators will need to keep evidence of such visits e.g. a receipt/invoice - and of any follow up action taken if problems occur – for checking by authorised officers. Purchasers (or processors) of raw milk are also required to ensure, e.g. through contracts, that checks have been carried out to assess compliance with relevant animal health standards. Immediate problems that may affect the safety of milk will normally be notified to Competent Authorities by the FSA, APHA or private veterinary surgeons. Longer-term issues arising from records can also be referred to Competent Authorities. Where Competent Authorities suspect that requirements are not being complied with, or that follow up action has not been taken, they should

raise the matter with the purchaser/processor, or with the producer direct, and advise them to take appropriate advice e.g. from their private veterinary surgeon.

#### **7.4.6 Criteria and standards for raw milk**

In the case of the standards laid down in Regulation 853/2004, Annex III, Section IX, Chapter I, Part 3 for plate counts and somatic cell counts the Regulations specify a minimum frequency of sampling by the producer or the purchaser. Authorised officers need to ensure that food business operators are carrying out the specified sampling programme. Authorised officers should check Food Business Operators' records, and if they have concerns about the test results, consider random official checks to satisfy themselves that the required standards are being met. Arrangements relating to milk for heat-treatment are set out in Annex III, Section IX, Chapter II of Regulation 853/2004, as amended by Article 8 / Annex VII(2)(d) of Regulation 2074/2005<sup>32</sup>

#### **7.4.7 Temperature requirements for milk used for the manufacture of dairy products**

Regulation 853/2004, Annex III, Section IX, Chapter II, Part 1, Paragraph 1 stipulates that the acceptability of raw milk applies from the arrival of the milk at a processing establishment. Paragraph 2 allows temperatures and times specified for treatment of raw milk to be exceeded for "technological reasons". These reasons will include cases where higher temperatures may be essential to the manufacture of certain products e.g. cheeses and also instances over a weekend for example when establishments are unable to process milk within the specified period. Authorisation by the Competent Authority is required whenever it is anticipated that these times will be exceeded.

#### **7.4.8 Heat treatment of raw milk or dairy products**

Requirements for pasteurisation and ultra-heat treatment are set out in Annex III, Section IX, Chapter II of Regulation 853/2004, as amended by Article 8 / Annex VII (2) (d) of Regulation 2074/2005.

#### **7.4.9 Phosphatase Testing**

Commission Regulation (EC) No 1664/2006, which amended Regulation (EC) 2074/2005, implemented new requirements for the alkaline phosphatase (ALP) testing method for heat-treated milk:

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<sup>32</sup> Commission Regulation (EC) No 2074/2005 of 5 December 2005 (as amended) laying down implementing measures for certain products under Regulation (EC) No 853/2004 of the European Parliament and of the Council and for the organisation of official controls under Regulation (EC) No 854/2004 of the European Parliament and of the Council and Regulation (EC) No 882/2004 of the European Parliament and of the Council, derogating from Regulation (EC) No 852/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004

- All FBO's should have implemented the new reference method for ALP activity ISO 11816-1.
- An ALP test is considered to give a negative result if the measured activity in cow's milk is not higher than 350 mU/l

An alternative analytical method can be used as long as it is validated against the reference method.

#### **7.4.10 Labelling of cheeses made from raw milk**

Cheeses made from raw milk which are sold pre-packaged are required to be labelled on the packaging as being 'made with raw milk' at point of sale. The legislation provides that 'labelling' includes any packaging, document, notice, label, ring or collar accompanying or referring to such products.

Blocks of cheese on display at a delicatessen counter which it is intended will be cut into smaller portions for sale to the consumer are required to be labelled as 'made with raw milk' either by a label on the cheese or by a notice referring to it. However, such cheese once it is cut and wrapped and given to the consumer for purchase does not require to be labelled with the prescribed wording.

## 7.4.11 Officially Tuberculosis Free status and dairy hygiene legislation

### 7.4.11.1 Scope

This guidance provides information and advice for Competent Authorities in England who have dairy herds and/or dairy establishments in their area, including those producing raw cows' drinking milk<sup>1</sup> (RCDM) and/or unpasteurised milk-based products. The guidance will be of assistance to those involved with investigations following notification from Animal and Plant Health Agency (APHA) of the loss<sup>2</sup> of "Officially Tuberculosis Free" (OTF) status of dairy herds.

### 7.4.11.2 Introduction

Tuberculosis (TB) is an infectious disease of humans and many animal species, caused by some bacteria of the genus *Mycobacterium*. Most cases of human tuberculosis are caused by *Mycobacterium tuberculosis* (*M. tuberculosis*). TB in cattle is primarily caused by *Mycobacterium bovis* (*M. bovis*), which unlike *M. tuberculosis* has a very broad host range.

Regular tuberculin testing of dairy herds ensures that most cases of TB in cattle are detected in the early stages of infection, before the development of clinical signs and the shedding of bacteria in milk. *M. bovis* is however responsible for a very small proportion of all cases of human TB infection diagnosed in the UK. The gradual introduction of milk pasteurisation since the 1930's and the statutory regular TB testing programme in cattle herds have helped minimise the risk of zoonotic TB to the general public via the consumption of milk from infected cows. *M. bovis* infection in humans is now very rare in the UK – between 20 and 40 cases a year, which is less than 1% of all bacteriologically confirmed TB cases in the UK. Most of these cases are diagnosed either in older people (thought to be due to reactivation of latent *M. bovis* infection acquired in the past) or contracted abroad.

### 7.4.11.3 Legislative background

EC Regulation 853/2004, Annex III Section IX, Chapter 1, Part 1, 1,2(b) requires that RCDM must come from animals belonging to a herd which is officially tuberculosis free (OTF). Annex III Section IX, Chapter 1.1.3 requires that milk which does not satisfy this condition may only be sold for human consumption after it has been heat treated, with the authorisation of the FSA. If Competent Authorities investigating a notification of the loss of OTF status become aware that milk is being sold raw for direct human consumption, they must consider taking action (Annex III Section IX, Chapter 1, Part 1, paragraph 3 of EC 853/2004) to ensure that milk from herds that have lost their OTF

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<sup>1</sup> In this context raw cows' milk also includes raw buffalo's milk.

<sup>2</sup> For the purpose of this guidance and for the purposes of Dairy Hygiene legislation, the herd will have lost OTF status if: a reactor is disclosed by tuberculin testing, suspect lesions of TB are identified at routine post mortem meat inspection ('slaughterhouse cases'), inconclusive reactors are disclosed within 3 years of a previous confirmed TB incident in the same herd; or a tuberculin skin test has become overdue ("status suspended"-OTFS); or when *M. bovis* infection is confirmed in a herd by post mortem examination and /or bacteriological culture ('status withdrawn'-OTFW').



status is heat treated. A draft form of words which may be used by Competent Authorities to remind milk producers of this requirement is set out in 7.4.13.

While the law requires that raw milk based products may only be manufactured with milk from herds classified as OTF, the Regulations do not prohibit the marketing of products made before the removal of OTF status. If, following the procedures suggested for dealing with stocks of raw milk based products an agreed outcome cannot be concluded with the producer, any action taken will need to be under the Food Safety Act 1990 and the General Food Regulations 2004 (see paragraph 7.4.11.4).

EC Regulation 853/2004 requires that RCDM must come from animals belonging to a herd which is OTF (Annex III, Section IX, chapter 1.1.2 (b)). Milk, from non-reactor animals in herds which do not satisfy this condition, may be sold for human consumption only after it has been heat-treated (Annex III, Section IX, Chapter 1, 3). APHA will notify Competent Authorities of conditions in a herd that result in the loss of OTF status.

#### **7.4.11.4 Competent authority enforcement issues**

##### **Action to take on loss of OTF status of a dairy herd**

When a dairy herd is placed under TB movement restrictions for whatever reason, the APHA will send a notification to the relevant Chief Environmental Health Officer (CEHO). TB restrictions are imposed on the herd owner under the Tuberculosis (England) order 2014 and this effectively suspends (or withdraws) the OTF status of that herd until further notice.

On receipt of the notification, the Competent Authority should ensure that milk from the herd is no longer used for raw milk based products. Milk from negative-testing animals and inconclusive reactors (IRs) in the affected herd, may be used for human consumption, providing it has been pasteurised, or subjected to a stronger heat treatment. Processors making raw milk based products must not use milk from the affected herd and will only be able to continue their production of such products by obtaining an alternative source of supply from an OTF herd. Milk from individual TB test reactor animals awaiting slaughter within a herd cannot be used for human consumption in any circumstances. This includes reactors to the tuberculin skin test and/or the supplementary interferon-gamma blood test.

To give effect to this Competent Authority Enforcement Officers will need to:

Contact the herd owner to establish:

- a) that no milk from reactor animals is entering the food chain,
- b) whether milk from the herd is being or has been sold as raw cows' drinking milk (RCDM), or is being offered without heat treatment as part of an on-farm business, for example a Bed & Breakfast
- c) whether the milk is being, or has been used to make unpasteurised milk-based products either on the farm or elsewhere,

- d) who is the first purchaser of the milk and whether they have been notified of the loss of OTF status, and the need to ensure that all milk from non-reactor animals and any milk with which it may be mixed, will receive adequate heat treatment before consumption or use for milk based products,
- e) Contact the first purchaser(s) of the milk to establish:
  - that they are aware of the herd breakdown and that the milk from the non-reactor animals will be heat treated before sale or use in dairy products to confirm the cleaning in place systems (CIP) for the means of transport

These investigations can be facilitated by contacting the regional APHA office responsible for managing the TB breakdown, the FSA Dairy Hygiene Inspectors and other Competent Authorities, including the Competent Authority of the first purchaser who might need to become involved where appropriate.

Where the affected farm has heat treatment facilities installed, the Authority should confirm that all HACCP are in place and working effectively, including adequate heat treatment.

If, as a result of the enquiries above, milk from reactor animals is found to have entered the food chain after the loss of OTF status this must be notified to the FSA Incidents Team immediately. Similarly the FSA Incidents Team should be notified immediately if milk from the non-reactor animals in the herd is found to have entered the food chain without heat treatment.

### **Action to be taken on stocks of raw milk based products following loss of OTF status**

Competent Authorities will wish to consider the public health implications, via a risk assessment undertaken locally with the Consultant in Communicable Disease Control (CCDC) , the regional APHA office and the FSA Dairy Hygiene Inspectors, of products made prior to the herd losing its OTF status. Advice should also be obtained where appropriate from Public Health England (PHE). If, as a result of the risk assessment, it is concluded that it is appropriate to withdraw or destroy such products, (voluntary) withdrawal/destruction procedures should be pursued. Enforcement Officers will have to decide on appropriate action based on the circumstances of individual cases. The factors to be taken into account in the risk assessment will include:

- a) The reasons for the loss of OTF status. This can be due to the disclosure of TB test reactors, inconclusive reactors only, a reported slaughterhouse case, pending culture results, or an overdue TB test.
- b) The number of reactors and slaughterhouse cases identified. This might be the number of reactors in relation to the total herd size and number of cattle tested. A single or a low number of reactors in a large herd might represent a lower risk, since it might indicate that the infection has not had time to spread within the herd. A large number of reactors in any herd might indicate either a long term spread within the herd or multiple infections linked to a common source. Herds with larger number of reactors at the initial test are more likely to have additional reactors disclosed at subsequent tests.

- c) Types of cattle reacting to the test. For example, maiden non calved heifers or bullocks being non-milk-producing animals might be of less significance than infection detected in adult milking cows. A high proportion of reactor calves may be indicative of milk-borne spread of infection from a cow with TB of the udder.
- d) The number, severity and location of any TB lesions found at post mortem examination (PME) and the bacteriological culture results.  
 If no TB lesions are found, or lesions are confined to one organ or one part of the body other than the mammary gland, the risk of TB bacilli being present in milk can be considered low. If TB lesions were found in the mammary gland or in more than one organ or part of the body in a lactating dairy cow, the risk of TB bacilli being present in milk can be considered significant. TB bacilli can be present in milk even in the absence of obvious udder disease when the disease has been distributed systemically. Following PME tissue samples are collected from a small subset of reactors, including those where no visible lesions were found in the absence of lesioned cattle. Tissue culture takes a minimum of 6 weeks to positively identify *M. bovis*, with approximately <10% of reactors with no visible lesions at PME and >90% of reactors with visible lesions yielding a positive culture of *M. bovis*.
- e) Testing history of the individual herd. Aspects to consider include:
1. time elapsed since the last negative TB test;
  2. previous TB history of the herd (recurrent incidents); and
  3. the reason for conducting the test.
- f) The baseline testing frequency for the local area. This provides an indication of whether the herd is in a high TB prevalence area. The APHA case veterinary officer will provide expert opinion and judgement of the TB incidence and prevalence in the locality.
- g) General herd health and herd bio-security. Consideration should also be given to:
- milk somatic cell counts - higher cell counts might indicate a higher likelihood of TB organisms being present in the milk; and
  - animal trading record for the farm, highlighting numbers brought in, from where and their last TB test date (this is important because it can take a minimum of 6 weeks from the time of infection for an animal to react to the tuberculin test).
- h) Type(s) of milk-based product and production process. For example, the use of bought in milk might make it more difficult to establish the necessary herd information. Consideration must be given to any scientific evidence, including that provided by the milk processors, that the production process might eliminate the pathogens and that TB organisms are absent from the product.
- i) Fresh milk products. The shelf life of the product might have been exceeded by the time the post-mortem report or tissue culture results are received.

- j) Size of the TB restricted herd. The likelihood, severity and duration of TB incidents, as well as the probability of finding further reactors at follow-up tests, tends to increase with herd size

Where there is evidence of active disease in an animal, then it is likely that withdrawal of batches of the product produced before the date of TB testing would be appropriate as a precaution. The case Veterinary Officer dealing with the TB incident is often the person best placed to provide information and assist the Competent Authority with the risk assessment.

The Regulations do not prohibit the marketing of products made before the removal of OTF status. If a voluntary solution cannot be concluded with the producer any action taken will need to be under the Food Safety Act 1990 (as amended) and the General Food Regulations 2004. Enforcement Officers might consider further action under Section 9 of the Act if they suspect that the products concerned fail to comply with food safety requirements as defined in Article 14 of EC Regulation 178/2002 on general food law. It will however be necessary, for any prosecution to succeed, to prove that an offence had occurred under regulation 4 of the General Food Regulations 2004. This makes it an offence to contravene Article 14 of EC Regulation 178/2002.

#### **Action to take before OTF problems arise**

Competent Authorities should liaise with APHA to ensure that herds supplying RCDM and/or establishments or processors manufacturing unpasteurised dairy products are tuberculin tested annually. For example, Competent Authorities should notify APHA when they become aware of the sale of RCDM for human consumption or the production of unpasteurised dairy products in their area. Competent Authorities should advise manufacturers producing unpasteurised dairy products that the law requires that the milk they use may only come from herds classified as OTF. Therefore, enforcement officers should verify that those processors who buy in milk are able to produce evidence that the milk they purchase only comes from OTF dairy herds that are tested annually for TB. Competent Authorities should contact APHA who will be able to supply further information about these issues.

Competent Authorities might find it helpful to liaise with relevant Competent Authority Animal Health and Welfare Trading Standards Inspectors as their responsibilities include checking farm records under animal health legislation.

#### **7.4.11.5 Cases of human illness**

In the event of a CCDC being notified that a person(s) has confirmed bovine TB, and the infection is thought to be recently acquired, the CCDC should ascertain any connection with cattle that indicates the infection might have been caught from an animal source or might be passed to animals. If so they must inform the Competent Authority. If there is a risk that a herd and/or other farm stock might be infected then the enforcement officer should notify APHA so that checks can be made on the herds. It may also be appropriate to notify other relevant Competent Authorities, local farmers, dairies and producers, milk buyers or distributors that might be affected (with due regard for patient confidentiality). For detailed guidance on dealing with human cases

of TB please contact the Department of Health or consult the relevant PHE guidance that is available online:

<https://www.gov.uk/government/publications/bovine-tuberculosis-tb-public-health-management>

#### **7.4.11.6 Further Contacts and Information**

If further advice is needed on the action to be taken on stocks of raw milk based products following the loss of OTF status, Competent Authorities should contact the [FSA Food Incident Branch: Foodincidents@foodstandards.gsi.gov.uk](mailto:Foodincidents@foodstandards.gsi.gov.uk), , who will work with the local investigation team.

If more information is required on Defra procedures concerning TB controls Competent Authorities should contact the duty Veterinary Officer at local or regional Offices of APHA.

The following web sites may be useful:

<https://www.gov.uk/government/organisations/animal-and-plant-health-agency>

<https://www.gov.uk/government/collections/bovine-tb-information-notes>

<https://www.gov.uk/government/collections/tuberculosis-and-other-mycobacterial-diseases-diagnosis-screening-management-and-data>

#### **7.4.12 Animal health controls and the role of Animal and Plant Health Agency (APHA)**

##### **7.4.12.1 M. bovis infection in cattle**

Tuberculosis (TB) in cattle is caused by *Mycobacterium bovis* (*M. bovis*) and bovine TB can affect a range of domestic or wild species such as deer and badgers. Humans can also be affected, although this is now rare in the UK. In the past infection from raw milk occurred, but now with regular testing of herds, slaughter of reactors and milk pasteurisation, human cases are relatively rare and usually thought to be due to the reactivation of the disease contracted earlier, for example before milk pasteurisation was widely in use, or, occasionally infection contracted abroad. Regular testing of cattle on the farm detects most cases early before the organism is shed in milk. The bacteria can be inhaled in aerosols from the lungs of infected cattle, or ingested through drinking contaminated raw milk or consuming contaminated unpasteurised milk-based products.

Since the early 1980s the number of herds reported each year where the OTF status has been suspended or withdrawn has steadily increased. This initially affected mainly the southwest of England, but in the 1990s and early 2000s bovine TB (bTB) spread to parts of South and Mid Wales and across the West Midlands. In more recent years the incidence of bTB in England and Wales appears to have stabilised, if not reduced slightly. The disease is also endemic throughout Northern Ireland. Scotland, however was declared 'Officially Tuberculosis Free' in October 2009 and the disease occurs only sporadically in counties in the far North and East of England, usually as a result of introductions of infected cattle from the endemic regions.

The routine tuberculin skin testing of herds is the key element in the surveillance and control of TB in cattle in the UK. Any animal showing a positive reaction (i.e. a “reactor”) to this test is rapidly slaughtered and compensation paid. Slaughtered reactors undergo post-mortem examination and lymph node and other tissue samples are collected from some of the reactors in a herd for culture of the organism to identify the strain of *M. bovis* responsible for the incident. Approximately one half of all test reactors are found to have visible lesions of TB at post-mortem examination, or a positive culture for *M. bovis*.

The FSA meat inspectors carry out routine post mortem meat inspection of all carcasses of domestic mammals at abattoirs for macroscopic lesions of TB as part of the normal meat hygiene control. This supplements the routine surveillance testing of cattle herds.

#### **7.4.12.2 Routine testing of herds**

Most TB testing in England is carried out by Official Veterinarians. These are veterinarians in private practice appointed by APHA to carry out specific statutory duties. APHA is responsible for the day to day administration of the tuberculin testing programme, the supervision of OVs and the management of TB incidents. The latter includes notification of a new TB incident to the relevant environmental and public health officials. Where individual farmers have agreed with APHA that they wish to pay for additional private testing outside of the routine testing, the farmer must notify APHA of the results accordingly.

Farmers may wish to carry out private tests, for instance on purchased animals, to clarify their TB status and. Additionally, more frequent testing could be viewed as providing an early indication of problems for producers of unpasteurised cows’ milk and raw milk-based products intended for consumption in that state. Cattle keepers in annual testing areas are required by law to privately test animals before they move to other herds— this pre-movement TB testing of any purchased cattle provides an additional safeguard against the spread of the infection between herds..

In the West of England and in Wales, where the incidence of TB is greater, cattle herds are routinely tested every year. Most cattle herds in the North and the East of England are tested every four years, although APHA will place individual herds that are at a higher risk of TB in those areas on annual testing frequency. Furthermore, APHA can place individual herds on an annual TB testing regime on animal or public health grounds, regardless of the default routine testing frequency for their area. Examples of such herds are: cattle dealers’ and bull hirers’ herds, herds with a regular intake of cattle from areas with a high incidence of TB and retailers of RCDM. In Scotland, the majority cattle herds are routinely tested for TB every four years, but an increasing number of herds are not tested at all, so that surveillance for TB in those herds relies entirely on routine post-mortem meat inspection of culled animals.

#### **7.4.12.3 Finding a TB reactor**

Disclosure of TB test reactors at a routine herd test is the most common reason for the imposition of TB restrictions under the Tuberculosis Order, but other situations can also lead to the suspension of the OTF status of a herd. These include detection by the FSA of suspect lesions of TB at routine meat inspection in the abattoir; disclosure of inconclusive reactors within three years of the resolution of a confirmed TB incident; or TB tests that become overdue. Service of TB restrictions effectively suspends the OTF status of that herd. When a dairy herd is placed under TB movement restrictions for whatever reason APHA will inform the relevant Chief Environmental Health Officer (CEHO).

All TB test reactors are sent under licence for compulsory slaughter. When reactors are slaughtered and herd restrictions applied, APHA will make arrangements to re-test the herd at 60 day intervals until negative herd tests are obtained (one such test is generally required when no post mortem evidence of TB is found in the reactor herd, two consecutive tests otherwise). Additionally, in some herds with post mortem evidence of *M. bovis* infection (OTF status withdrawn), APHA will deploy the supplementary interferon-gamma blood test in conjunction with the skin test to enhance the sensitivity of TB testing, which may result in the detection of more test reactors.

Following a programme of skin testing of the affected herd with negative results, movement restrictions will be lifted, thereby restoring the herd's OTF status. APHA will notify the CEHO when the OTF status of a dairy herd has been regained.

#### **7.4.12.4 Laboratory confirmation of TB**

TB incidents (also known as herd breakdowns) are confirmed when at least one reactor animal in that herd presents with visible lesions of TB at post-mortem examination and/or when *M. bovis* is isolated by bacteriological culture from selected tissue samples. Additionally, a TB incident can also be confirmed when suspect lesions are found in carcasses of clear testing cattle during routine meat inspection and those lesions yield *M. bovis* on culture. The OTF status of the affected herd is withdrawn under any of those scenarios.

As indicated above, all reactors are slaughtered and undergo post-mortem examination for confirmation of infection. On average, just under half of these animals are found to have visible lesions on post-mortem examination. The remainder are called "no visible lesion" (NVL) reactors. A small proportion of those NVL reactors might be due to false positive tuberculin tests, but the majority represent cattle at an early stage of infection, where the lesions of TB are too small to be detectable by visual inspection of the carcass. APHA will collect appropriate tissue samples from a subset of reactor animals and bacteriological culture of *M. bovis* will be attempted. In NVL reactors, a pool of apparently normal lymph nodes is collected to attempt the isolation of *M. bovis* by bacteriological culture and thus confirm the infection. In reactors with visible lesions, infection is automatically confirmed and the main reason for taking samples of the lesions is to undertake molecular typing of the *M. bovis* strain responsible for the incident to inform epidemiological investigations. The outcomes of the post-mortem and bacteriological culture determine the number of 60-day interval tests that must be carried out in the remainder of the herd before TB restrictions can be lifted. Laboratory

confirmation of TB by culture will take a minimum of 6 weeks. It could take longer if samples are contaminated.

APHA will notify CEHOs of all TB incidents (whether subsequently confirmed or not) in dairy herds so that checks can be made and action taken under food hygiene regulations<sup>4</sup>. APHA will notify the CCDC of confirmed TB incidents in any animal, for human health screening purposes. A courtesy copy of the notification of confirmed TB is often sent to the CEHO. In the unlikely event of TB of the udder being found on post-mortem examination, both the CEHO and the CCDC will be notified by APHA.

#### **7.4.12.5 Inconclusive reactors**

On occasions the result of the skin test on animals will be in an intermediate range between positive and negative. These animals are classed as inconclusive reactors (IRs). Cattle may react in this way for a number of reasons including exposure to other bacteria but experience has shown that a significant proportion of inconclusive reactions are non - specific and resolve at retest. Animals that do not resolve at retest are classified as reactors.

In herds where there has been a recently confirmed TB breakdown (within the last 3 years), finding an IR results in the whole herd being placed under restrictions and the OTF status of the herd is suspended. CEHOs will be notified of these situations and all milk from the herd must be heat treated.

In herds where there is no recent history (within the last 3 years) of confirmed TB, IR animals are isolated and re-tested after –a minimum period of 60 days. There are no restrictions regarding milk from these animals and OTF status of the herd is not compromised. IRs that are retested with negative results, will re-join the herd. Otherwise those animals will be reclassified as reactors and slaughtered. The herd will then be classed as a TB breakdown and its OTF status will be suspended or withdrawn depending on the post-mortem findings.

Post-mortem examinations are also carried out at the slaughterhouse on all IRs that are slaughtered by APHA for TB control reasons before re-testing and tissue samples may be submitted for culture and molecular typing as necessary.

#### **7.4.13 Documentation**

The following template forms are available:

| <b>Practice Guidance Reference</b> | <b>Template Form</b>   |
|------------------------------------|--|
| <b>7.4.13.1</b>                    | Template wording for use following loss of OTF status for milk producers |

<sup>4</sup> EC Regulations 852/2004 and 853/2004



**7.4.13.1 Template wording for use following loss of OTF status for milk producers**

NAME OF OCCUPIER  
ADDRESS

NAME OF LOCAL AUTHORITY  
ADDRESS  
TELEPHONE NUMBER

Milk from herds that have lost their Officially Tuberculosis Free (OTF) Status and milk from TB reactor animals

When a dairy herd is placed under TB movement restrictions, the herd effectively loses its Officially Tuberculosis Free status. The following conditions apply from that date-

1. Milk from any reactor animals awaiting slaughter must not enter the food chain; and
2. Milk from non -reactor and any inconclusive reactor animals in the herd must be pasteurised or subjected to a stronger heat treatment before it may be sold for human consumption, or used in the manufacture of products for human consumption.

Further please be advised that any person who sells or uses milk or milk-based products in breach of Article 4 (1) of Regulation (EC) 853/2004 may be convicted of an offence under the Food Safety and Hygiene (England) Regulations 2013. The legislative rules detailing the herd health requirements for raw milk production are contained in Annex III, Section IX, Chapter I of Regulation (EC) No. 853/2004. Annex III, Section IX, Chapter I, Part 1 3(a) requires that raw milk from animals that do not belong to an Officially Tuberculosis Free herd may, with the authorisation of the Competent Authority, only be used for human consumption after having undergone a heat treatment such as to show a negative reaction to the phosphatase test.

To safeguard your own health, that of your family or staff it is strongly recommended that you do not drink or use unpasteurised milk in your home.

Signed.....

Environmental Health Services

Date .....

## **7.5 Egg Packing Centres**

### **7.5.1 Introduction**

This section provides specific guidance to Competent Authorities for the enforcement of Annex III, Section X, Eggs and Egg Products, Chapter 1 of Regulation 853/2004.

In addition to the relevant requirements of Regulation 852/2004, this part of the aforementioned Regulations lay down requirements for egg packing centres covering:

- hygiene and temperature requirements for the storage and transport of eggs
- the maximum time limit in which eggs must be delivered to the consumer

### **7.5.2 Scope of the Regulations**

The Regulations apply to establishments engaged in the following activities:

- Egg Packing Centres – the grading, packing, handling, and storage of eggs
- Wholesalers and Retailers – the handling and storage of eggs

The production and collection of eggs at the producer's establishment are activities that take place at the primary production level.

Under the terms of the EU hygiene legislation, egg packing centres are not classed as primary producers, as they are engaged in activities one step removed from primary production.. Therefore, in addition to the specific egg hygiene provisions contained in Regulation 853/2004, egg-packing centres will be subject to the appropriate provisions of Regulation 852/2004, including the Article 5 HACCP requirements and the relevant chapters of Annex II.

Egg packing centres will generally receive eggs from primary production units. From the packing centre, eggs will be distributed throughout the food distribution chain – to wholesalers, retailers and the catering trade. Packing centres may be located on the same site as the production holding but they might also be sourcing eggs from a number of different production sites and may even take bulk supplies of eggs from the wholesale market and repackage them into smaller containers. These practices are acceptable; however Competent Authorities must verify that egg packing centres comply with the relevant requirements of the food hygiene regulations and general food law

Egg wholesalers, while subject to the requirements of Annex III, Section X, Chapter 1 of Regulation 853/2004, may be considered to be 'retail' as defined in Article 3(7) of Regulation 178/2002 and included in the retail exemption. However, if a wholesaler also carries out egg packing then approval is required for the area of the establishments involved in packing eggs.

### **7.5.3 Specific hygiene requirements for shell eggs**

The specific requirements set out in the Regulations are:

- At the producer's establishment, and until sale to the consumer, eggs must be kept clean, dry, free of extraneous odour, effectively protected from shocks and out of direct sunshine
- Eggs must be stored and transported at a temperature, preferably constant, that is best suited to assure optimal conservation of their hygiene properties
- Eggs must be delivered to the consumer within a maximum time limit of 21 days of laying

These specific requirements are self-explanatory save for the requirement to deliver eggs to the final consumer within 21 days from laying. It is not possible to determine the age of an egg directly and any legal requirement to provide the date of lay or the age of an egg is covered in egg marketing legislation. Eggs might be stamped with 'best before dates'. In the case of Class A eggs, it is a legal requirement for a 'best before date' to be applied on all labels/packs. On the basis of this information, if an enforcement officer suspects eggs are being sold beyond the time limit required on food safety grounds, they must examine documentation from the egg producer to determine the age of an egg. The enforcement officer should also contact the relevant egg-marketing inspector (EMI) for further guidance and help in taking the appropriate action. From a hygiene perspective, eggs need to be used within 28 days of lay. Retailers need to sell fresh eggs to the public within 21 days so that consumers have 7 days in which to use the eggs.

The Eggs and Chicks (England) Regulations 2009 cover most aspects of egg production, marking, transport, grading, packing and onward marketing.

The Registration of Establishments (Laying Hens) Regulations 2003 require all laying hen establishments with 350 or more laying hens - whether from caged, barn, free range or organic egg-producing hens - to be registered with the Animal and Plant Health Agency (APHA).

Producers must also register with APHA if:

- they have 50 or more hens and any of the eggs are marketed at a local public market
- any of the eggs are marketed to registered packing centres

Note too that if the eggs are supplied to shops, restaurants or bakeries, the producer will need to be approved and authorised as a packing centre by EMI in order to be permitted to grade them as Class A eggs.

All registered establishment are allocated with a distinguishing number must be stamped on all eggs graded as Class A.

#### **7.5.4 Egg marketing**

Egg producers, packing stations, and wholesalers are also subject to [egg quality and marketing regulations](#). These regulations are the responsibility of DEFRA. Inspections under these regulations are carried out by egg marketing inspectors. It

is recommended that enforcement officers liaise with their respective EMI prior to inspecting egg packing stations and wholesalers.

### **7.5.5 Lion scheme and other industry-led quality assurance schemes**

There are a number of industry based quality assurance schemes operating throughout the UK that enforcement officers should be aware of. These include the 'Lion' and 'Laid in Britain' schemes. The Lion Quality Code incorporates food safety procedures based on the Food Hygiene Regulations but also includes additional requirements. These include compulsory vaccination against Salmonella Enteritidis of all pullets destined for flocks producing 'Lion eggs'. The Lion scheme also has a "best-before" date stamped on the shell as well as on the pack. In addition, there is the "Laid in Britain" scheme offered to independent egg producers who are members of , the UK Egg Producers Association Ltd (UKEP). With these schemes, there are additional on-farm and packing station hygiene controls including a compulsory HACCP plan for packing stations. The regular inspections of egg packing and production sites by independent inspectors are part of these schemes but are different to Competent Authorities or the EMI inspections.

## **7.6 Matters relating to Egg Products and Liquid Egg**

### **7.6.1 Introduction**

This Chapter provides specific guidance to Competent Authorities on the enforcement of Section X, Eggs and Egg Products Chapter II of Regulation 853/2004. This lays down the public health rules for the manufacture and placing on the market of egg products and liquid egg for human consumption.

The Regulations lay down requirements for:

- establishments
- raw materials for the manufacture of egg products
- special hygiene requirements for the manufacture of egg products
- analytical specifications
- labelling and identification marking

### **7.6.2 Scope of the Regulations**

The Regulations apply to establishments manufacturing egg products and liquid egg for human consumption, which include food businesses involved in the production of:

- processed products resulting from the processing of eggs, or various components or mixtures of eggs, or from the further processing of such processed products
- liquid egg for onward transportation to approved processing establishments.

All establishments need to be approved if the Regulations apply to them.

None of the requirements in Section X, Chapter II of Regulation 853/2004 apply to retail, as defined by Regulation 178/2002, so establishments such as bakers and caterers that process eggs and supply to the final consumer are not subject to any of the requirements of Regulation 853/2004. However, there is a requirement under Defra marketing legislation for caterers to only use class A eggs, so they must have come from an approved egg packing establishment which meets the requirements in Regulation 853/2004

### **7.6.3 Types of approved premises**

Premises requiring approval fall into two categories:

- premises where egg products are manufactured and placed on the market, i.e. where processing of raw eggs takes place
- premises where liquid egg is produced for later processing by an approved egg product manufacturer,

Category (ii) exists because egg packing centres might prefer to break out eggs, including cracked eggs, to produce liquid egg rather than risk breakage before they are sent to a processing establishment described in category (i). Such approvals must require that the eggs are broken out as soon as possible in accordance with

the FBO's HACCP-based procedures and the resulting liquid egg frozen or chilled for transport to another approved establishment. If chilled, the storage temperature must not exceed 4°C and the storage period before processing must not exceed 48 hours. Any establishment approved for category ii) only, must comply with the same requirements for approval as egg product manufacturers in category i). When notifying the FSA of approvals, the Authority should specify whether the approval is for i) or ii) and if the premise is also a packing centre.

#### **7.6.4 Dirty eggs**

Eggs cannot be broken out unless they are clean and dry. Dirty eggs (non-Class A eggs) may be cleaned, but Authorities must ensure that any washing, drying and disinfecting of eggs is separated from all other operations of the business.

#### **7.6.5 Centrifuging or crushing**

The Regulations prohibit the use of centrifuges or crushing to obtain egg contents or obtain egg whites from shells for human consumption. However, centrifuges can be used for the disposal of waste, and in such cases, the centrifuge must be situated completely separately from other operations of the approved establishment. Authorised officers must satisfy themselves that centrifuged material cannot contaminate egg products intended for human consumption. Waste material must be denatured upon entry to the centrifuge, for example by use of a dye.

#### **7.6.6 Identification Marking**

The general requirements for identification marking laid down in Annex II, Section I of Regulation 853/2004 must be complied with and are set out in 3.3.14 of the Code. However, there are additional specific requirements for egg products. Regulation 853/2004, Annex III, Section X, Chapter II, Part V requires that consignments of egg products to be used as an ingredient in the manufacture of another product must have a label giving the temperature at which the egg products must be maintained and the period during which conservation may thus be assured.

#### **7.6.7 Pasteurisation and Heat Treatment**

The Regulations do not prescribe a time / temperature combination for the heat treatment of eggs, but they do require that the process must eliminate microbiological hazards or reduce them to an acceptable level. Processing is not required for egg white intended for the manufacture of dried or crystallised albumen destined subsequently to undergo heat treatment.

Competent Authorities will need to be satisfied that the heat treatment process is sufficient to ensure a reduction in the level of micro-organisms in the egg product to any levels laid down in EC Regulations on microbiological criteria.

Where a non-standard process is proposed, the onus is on the occupier to show that adequate research has been carried out into its effectiveness. In establishments where heat processing takes place, Competent Authorities must establish that the operator of the heat process has an acceptable and appropriate level of expertise.

### **7.6.8 Analytical specifications**

Part IV of Annex III, Section X, Chapter II of Regulation 853/2004 lays down analytical specifications that the end product must not exceed. Although there are no prescribed EU methods for testing for lactic or butyric acids, methods do exist. Where such methods are used, due consideration must be given to the reliability of the results. Where samples are tested, the results must be compared with the standards specified.

Authorised officers can help occupiers develop sampling plans since these also are not prescribed in the Regulations.

### **7.6.9 Temperature Control**

The Regulations require that products that have not been stabilised so as to be kept at room temperature must be cooled to not more than 4°C. Products for freezing must be frozen immediately after processing.

### **7.6.10 Storage and transport**

Establishments must keep eggs and egg products separate to avoid contamination. If separate rooms are not available, egg products may be stored in separate containers and areas.

Storage rooms must be capable of maintaining any required temperature controls.

The Regulations do not cover egg products that are stored in separate establishments such as depots or warehouses outside approved egg products establishments. Such storage is covered by Regulation 852/2004.

### **7.6.11 Egg marketing**

Egg packing centres, whether or not approved to produce liquid egg under the Regulations, are the responsibility of Defra in respect of egg quality and marketing regulations and are inspected by Egg Marketing Inspectors (EMIs).

It is recommended that authorised officers liaise with EMIs prior to inspecting egg product facilities at egg-packing centres.



## 7.7. Legislative Requirements for Infant Formula, Follow on Formula and Baby Foods

Information on legislation in this area can be found on the EU website at:  
[http://ec.europa.eu/food/food/labellingnutrition/children/index\\_en.htm](http://ec.europa.eu/food/food/labellingnutrition/children/index_en.htm)

### 1. Infant formula and follow-on formula

**Infant formula and follow-on formula** are products designed to satisfy the specific nutritional requirements of healthy infants (from birth to 3 years). These products are specifically covered by Commission Directive 2006/141/EC<sup>33</sup>

The Directives set out the requirements for the composition, labelling and advertising of infant formula and follow-on formula. This includes restrictions on advertising of infant formula and requirements to draw a clear distinction between the two products. The annexes of the Directive give criteria for the composition (protein, carbohydrate, fat, mineral substances, vitamins and certain other ingredients) of infant formulae and follow-on formulae including, where necessary, minimum and maximum levels. The Directive also requires all infant formula to be notified to the Department of Health prior to being placed on the market.

Directive 2006/141/EC also encompasses the specific rules on the presence of **pesticides residues in infant and follow-on formulae**, previously set out in Commission Directive 1999/50/EC. It requires that baby food contains no detectable levels of pesticide residues, meaning not more than 0.01 milligrams of pesticide residues per kilogramme. The Directive also prohibits the use of certain **very toxic pesticides in the production of infant and follow-on formulae** and establishes levels lower than the general maximum level of 0.01 milligrams per kilogramme for a few other very toxic pesticides<sup>34</sup>

In addition to the requirements relating to infant formulae and follow-on formulae in Directive 2006/141/EC, there are also specific provisions on hygiene, on the use of food additives, on the presence of contaminants in the products and on the use of materials intended to come into contact with foodstuffs.

Detailed guidance on the national provisions of the Infant Formula and Follow-on Formula (England) Regulations 2007 (SI 2007/3521) as amended by the Infant Formula and Follow-on Formula (England) (Amendment) Regulations 2008 (SI

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<sup>33</sup><http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ%3AL%3A2006%3A401%3A0001%3A0033%3AEN%3APDF>

<sup>34</sup> The results from monitoring undertaken at national level by the Chemical regulatory Directorate for pesticide residues in food including infant foods are published on the Pesticide Residues in food website [http://www.pesticides.gov.uk/guidance/industries/pesticides/advisory-groups/PRI\\_F](http://www.pesticides.gov.uk/guidance/industries/pesticides/advisory-groups/PRI_F)

2008/2445) (Separate, but parallel legislation is implemented in Scotland, Wales and Northern Ireland.) can be found at the following link:

<https://www.gov.uk/government/publications/infant-formula-and-foods-for-particular-nutritional-uses-parnuts-notification-requirements>

## 2. Processed-cereal based foods and other baby foods

**Processed-cereal based foods and other baby foods (*weaning foods*)** are specifically intended for infants (children under the age of 12 months) and young children (between one and three years) as they progress onto a mixed family diet.

Processed cereal-based foods and baby foods for infants and young children are covered by Commission Directive 2006/125/EC<sup>35</sup>. It sets out rules on the composition and labelling of processed-cereal based foods and other baby foods. It also gives criteria for the composition (protein, carbohydrate, fat, mineral substances and vitamins) of weaning foods including, where necessary, minimum and maximum levels.

The Directive encompasses the specific rules on the presence of **pesticides residues in processed cereal-based baby foods and baby foods** set out in Commission Directive 99/39/EC and requires that baby food contains no detectable levels of pesticide residues, meaning not more than 0.01 milligrams of pesticide residues per kilogramme. In addition, the Directive prohibits the use of **certain very toxic pesticides in the production of processed cereal-based baby foods and baby foods** and establishes levels lower than the general maximum level of 0.01 milligrams per kilogramme for a few other very toxic pesticides.

In addition to the requirements relating to processed-cereal based foods and other baby foods in Directive 2006/125/EC there are also specific provisions on hygiene, on the use of food additives, on the presence of contaminants in the products and on the use of materials intended to come into contact with foodstuffs.

National provisions in England are the Processed Cereal Based Foods Regulations SI 2003 No. 3207 as amended by the Food for particular Nutritional Uses (Miscellaneous Amendments) Regulations 2007. Separate, but parallel legislation is implemented in Scotland, Wales and Northern Ireland.

## 3. Other legislation relevant to baby food

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<sup>35</sup> <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:339:0016:0016:EN:PDF>

When considering the Manufacture and placing on the market of these products the following areas of General Food Law and Food Hygiene legislation should be taken into account:

Regulation (EC) No 178/2002 laying down the general principles and requirements of food law;

Regulation (EC) No 852/2004 on the hygiene of foodstuffs;

Regulation (EC) No 853/2004 on hygiene rules for food of animal origin;

Regulation (EC) No 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules;

Regulation (EC) No 854/2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption.

Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs;

Regulation (EC) No 31333/2008 on food additives

Regulation (EC) No 1129/2011 implementing annex II to Regulation 31333/2008

Regulation (EC) No 1130/2011 implementing annex III to Regulation 31333/2008

Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs

Directive 2000/13/EC on the labelling, presentation and advertising of foodstuffs . As from 13 December 2014 this will be replaced by Regulation (EU) No 1169/2011 on the provision of food information to consumers

Regulation (EC) No 1924/2006 on nutrition and health claims made on foods

#### **4. Microbiological criteria for baby foods**

Chapters 1 and 2 of Annex I to Regulation (EC) No 2073/2005 set out food safety criteria and process hygiene criteria regarding dried infant formulae, dried dietary foods for special medical purposes intended for infants below six months of age (dried infant formulae and dried dietary foods), ready-to-eat foods intended for infants and ready- to-eat foods for special medical purposes.

Salmonella and Enterobacter sakazakii are the micro-organisms of greatest concern in infant formulae, formulae for special medical purposes and follow-on formulae. The presence of these pathogens constitutes a considerable risk if conditions after reconstitution permit multiplication. Part 2.2 of Chapter 2 of that Annex provides that where dried infant formulae and dried dietary foods are tested and Enterobacteriaceae are detected in any of the sample units, the batch is to be tested for Enterobacter sakazakii and Salmonella.

Food business operators responsible for the manufacture of the product must conduct studies in accordance with Annex II to Regulation (EC) No 2073/2005 in order to investigate compliance with the criteria throughout the shelf-life. In particular, this applies to ready-to-eat foods that are able to support the growth of Listeria monocytogenes and that may pose a Listeria monocytogenes risk for public health

The following Criteria apply to foods intended for infants:

##### **1. Food safety criteria**

| Food category  | Micro-organisms/their toxins, metabolites       | Sampling plan (1) |   | Limits (2)      |   | Analytical reference method (3) | Stage where the criterion applies                     |
|--|---|-------------------|---|-----------------|---|---------------------------------|---|
|  |   | n                 | c | m               | M |                                 |   |
| 1.1 Ready-to-eat foods intended for infants and ready-to-eat foods for special medical purposes (4)                              | <i>Listeria monocytogenes</i>                   | 10                | 0 | Absence in 25 g |   | EN/ISO 11290-1                  | Products placed on the market during their shelf-life |
| 1.22 Dried infant formulae and dried dietary foods for special medical purposes intended for infants below six months of age     | <i>Salmonella</i>                               | 30                | 0 | Absence in 25 g |   | EN/ISO 6579                     | Products placed on the market during their shelf-life |
| 1.23 Dried follow-on formulae  | <i>Salmonella</i>                               | 30                | 0 | Absence in 25 g |   | EN/ISO 6579                     | Products placed on the market during their shelf-life |
| 1.24 Dried infant formulae and dried dietary foods for special medical purposes intended for infants below six months of age (5) | <i>Cronobacter spp (Enterobacter sakazakii)</i> | 30                | 0 | Absence in 10 g |   | ISO/TS 22964                    | Products placed on the market during their shelf-life |

## 2. Process hygiene criteria

| Food category  | Micro-organisms/their toxins, metabolites | Sampling plan (1) |   | Limits (2)      |           | Analytical reference method (3) | Stage where the criterion applies                     | Action in case of unsatisfactory results  |
|--|---|-------------------|---|-----------------|-----------|---------------------------------|---|---|
|  |   | n                 | c | m               | M         |                                 |   |   |
| 2.2.9 Dried infant formulae and dried dietary foods for special medical purposes intended for infants below six months of age  | <i>Enterobacteriaceae</i>                 | 10                | 0 | Absence in 10 g |           | ISO 21528-1                     | Products placed on the market during their shelf-life | Improvements in production hygiene to minimise  |
| 2.2.10 Dried follow-on formulae  | <i>Enterobacteriaceae</i>                 | 5                 | 0 | Absence in 10 g |           | ISO 21528-1                     | Products placed on the market during their shelf-life | Improvements in production hygiene to minimise  |
| 2.2.11 Dried infant formulae and dried dietary foods for special medical purposes intended for infants below six months of age | <i>Presumptive Bacillus cereus</i>        | 5                 | 1 | 50 cfu/g        | 500 cfu/g | EN/ISO 7932 (10)                | End of the manufacturing process.                     | Improvements in production hygiene. Prevention of recontamination. Selection of raw material. |

(1) n = number of units comprising the sample; c = number of sample units giving values between m and M.

(2) For points 1.1 - 2.2.10 above, m = M.

(3) The most recent edition of the standard shall be used.

(4) Regular testing against the criterion is not required in normal circumstances for the following ready-to-eat foods:

- those which have received heat treatment or other processing effective to eliminate *L. monocytogenes*, when recontamination is not possible after this treatment (for example, products heat treated in their final package),
- fresh, uncut and unprocessed vegetables and fruits, excluding sprouted seeds,
- bread, biscuits and similar products,
- bottled or packed waters, soft drinks, beer, cider, wine, spirits and similar products,
- sugar, honey and confectionery, including cocoa and chocolate products,
- live bivalve molluscs.

(14) Parallel testing for Enterobacteriaceae and *E. sakazakii* shall be conducted, unless a correlation between these micro-organisms has been established at an individual plant level. If Enterobacteriaceae are detected in any of the product samples tested in such a plant, the batch must be tested for *E. sakazakii*. It shall be the responsibility of the manufacturer to demonstrate to the satisfaction of the competent authority whether such a correlation exists between Enterobacteriaceae and *E. sakazakii*.

( Cronobacter species) .Enterobacteriaceae n=10 c=0 absent in 10g

(Cronobacter species)

## **5. The EU Commission Non-paper on implementation of microbiological criteria to infant formulae, follow on formulae and baby food**

The aim of the Non-paper is to help food business operators and competent authorities in the implementation of the Reg. 2073/2005. The Non-paper can be found at the following site.

[http://ec.europa.eu/food/food/biosafety/salmonella/docs/20100614\\_non-paper\\_infant\\_formulae\\_baby\\_food.pdf](http://ec.europa.eu/food/food/biosafety/salmonella/docs/20100614_non-paper_infant_formulae_baby_food.pdf)

## **6. Codex Alimentarius Standards**

The Following Standards and the recommended codes of practice should be taken into account by Food Business manufacturing and handling these type of foods

**Codex Standards for Canned Baby Foods** (codex standard 73-1981 amended 1989 see the link: <http://www.codexalimentarius.org/codex-home/en/>

**Codex Standard for Processed Cereal Based Foods for Infants and Young Children** (codex standard 74-1981 Revised 1986)

**Recommended code of hygienic practice for Powdered formula for infants and young children** (CAC/RCP 66-2008 amended 2009)

**Code of hygienic practice for milk and Milk products** (CAC/RCP 57-2004 amended 2009)

## **7. Council Directive 92/52/EEC on infant formulae and follow-on formulae intended for export to third countries**

Council Directive 92/52/EEC on infant formulae and follow-on formulae intended for export to third countries refers to Directive 91/321/EEC. Directive 91/321/EEC was subsequently replaced by Commission Directive 2006/141/EC. Article 2 of Directive 2006/141/EC defines Infant formulae and follow-on formulae.

Council Directive 92/52/EEC states that no product other than infant formulae may be represented (packaged/labelled/marketed/advertised) as suitable for satisfying by itself the nutritional requirements of normal healthy infants during the first four to six months of life. You cannot market any other product for feeding to normal healthy infants during the initial four to six months.

Directive 92/52/EEC also requires that formula milks comply with relevant provisions of Directive 2006/141/EEC or Relevant applicable world standards established by Codex Alimentarius (Codex Standard 72-1981 Infant Formula; Codex Standard 156-1987 Follow-up Formula), unless otherwise stipulated by the importing country.

With regards to export rules, the provisions of Directive 92/52/EEC have been superseded by Article 12 of Regulation (EC) No 178/2002 laying down the general principles and requirements of food law. For the sake of simplification and legal certainty, Regulation 609/2013 will repeal Directive 92/52/EEC with effect from 20 July 2016.

## **8. Substances which may endanger the health of children and young infants**

Infant formulae and follow-on formulae and baby foods must not contain any substance in such quantity as to endanger the health of infants and young children. This includes pesticides, chemical contaminants, additives, food contact materials and anything else that may be a risk to the health of this vulnerable sector of the population.

## **8.a Contaminants (Commission Regulation 1881/2006)**

### Legislation

Commission Regulation 1881/2006 sets maximum levels for certain contaminants in foodstuffs. It includes limits for baby foods and foods for infants and young children, infant formulae and follow-on formulae, including infant milk and follow-on milk, and dietary foods for special medical purposes intended specifically for infants, which are set out in the Annex. There are limits for nitrates (Section 1), various mycotoxins (Section 2) and metals (lead and tin, Section 3). Limits for dioxins and PCBs are set out in the Annex to Commission Regulation 1259/2011 amending Section 5 of the Annex to 1881/2006 and limits for polycyclic aromatic hydrocarbons are set out in the Annex to Commission Regulation 835/2011 amending Section 6 of the Annex to 1881/2006.

There are also Commission Regulations laying down the methods for sampling and analysis for official control. These are 401/2006 (mycotoxins), 1882/2006 (nitrates), 333/2007 (metals), as amended by 836/2011 (PAHs), and 252/2012 (dioxins and PCBs).

### Enforcement

Food Business Operators should be aware of their obligations under general food law and also of their specific obligations to ensure compliance with the limits set out in Commission Regulation 1881/2006 as amended. Common to all of the recent surveys in this area, contaminants were found to be very low or non-detectable, with no non-compliances reported. On this basis, baby food and infant formulae are generally considered to be low risk and therefore not a priority for official controls.

Nevertheless, keeping in mind the responsibilities of Food Business Operators under General Food Law, testing for enforcement purposes may be appropriate if a Food Business Operator is found not to be operating with due diligence.

Food Business Operators should be able to demonstrate checks and certificates to indicate the suitability of raw materials and packing materials for use in this type of products.

### Surveys

The Food Standards Agency has conducted a number of surveys to determine the levels of contaminants in baby foods and infant formulae in order to assess the associated risk.

Mycotoxins:

<http://www.food.gov.uk/science/research/surveillance/fsisbranch2011/mycotoxins>

Metals:

<http://tna.europarchive.org/20110116113217/http://tna.europarchive.org/20110116113217/http://www.food.gov.uk/news/newsarchive/2003/sep/infantmultielements>

<http://tna.europarchive.org/20110116113217/http://www.food.gov.uk/news/newsarchive/2006/oct/weaning>

Polycyclic aromatic hydrocarbons (PAHs):

<http://tna.europarchive.org/20110116113217/http://www.food.gov.uk/news/newsarchive/2006/may/pahsurvey>

Dioxins and PCBs:

<http://tna.europarchive.org/20110116113217/http://tna.europarchive.org/20110116113217/http://www.food.gov.uk/news/newsarchive/2004/jul/babyfood>

<http://tna.europarchive.org/20110116113217/http://tna.europarchive.org/20110116113217/http://www.food.gov.uk/news/newsarchive/2004/mar/dioxinform>

## **9. Foodstuffs intended for Particular Nutritional Use**

Directive 2009/39/EC (recast of Directive 89/398/EEC) on foodstuffs intended for particular nutritional uses makes nutritional requirements for those persons whose digestive processes or metabolism are disturbed; for persons who are in a special physiological condition and who are therefore able to obtain special benefit from controlled consumption of certain substances in foodstuffs and for infants or young children in good health. Foodstuffs for infants and young children who are not in good health and who require dietary foods for special medical purposes which is intended specifically for infants and young children are covered by Directive 1999/21/EEC.

A new framework Regulation (EU) 609/2013 on foods for specific groups was published on 12 June 2013. This will replace Directive 2009/39EC. The specific requirements for infant formula, follow on formula, baby foods and medical foods will be reviewed by 20 July 2015 and the new legislation will apply by 20 July 2016.

### **Key Contacts**

#### **Food Standards Agency:**

The FSA is responsible for liaising with Competent Authorities on enforcement. FSA is also responsible for the food safety aspects of legislation on infant formula, follow-on formula; cereal-based foods and baby foods for infants and young children.

Standards Branch,  
Enforcement and Local Authority Division,  
Food Standards Agency,  
Rm 1B Aviation House, 125, Kingsway, London WC2B 6NH.

**Email:** Standards.support@foodstandards.gsi.gov.uk

## **Chemicals Regulatory Directorate (CRD)**

### **Pesticides.**

The strategic policy lead for pesticides in England and Wales rests with DEFRA with day to day work and regulatory control resting with HSE (administered by the Chemicals Regulation Directorate.). CRD undertake national monitoring of food for pesticide residues. They have agreed to include one survey each year of an infant food. If non-compliance is found then CRD inform FSA and a risk assessment is undertaken. The FSA in conjunction with the Department of Health determine whether further follow up action is required.

### **Contact Points**

On a day to day basis where Local Authority officers find residues of pesticide in infant food they should contact [Standards.support@foodstandards.gsi.gov.uk](mailto:Standards.support@foodstandards.gsi.gov.uk) at the FSA.



## **7.8 Temperature Control Provisions**

### **7.8.1 Introduction**

This section provides guidance on the enforcement of Regulation 32 / Schedule 4 of the Food Safety and Hygiene (England) Regulations 2013. In respect of circumstances exempted from the requirements of Regulation 32 / Schedule 4 and where food is required to be kept under temperature control for safety reasons, the general requirements of Annex II of Regulation (EC) 852/2004 which include Chapter I, Paragraph 2 (d), Chapter III Paragraph 2(g), Chapter IV Paragraph 7, Chapter V Paragraph (2) and Chapter IX Paragraphs (2), (5), (6) and (7), of Regulation 852/2004 would still apply, as appropriate.

Regulation 32 / Schedule 4 does not apply in respect of any food business operator to which Regulation 853/2004 applies.

### **7.8.2 General approach to temperature checks**

Schedule 4 does not apply to any food business operation on ships and aircraft and those businesses to which Regulation 853/2004 applies. Where applicable, the Schedule requires certain types of perishable food to be maintained within specified temperature ranges. The purpose of checking the temperature of such foods for enforcement purposes is to establish whether these requirements are being met, taking account of any exemptions or tolerances that might apply.

Where appropriate, regard must be given to any relevant temperature requirements of Annex II of Regulation 852/2004.

Authorised officers should normally adopt a staged approach to verifying compliance with the temperature requirements of the Regulations as follows:

#### **Stage 1 - Air Temperature Monitoring**

Air temperature monitoring provides an indication of the performance of a refrigeration system over time, and a single reading at any one time will not necessarily be an indication of product temperature. Air temperature monitoring records are an indication of temperature history, including defrost cycles, door openings, breakdowns etc. They must be regarded as a guide to how a particular system is functioning.

#### **Stage 2 – Between-pack Testing**

Non-destructive temperature measurement, or between-pack testing, must normally be used as the next step in the enforcement process. This is done with a pre-cooled flat-headed probe, suitable for measuring surface or between-pack temperatures.

It is important to ensure good thermal contact between the product and the probe when taking between-pack measurements. A total tolerance of +2.8°C (0.8°C as specified for instrument accuracy and 2°C for the limitation of the methodology) must be allowed. Care must be taken to allow time for the reading to stabilise, and to

ensure that the temperature reading relates to the product, not the surrounding air, which can happen if the probe is not properly sandwiched between the packs. Testing must be conducted with the minimum of disturbance to the product or its temperature-controlled environment, particularly the airflow patterns in retail display cabinets. For products within an outer casing it will be necessary to open the casing and insert the temperature probe between packs.

Not all packs or packaging materials are suitable for between-pack testing. Irregularly shaped packs where good thermal contact is not possible, packaging materials that act as an insulator and products in cartons or bubble packs where large air spaces exist are all examples where a between-pack temperature measurement might not be sufficiently accurate to give an indication of product temperature. In such instances it might be necessary to proceed directly to a destructive temperature measurement.

### **Stage 3 - Product Testing (Destructive)**

If a “stage 2” temperature measurement has not been possible, or there is reasonable doubt after a “stage 2” test about compliance with temperature requirements, it will be necessary to progress to destructive testing.

Sample preparation and temperature measurement must normally be undertaken with the sample in its temperature-controlled environment. If this is not possible, the sample must be removed to an appropriately refrigerated environment, provided the transfer does not prejudice product temperature. Any transfer must take place prior to preparation of the sample. Transfer of products within the normal cold chain, e.g. from a vehicle to a cold store, is acceptable.

When a “stage 3” measurement is being carried out, insertion of the temperature probe into the food might render the food unsaleable. In such circumstances, the authorised officer must consider purchasing the food in question.

The selection of items to be tested is at the discretion of the officer. However, if “stage 2” testing has been carried out and there appears to be a breach of the relevant temperature requirements, it must not normally be necessary to select large numbers of items for “stage 3” testing.

In the first instance, items must be taken for “stage 3” testing from the warmest part of the refrigeration system. This can usually be identified using thermochromic (liquid crystal) strip temperature indicators. Although these do not give an accurate temperature reading, they can provide a useful guide to relative temperature distribution within a refrigeration system.

### **General approach**

If an authorised officer is satisfied after “stage 1” or “stage 2” that the relevant temperature requirements are being met, there is no need to move to the next stage and enforcement action should cease.

If there is no temperature monitoring system, or the officer has reasonable doubt about the information derived from the system where there is one, the officer should carry out a “stage 2” check.

If the temperature measured at “stage 2” gives the officer reasonable doubt that the relevant temperature requirements are being met, the officer should move on to “stage 3” and measure the temperature of the food itself.

“Stage 3” product testing (destructive) methods must always be used to produce evidence for prosecution.

The food business operator or manager should, if present, be invited to witness temperature measurement. This is especially important when evidence is being gathered with a view to possible legal proceedings.

### **7.8.3 Taking temperature measurements**

The temperature of a product must not be prejudiced by, for example, opening the doors in a vehicle too often or for too long; disturbing the air curtain in a chill cabinet, or removing the food from a refrigerated environment for long periods.

Any opened cases or cartons must be re-sealed and appropriately labelled or marked with the date and time of the inspection; the name of the person who opened it, and the name of the Competent Authority. This is to show that the case or carton was opened for an official inspection and removes any suspicion of malicious tampering.

### **7.8.4 Tolerances**

“Stage 2” temperature readings might be up to 2°C warmer than the true product temperature, especially product with thick packaging. They might also be affected by recent movement of goods, defrost cycles or instrumental inaccuracy as described below.

Authorised officers must use professional judgement in borderline cases to decide whether further “stage 2” measurements are necessary before proceeding to “stage 3”.

### **7.8.5 Checking and calibration of enforcement measuring thermometers etc**

Thermometers and other temperature measuring devices used for inspection and/or enforcement purposes must be periodically tested and calibrated by a suitably accredited tester (e.g. the instrument manufacturer or a UKAS accredited laboratory or testing house), in accordance with any recommendations of the manufacturer or supplier, to ensure accuracy, integrity and reliability. A certificate of such calibration must be obtained.

Competent Authorities must also check devices for accuracy at regular intervals between each calibration (e.g. against a reference thermometer used only for that

purpose) to ensure they remain within relevant tolerances. Details of such checks must be recorded and these records retained.

Competent Authorities must ensure that temperature measurements that are to be used in evidence are taken with a thermometer or other measuring device that has a current certificate of calibration.

The accuracy of the thermometer or other temperature measuring device, and any detachable probes, must be checked against a reference thermometer or calibrator that is certified to an appropriate standard, e.g. NPL, and the result recorded, before and after taking any temperature measurements that are likely to result in enforcement action.

The record of such a check must be referenced to the instrument's certificate of calibration and include serial numbers of the instrument and any interchangeable probes.

If a reference thermometer is not available, the sensor can be checked in a wet ice mixture. In this case, the system must be calibrated at 0°C. The temperature of wet ice from distilled water is 0°C. Drinking water with a salt content of 0.1% will only depress the melting point to -0.06°C. Therefore, in most cases drinking water can be used to make the ice for the checking procedure. Ice must be broken up into very small pieces, packed into a wide-necked vacuum flask, wetted with cold water and stirred. The sensor must be placed at the centre of the flask at a depth of at least 50mm and agitated frequently and the temperature read after three minutes when stabilised. The read-out instrument can be checked separately using calibration attachments at two or three different temperatures. The combination of checking the system at 0°C with that of checking the instrument must ensure accuracy at higher temperatures.

#### **7.8.6 Pre-cooling of instruments**

The thermometer or other temperature measuring device and the penetration probe must be pre-cooled before being used to measure product temperature to ensure that instruments are as close as possible to the temperature of the product being measured. Pre-cooling reduces the likelihood of a rise in product temperature due to the temperature of the probe and the action of making the hole and can usually be done by leaving the instruments and probe in the same temperature controlled environment as the sample for about 10 minutes. Provided there is no significant rise in the temperature of the instrument or probe, subsequent measurements can be made after a much shorter pre-cooling period.

#### **7.8.7 Preparation of samples for temperature measurement**

Only temperature measuring probes that are specifically designed for the purpose must be used to make a hole in the product. If the probe is not designed for this purpose a separate pre-cooled product penetration implement must be used. The diameter of the hole must provide a close fit to that of the probe and its depth will depend on the type of product being tested (as described below).

### 7.8.8 Measurement of Product Temperature

Preparation of the product for testing and its temperature measurement must take place with the product in its temperature-controlled environment. Measurement is as follows:

- a) Where the product dimensions allow, insert the pre-cooled probe to a depth of at least 2.5cm from the nearest outside surface of the product.
- b) Where (a) is not possible the probe must be inserted to a minimum depth from the surface of at least 3 times the diameter of the probe. With some products, because of their small size, greater care has to be taken to avoid excessive rises in product temperature from unnecessary handling of the sample.

Certain foods, because of their size or composition, cannot be penetrated satisfactorily to determine their internal temperature. In these cases, the internal temperature of the food package must be determined by insertion of a suitable pre-cooled sharp-stemmed probe to the centre of the pack to measure the temperature in contact with the food.

It may not always be possible to determine the internal product temperature accurately, especially of fragile or open-textured products. The temperature of such products must be measured by carefully removing the product from its packaging and firmly sandwiching a pre-cooled flat-headed probe between two items of product.

The temperature reading must not be recorded until it has stabilised.

### 7.8.9 Equipment used for chilled product temperature measurement

Temperature measurement systems that are used for enforcement purposes must meet the following requirements:

- the system must reach 90% of its final reading within 3 minutes
- the system must have an accuracy of  $\pm 0.5^{\circ}\text{C}$ , or better when the sensor is measuring within the temperature range  $-20^{\circ}\text{C}$  to  $+30^{\circ}\text{C}$
- the accuracy must not change by more than  $\pm 0.3^{\circ}\text{C}$  when the instrument is operated in temperatures of  $-20^{\circ}\text{C}$  to  $+30^{\circ}\text{C}$
- the instrument display must be readable to at least  $0.1^{\circ}\text{C}$
- the system must be robust and shock proof
- the temperature sensitive part of the system must be constructed to facilitate good thermal contact with the food and be easily cleaned

A dry cell battery, not mains electricity, must power the measuring instrument. The instrument must incorporate a method of checking the battery voltage to indicate when replacement or re-charging is necessary. The design of the probe depends on the type of temperature measurement:

**For product tests:** a robust rigid stem with a sharpened point suitable for insertion into the product and capable of being sterilised;

**For between-pack tests:** a flat head suitable for a between-pack measurement with good surface contact, low thermal mass and high thermal conductivity. If a suitable flat probe is not available, one can be constructed using a calibrated sensor crimped in the centre of a square, (approximately 4cm long) or circle (approximately 4cm diameter) or a double layer of aluminium foil. Any inter-connecting cables must be flexible between 0°C and +30°C.

#### **7.8.10 Food that is warmer than prescribed chill holding temperature**

When measuring the temperature of food itself, authorised officers must be aware that the Schedule allows the temperature of a food subject to chill holding temperatures, whilst it is for service or on display for sale, to rise above 8°C for one period only of less than four hours (Schedule 4, paragraph 5(1)(b) and (c)).

The officer must be satisfied that the food business operator has measures in place, as appropriate, to ensure that the chill holding tolerance described above is not exceeded.

#### **7.8.11 Food that is cooler than prescribed hot holding temperature**

When measuring the temperature of food itself, authorised officers must be aware that the Schedule allows the temperature of a food subject to hot holding temperatures, whilst it is for service or on display for sale, to fall below 63°C for one period only of less than 2 hours. (Schedule 4, paragraph 7(2) (a) and (b)).

The officer must be satisfied that the food business operator has measures in place, as appropriate, to ensure that the hot holding tolerance described above is not exceeded.

#### **7.8.12 Temperature deviations resulting in a breach of regulation 32/Schedule 4 of the Food Safety and Hygiene (England) Regulations 2013**

Where the FBO suggests that specified temperatures have not been complied with for unavoidable reasons, the authorised officer must discuss the reasons with the FBO and, where possible, seek agreement on action to prevent any recurrence.

Authorised officers must always ensure that any measures taken by the FBO with respect to food that has been exposed to temperatures in excess of, or below, those permitted by the Regulations are consistent with food safety, and take appropriate action to remove such food from the food chain if necessary.

If the food itself is at a higher temperature than the prescribed chill holding temperature, or a lower temperature than the prescribed hot holding temperature, and the authorised officer is of the opinion that the food has not been produced, processed, or distributed, in accordance with the Food Safety and Hygiene (England) Regulations 2013, the officer must deal with the food under regulation 29 of the Regulations (see also regulation 25 in this regard). Voluntary Procedures to

remove food from the food chain can, however, be used in appropriate circumstances.

If food is at a higher temperature than 8°C (chill holding) or below 63°C (hot holding), but does not fail food safety requirements, the authorised officer must use professional judgement to determine the most appropriate action in the circumstances. The food can still be fit for consumption, even if it has been maintained at temperatures higher than those specified in the Regulations beyond the time limits allowed.

Authorised officers should enquire into the history of the food, in particular to ascertain whether it could previously have been exposed to temperatures above 8°C. Enforcement decisions must take account of the history of the food and whether it is consistent with food safety. Authorised officers can adopt an educative approach as the first step towards securing compliance, and discuss the requirements of the legislation with the FBO to ensure they understand the controls, why they are needed, and how they can be achieved.

## **7.9 Bottled Waters**

### **7.9.1 Introduction**

This Chapter provides guidance to Competent Authorities on enforcement of The Natural Mineral Water, Spring Water and Bottled Drinking Water (England) Regulations 2007, as amended (the Regulations).

### **7.9.2 Legislation**

The Regulations transpose into UK legislation the provisions of: European Parliament and Council Directive 2009/54/ and Council Directive 98/83/EC, relating to the quality of water for human consumption as it applies to bottled water.

The legislation also implements Commission Directive 2003/40/EC establishing the list, concentration limits and labelling requirements for the constituents of natural mineral waters and the conditions for using ozone-enriched air for the treatment of natural mineral waters and spring waters. The Instrument was amended in 2009 to reflect the recast of the original Directive into 2009/54/EC. It was further amended in 2010 to put in place enforcement powers for by Commission Regulation (EU) 115/2010 laying down conditions for the use of activated alumina for the removal of fluoride from natural mineral water and spring water and to incorporate text from Council Directive 98/83/EC on monitoring by Competent Authorities for regulatory purposes.

### **7.9.3 Natural mineral waters**

The Regulations require each UK natural mineral water source to be recognised by the Competent Authority for the area in which the source is located.

Once recognition has been granted, the Competent Authority is required to make periodic checks to ensure that the source remains free from all risk of pollution and that the composition of the water remains stable.

It is not permitted to sell water as natural mineral water if the source has not been recognised.

The most recent list of all recognised sources within the EU is available on the EU's website at:

[http://europa.eu.int/comm/food/food/labellingnutrition/water/index\\_en.htm](http://europa.eu.int/comm/food/food/labellingnutrition/water/index_en.htm)

### **7.9.4 Recognition of natural mineral waters**

Applications for recognition of natural mineral waters in Great Britain are submitted in writing to the Competent Authority. The Competent Authority is required to assess all the information required by the Regulations.



Competent Authorities must notify the FSA; or Defra whenever they recognise a new natural mineral water, withdraw recognition, or approve a change in the name of the source or trade description of a natural mineral water.

For Defra: email [Bottled.Water@defra.gsi.gov.uk](mailto:Bottled.Water@defra.gsi.gov.uk)

Bottled Drinking Water  
Area 3A  
Nobel House  
17 Smith Square  
London  
SW1P 3JR

Competent Authorities should also notify the London Gazette, of any recognition, of a natural mineral water.

Natural mineral water cannot be tankered, unless it was tankered for the purposes of exploiting the *spring* before 17 July 1980. Hence transport of water from the spring to the packaging line must be in a closed pipeline made of a suitable material and the filling system must ensure that there is no microbiological contamination of the water before closure of its container.

Applications for recognition of natural mineral waters from outside the EEA should be submitted in writing to Defra in England

### **7.9.5 Labelling of natural mineral waters**

The Regulations include detailed labelling requirements for containers of natural mineral water that must be met when natural mineral waters are packaged.

### **7.9.6 Spring and other bottled drinking water**

The recognition and monitoring procedures by Competent Authorities that apply to natural mineral waters do not apply to spring and other bottled drinking waters, although these waters are subject to specific compositional and microbiological standards that are set out in the Regulations.

However, like natural mineral water, spring water cannot be tankered, unless it was being transported in tankers on or before 13 December 1996. The right to tanker is linked to the *spring*, not the bottler.

### **7.9.7 Labelling of spring and other bottled water**

Any bottled water that is described as “spring water” must meet the relevant labelling and exploitation requirements in the Regulations.

Bottled drinking waters are subject to the general labelling requirements of the Food Information Regulations 2014.

## **7.10 Food Waste and Animal By-Products**

### **7.10.1 Introduction**

This Chapter provides guidance to Competent Authorities on the control of food waste.

The legislative framework that controls the identification, categorisation, segregation, collection and disposal of food waste includes regulations and orders that are made under both the Food Safety Act 1990 and the Animal Health Act 1981 and (EC) regulation 852/2004

For the purposes of this guidance, “food waste” includes food material that is not fit or not intended for human consumption.

### **7.10.2 Inspection of Food Businesses**

Any inspection of a food business, including inspections of mobile establishments / premises, ships, aircraft and trains, must include a check on the arrangements that the business has for the collection and disposal of food waste.

Checks must also include the arrangements in ports and airports for the collection and disposal of imported food waste from ships and aircraft.

Checks must verify that threats to human or animal health which can arise from the illegal disposal of food waste are effectively controlled by proper disposal in accordance with the requirements of the relevant legislation.

### **7.10.3 Disposal of Animal by-products**

According to Regulation (EC) 1069/2009 Animal by-products (ABP) means entire bodies or parts of animals, products of animal origin or other products obtained from animals, which are not intended for human consumption. Articles 8-10 of Regulation (EC) 1069/2009 set out what is comprised by Category 1, 2 and 3 materials and should be referred to.

Where appropriate, inspections should include checks that FBOs ensure that their food safety management system includes a documented procedure for identification, labelling (cat 1, 2 or 3), handling and disposal of such products. Containers used for collection of ABP need to be clearly labelled and easily distinguishable from containers used for collection of products destined for processing and subsequent human consumption. Articles 12- 14 of Regulation (EC) 1069/2009 sets out requirements for the disposal of Category 1, 2 and 3 ABP.

Checks should also verify that these documented procedures are carried out accordingly at the premises by the FBO.

Further, detailed guidance on the Identification, labelling, storage and transport of ABP can be found in Chapter 5 of the Industry Guide to Edible co-products and Animal By-products<sup>36</sup>

#### **7.10.4 Major Investigations**

Competent authorities might become aware of instances of apparent food fraud involving the misuse of food waste that could have potentially serious implications for public or animal health, e.g. unfit meat being diverted into the human food chain.

The investigation of such cases might have serious resource implications for Food Authorities, both in terms of time and other resources. Nevertheless, it is vitally important that the very serious risks to human health and animal health that such cases might involve are brought to the attention of the relevant enforcement authority and investigated without delay, and that all necessary steps are taken to deal with them thoroughly.

The resources required can impact on a Competent Authority's ability to carry out its routine inspection and enforcement programme. If such circumstances arise, it is important that the Competent Authority contacts the FSA as soon as practicable.

The FSA and the Competent Authority will then be able to discuss options, including whether support might be available, or whether the Competent Authority's inspection programme must be re-prioritised to ensure that inspections of higher-risk premises are maintained.

#### **7.10.4 FSA Resources Available to Assist Competent Authority Investigations into Food Fraud**

##### **7.10.4.1 Fighting Fund**

Decisions on resourcing for enforcement activity are a matter for local authorities. However, it is acknowledged that some local authorities have to deal with cases with unexpected resource implications.

The FSA has agreed a process developed through its Enforcement Liaison Group which sets out criteria for competent authorities who wish to apply for FSA support for their enforcement work and for the FSA to consider such applications.

Decisions on the nature and extent of FSA financial support will be made on a case by case basis and will take account of the limited FSA resources available.

Details of how to apply and the criteria against which applications are considered can be found on the FSA's website at:

<http://www.food.gov.uk/multimedia/pdfs/enforcement/fflaguidance10.pdf>

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<sup>36</sup> <http://www.food.gov.uk/business-industry/guidancenotes/meatregsguid/coproductbyproductguide>

#### **7.10.4.2 Food Fraud Advisory Unit (FFAU)**

The Food Fraud Advisory Unit (FFAU) provides an advisory resource for Competent Authorities carrying out investigations into fraud that includes any illegal activity relating to food or animal feed.

FFAU membership consists of Competent Authority enforcement officers working in environmental health, trading standards and port health. All members have extensive experience in carrying out food fraud investigations.

Competent authorities can draw on the FFAU's expertise for advice, including the in following example areas:

- the legal framework for an investigation;
- highlighting appropriate use of evidence gathering techniques, such as surveillance;
- coordination of multi-agency investigations;
- following relevant protocols to ensure the integrity of an investigation.

This advice can be given over the telephone, by email or at meetings with an FFAU member or members.

Responsibility for leading the investigation will always remain with the authority requesting support.

Further information on how to be put into contact with a member of the FFAU can be found on the FSA's website at:

<http://www.food.gov.uk/enforcement/enforcework/foodfraud/ffau>

#### **7.10.4.3 Food Fraud Database (FFDB)**

The FSA has established a national food fraud database. The database is an important resource for competent authorities might be seeking additional information to assist with their investigations into food fraud incidents.

Intelligence is received from a variety of sources, including consumers, industry, Government Departments and other enforcement bodies, but particularly from local authorities. It is important that local authorities share with the FSA, all intelligence they become aware of in relation to known or even suspected food fraud incidents, including historical cases. This intelligence will then be used to populate the database along with data from all other sources.

The FSA also welcomes database search requests from Food Authorities. The FSA might already hold an important piece of information that might be relevant to the requesting Authority.

Further information on the FFDB and how to request a search of the system can be found on the FSA's website at:

<http://www.food.gov.uk/enforcement/enforcework/foodfraud/foodfrauddatabase>

## **7.11 Distance Selling/Mail Order**

### **7.11.1 Introduction**

This Chapter provides guidance to Competent Authorities on the enforcement of food law in relation to the distance selling of food, and information on other generic legal requirements that relate to distance selling.

For the purposes of this guidance, “the distance selling of food” means the advertisement of food for sale directly to consumers where the subsequent sale of the food to the consumer takes place without the buyer and seller meeting face-to-face. Examples of distance selling include the sale of food through internet websites, mail order transactions, and telephone sales.

The enforcement issues for Competent Authorities that relate to the distance selling of food depend primarily on the location of the advertiser and/or seller.

### **7.11.2 Location of the seller**

The ability of Competent Authorities to enforce food law in relation to the distance selling of food depends on where the seller is based.

It is important to bear in mind that food bought via an internet website involves a sale via the World Wide Web, and that the seller could therefore be located anywhere in the world.

If the seller is in the UK, the enforcement and consumer protection issues are likely to be within UK jurisdiction, and UK legislation will bind the seller.

Similarly, if the seller is based elsewhere in the EU, that Member State’s legislation, including EU legislation is likely to apply to the sale.

However, the difficulties are not so easily addressed when the seller is outside the EU because the enforcement powers of Competent Authorities and consumer protection laws might not reach beyond the UK’s jurisdiction. There are, therefore, important distinctions between UK, EU and non-EU distance selling transactions.

### **7.11.3 Location of the buyer**

The location of the buyer in a distance selling transaction is important only insofar as it affects the ease with which the buyer might be able to invoke an appropriate remedy, must there be a problem with the transaction, e.g. food not as described, food unfit for consumption on delivery etc.

### **7.11.4 Distance selling of food from the UK**

The distance selling of food from the UK takes place when the advertisement of food for sale or the sale transaction itself takes place within the jurisdiction of the UK legal system.

The distance selling of food from the UK is covered by relevant food law. Food that is sold by a distance selling method from the UK, and advertisements for such food, must therefore comply with exactly the same legal requirements as food sold from a high street supermarket or advertised in a UK national newspaper.

Competent Authorities are therefore responsible for enforcing food law in relation to the distance selling of food from the UK, including food that is advertised or sold through UK-based internet sites.

Competent Authorities must therefore have appropriate means of monitoring the distance selling of food by businesses for which they act as home authority.

Competent Authorities must include an assessment of relevant food hygiene, safety, advertising, compositional, and labelling matters in programmed inspections of businesses involved in the distance selling of food from the UK in their areas.

Competent Authorities must also encourage distance sellers of perishable food that are based in their areas to adopt best practice by:

- ensuring the maintenance of appropriate temperature controls during transit
- clearly marking consignments on the outermost packaging with the date of despatch and the appropriate durability indication.

#### **7.11.5 Distance Selling of Food from the EU (Outside the UK)**

The distance selling of food from the EU takes place when the advertisement of food for sale or the sale transaction itself takes place outside the jurisdiction of the UK legal system, but within the jurisdiction of another Member State.

UK consumers who purchase food from a distant seller in another Member State cannot rely on the protection of UK food law.

However, as most UK food law derives from EU single market rules, similar provisions to those that apply in the UK will apply in the other Member State.

Competent Authorities must generally use the liaison role of the FSA (See Chapter 2.5 of both the Code of Practice and of this Guidance) to resolve problems relating to the distance selling of food from the EU.

#### **7.11.6 Distance selling of food from third countries**

The distance selling of food from third countries takes place when the advertisement of food for sale or the sale transaction itself takes place outside the jurisdiction of any EU Member State.

UK consumers who purchase food from a distance seller in a third country cannot rely on the protection of UK food law.

#### **7.11.7 Generic distance selling legislation**

Generic law regulating distance selling in the UK is set out in the Consumer Protection (Distance Selling) Regulations 2000<sup>37</sup>, which implement Council Directive 97/7/EC in the UK.

The primary aim of this legislation is to facilitate cross-border distance selling consumer transactions within the EU by laying down basic levels of consumer protection that apply throughout the EU, irrespective of the Member State that has legal jurisdiction over the transaction.

The Regulations lay down minimum levels of information that must be provided to the consumer by distance sellers of goods or services in the EU. These include:

- the name of the supplier and a geographical (rather than an internet) address
- a description of the goods or services
- the period that the offer remains open
- the price (including all taxes)
- the right to withdraw
- the arrangements for delivery of any goods

The central UK Competent Authority with responsibility for these Regulations is the Department for Business, Innovation and Skills (BIS). Enforcement is the responsibility of the Office of Fair Trading (OFT) and Trading Standards Departments.

BIS, OFT and LGA have each published guidance on the Regulations for businesses, consumers, and enforcement agencies. Copies of the guidance are available either directly from the LGA website at

<https://knowledgehub.local.gov.uk/>

or via links from the relevant BIS or OFT web addresses. If any further advice is required, officers must contact the Contract Regulation Unit at OFT.

#### **7.11.8 Other references**

[A Guide to Good Hygiene Practice](#) for the mail order food industry, developed in accordance with Article 8 of Regulation 852/2004, was published in 2007.

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<sup>37</sup> SI 2000 No. 2334

## Chapter 8 – Sampling and Analysis

### 8.1 Sampling and Analysis - Introduction

See Chapter 8 of the Code of Practice for Sampling and Analysis

See 5.2.8 of this Practice Guidance for further information on Sampling visits

See 5.5.13 of this Practice Guidance for information on Sampling of Imported Food.

This section concerns the procedures that should be followed when food samples are procured under Regulation 14 of the Food Safety & Hygiene (England) Regulations 2013 or Section 29 of the Food Safety Act 1990, and the associated requirements of the Food Safety (Sampling and Qualifications) Regulations 2013. Guidance to help ensure sampling by Competent Authorities is undertaken effectively and consistently is set out below and on microbiological sampling in LGA advice which can be found at:- <https://khub.net/>

The Food Safety and Hygiene (England) Regulations 2013 and the Food Safety Act 1990 allow samples to be procured either by “purchasing” or “taking”. The choice is at the discretion of the authorised officer, having regard to the policy of the Competent Authority. Where the quantity or frequency of sampling gives rise to significant financial consequences for the owner of the food, the Competent Authority could offer an ex-gratia payment if samples are not purchased. The officer must give the owner a receipt for, or a record of, all samples the officer has taken. If enforcement action is anticipated following microbiological examination or chemical analysis the sampling officer must purchase the sample.

### 8.2 Certificate Issued by Public Analyst or Food Examiner

Also see 8.1.11 of the Code of Practice. A Public Analyst or Food Examiner should give the officer who submitted the sample a certificate specifying the result. Competent Authorities must discuss with the Public Analyst or Food Examiner how these requirements are to be met, including the means by which results that indicate a significant risk to public health, or where legislative deadlines apply, such as water in poultry, can be notified without delay.

Please note that Certificates of Examination (as specified in Schedule 3 of the Food Safety (Sampling and Qualifications) (England) Regulation 2013) are available for formal samples on request from either a Public Analyst or Food Examiner. The test report and Certificate of Examination are within the scope of accreditation of the issuing laboratory to the ISO/IEC 17025:2005 (General requirements for the competence of testing and calibration laboratories) standard which is an essential requirement of Official laboratories testing foods for food control under Regulation EC No 882/2004. **The test report and Certificate of Examination are the only authoritative versions of the test results** and other sources of information (such as results in UKFSS) are outside the control of the Public Analyst or Food Examiner and should be used (and interpreted) at the risk of the final users.



### **8.3 Samples for examination - Avoiding Contamination**

Care must be taken to prevent contamination of samples and instruments, and containers used for samples must be clean and dry. It is important to avoid the use of cleaning and sterilising methods that might leave residues on instruments or containers that might, in turn, affect the results of the analysis or examination (e.g. alcohol).

### **8.4 Samples for examination - Continuity of Evidence**

Food samples are normally dealt with in a food laboratory and faecal specimens in a clinical laboratory, operating independently of the Competent Authority. Laboratory personnel might therefore need to be reminded of the possibility of legal action, the need to treat food samples and other specimens as evidence, and to ensure the continuity of such evidence.

Records must therefore be kept of all stages of transport, including:

- dates and times of transport
- identity of custodians
- date and time of receipt in the laboratory
- identity of the person receiving sample

For food samples, the temperature of transport must be monitored, and recorded on receipt at the laboratory. If the sample has been posted, proof of posting or a record of the method of despatch to the Food Examiner or Clinical Microbiologist must be kept. The Food Examiner or Clinical Microbiologist must be made aware that the results of their examination of the food or faecal specimen(s) might be used as evidence in Court, and that by examining the sample/specimen, they might be required to produce a certificate of examination, give a sworn written statement, and/or give oral sworn testimony in court.

Other laboratory personnel might also be required to give evidence as to the handling of food samples and faecal specimens and the testing and examination thereof in a criminal prosecution.

Full traceability in the laboratory therefore needs to be ensured, including recording the identity of everybody who has been involved in handling and examining the sample or specimen, and the action they took. Specifically there must be a system at the laboratory for logging the sample or specimen's arrival, and its storage, which must be secure. For food samples, the temperature of storage must be such as to minimise microbial change, and be monitored using a calibrated thermometer or other similar device. Continuity preservation at the laboratory is vital so that there is certainty that the result relates to the sample/specimen submitted. There must be no possibility that the result would refer to a different sample or specimen. Neither must the results raise any doubt as to their reliability, or the reliability or accuracy of

laboratory procedures. An individual in the laboratory must be capable of making a sworn statement and of providing sworn oral testimony on these points.

It must also be made clear that if the Food Examiner/Clinical Microbiologist does not carry out the actual examination, but has it conducted under their direction, the person who actually examines the sample or specimen might also be required to give evidence.

### **8.5 Samples for Analysis - Quantity of samples for analysis**

The nature and quantity of any sample must be such as to enable the required analysis to be made. The nature of the samples that are appropriate will depend on the purpose for which the analysis is being undertaken. The quantity will vary according to the product and type of analysis to be carried out. The Public Analyst must be consulted in case of doubt.

National sampling protocols must be taken into consideration, where they exist. Some modification to the protocols might be necessary in the case of large consignments of imported foods.

### **8.6 Samples for Analysis - Containers for samples**

Samples of non-pre packed food or opened cans or packets, must first be placed in clean, dry, leak-proof containers such as wide-mouth glass or food quality plastic jars, stainless metal cans or disposable food quality plastic bags. Jars, bottles or cans must be suitably closed. Disposable food quality plastic bags must be sealed securely after filling, so that they cannot leak or become contaminated during normal handling. Samples of alcoholic drinks must be placed in glass bottles.

The contained final parts must each be secured with a tamper evident seal and labelled, specifying the name of the food, the name of the officer, the name of the Competent Authority, the place, date and time of sampling and an identification number. Where necessary, it must then be placed in a second container, such as a plastic bag, which must be sealed in such a way as to ensure that the sample cannot be tampered with. A copy of the food label if available and any other relevant details must be submitted to the Public Analyst with a final part.

### **8.7 Samples for Analysis - Transport and storage of samples<sup>38</sup>**

Final parts of food which are perishable must be kept refrigerated or in a frozen state, as necessary. The method of storage used will differ, depending on whether the final part is to be submitted to the Public Analyst, or retained for possible submission to the Laboratory of the Government Chemist.

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<sup>38</sup> The Campden and Chorleywood Food Research Association publication "Guidelines for the preservation of official samples for analysis" (CCFRA Guideline No. 36) includes further guidance.

The final part to be submitted to the Public Analyst must be transmitted as soon as practicable after sampling, particularly where tests are to be made for substances which might deteriorate or change with time (e.g. certain pesticides, sulphur dioxide, etc). In any case, where doubt exists about suitable storage or transport arrangements for samples for analysis, the Public Analyst must be consulted. Since retained final parts might need to be stored for several months prior to submission to the Laboratory of the Government Chemist, it is important that they are appropriately stored.

### **8.8 Samples for Analysis - Samples which present difficulties in dividing into parts**

An exception to division into three parts applies where the authorised officer is of the opinion that division of the sample is either not reasonably practicable, or is likely to impede proper analysis. Regulation 7(4) of the Food (Sampling and Qualifications) Regulations 2013 allows for the sample to be submitted for analysis complete without division into three parts. There is no final part for the seller/owner, neither is there a final part to be retained. This procedure must therefore be used with caution. Situations where this procedure might be used will depend on the tests to be carried out but might include the following:

- where there is insufficient product available to comply with the procedures in Regulations 7(1) or 7(2)
- there is no way of storing a final part for further analysis as with tests for previously frozen meat

This situation might also arise where foods are not pre-packed and are not homogeneous and it is difficult to divide the food into three parts, so that each part contains the same proportion of each ingredient, e.g. meat products with lumps of meat, pies where it is difficult to divide the pastry and the filling into three, fruit cocktail/yoghurts with fruit where an ingredient is to be quantified.

In any case, where a single sample is taken in accordance with Regulation 7(4) the owner must be notified of its submission for analysis.

Regulation 7(2) sets out an exception from the general procedures where the sample consists of unopened containers and opening them would, in the opinion of the authorised officer, impede proper analysis. In these circumstances the authorised officer must divide the sample into parts by putting containers into three lots and each lot must be treated as a final part.

Where any doubt exists, the Public Analyst must be consulted.

### **8.9 Samples for examination**

Samples for examination are not required to be divided into three parts, since the non-homogeneous distribution of bacterial contaminants means that no two samples will be the same. It is not appropriate to retain a part for examination later in the

event of a dispute, as bacteria might not survive prolonged storage or conversely, might greatly multiply.

### **8.10 Samples for examination - Quantity of samples**

The quantity of any sample procured must be such as to enable a satisfactory examination to be made. The quantity will vary according to circumstances, but must normally be at least 100 grams. In any case of doubt the Food Examiner must be consulted.

### **8.11 Samples for examination - Handling of samples**

Full traceability in the taking and handling of the sample must be ensured, including the identity of those who have had dealings with the sample, and what they did with it. Samples of non-pre packed food, or from opened cans or packets of food, must be first placed in sterile, leak-proof containers or disposable sterile plastic bags. Disposable sterile plastic sampling bags must be sealed securely after filling, so that they cannot leak or become contaminated during normal handling. Advice must be sought from the Food Examiner in case of doubt. In any event, liaison with the Food Examiner before samples are submitted to the laboratory will ensure correct procedures are followed.

The samples, thus packaged, must be secured with a tamper evident seal and labelled, specifying:

- type of food sample
- name of the Officer
- the exhibit identification number (e.g. RG/1)
- the date, place and time of sampling

Containers that might be easily damaged, or that cannot themselves be made tamper-evident, must then be placed in a second container, such as a plastic bag, which must be sealed in such a way as to ensure that the sample cannot be tampered with. A copy of the food label, if available and any other relevant details must be given to the Food Examiner, e.g. food handling techniques/storage methods observed in respect of the food sampled.

For general sampling information see the LGA “Guidance on Food Sampling for Microbiological Examination”, January 2006. The guidance can be found on Knowledge Hub. Note that the substance of the guidance is still relevant, but the references to legislation are out of date.

<https://khub.net/>

Officers must take steps to ensure that, as far as possible, samples for examination reach the laboratory in a condition microbiologically unchanged from that existing when the sample was taken. During sampling it is vital that the sample is not contaminated by the sampling officer. Appropriate action must be taken to avoid

contamination of the sample and microbial growth or death during sampling, transport and storage. The temperature of transport must be monitored and recorded.

### **8.12 Samples for examination - Handling, transport and storage of faecal specimens**

On occasions, officers will be required to investigate reported or suspected cases of foodborne illness and obtain faecal specimens. Officers must therefore have a ready supply of appropriate leak-proof containers for the collection of faecal specimens.

Such specimens must be collected as soon as possible after the onset of symptoms and submitted to the laboratory with relevant individual's details included on the container and on any accompanying documentation.

It is important that faecal specimens are transported to the laboratory as soon as possible; some important pathogens might not survive the pH changes that occur in stool specimens which are not promptly delivered to the laboratory, even if transported in a refrigerated state. Liaison with the laboratory will help ensure that the specimens receive prompt attention on their arrival.

### **8.13 Samples for examination - Request for examination**

The officer must ensure that all relevant information is passed to the Food Examiner with the sample to ensure that the sample is subjected to the most appropriate examination and to enable the Examiner to interpret the results.

## **ANNEX 1 Additional Guidance notes for Competent Authorities**

### **A1.1 Q&A Live Bivalve Molluscs/shellfish**

#### **A1.1.1 Approval of Establishments**

1. When does a harvester or handler of shellfish need to consider becoming an approved dispatch centre?
2. Might inland markets become dispatch centres?
3. Are separate approval numbers needed for dispatch and purification centres operating from the same site?
4. What locations are considered suitable for dispatch centres and purification centres?
5. Does the dispatch centre working area need to be physically identifiable from the purification centre working area, where both activities are carried out on the same premises?

#### **A1.1.2 Registration documents**

6. Can a Competent Authority issue registration documents to gatherers of shellfish in another Competent Authority's area?

#### **A1.1.3 Identification Marking**

7. If a dispatch centre is selling live shellfish to individual consumers on a retail basis, does the identification mark need to be applied to each sale?

#### **A1.1.4 Seed Shellfish**

8. What is the minimum period of on-growing of seed mussels before they can be harvested for human consumption?

### **Approval of Establishments**

#### **When does a harvester or handler of shellfish need to consider becoming an approved dispatch centre?**

Annex 1(2) of Regulation 853/2004 defines a dispatch centre as 'any on-shore or off-shore establishment for the reception, conditioning, washing, cleaning, grading, wrapping and packaging of live bivalve molluscs fit for human consumption.' All dispatch centres must be [approved](#). As fishing vessels are considered primary production, fishing vessels do not need approval for washing and grading live bivalve molluscs at sea. Though fishing vessels will need to be registered & subject to the Competent Authorities Food Hygiene Interventions programme.

Annex III, Section VII, Chapter I of Regulation 853/2004 requires all live bivalve molluscs destined to be placed on the market for retail sale to enter the market via a

dispatch centre. At the dispatch centre they are sampled, wrapped and identification marked. The dispatch centre may not be on the shoreline and could be some distance away, even in another Member State.

### **Might inland markets become dispatch centres?**

Yes. The market would need to meet the approval conditions for dispatch centres. Approval as a dispatch centre is not necessary to enable a market to unwrap parcels of live shellfish already sent from a dispatch centre and to split up the parcels for sale to retailers or consumers.

### **Are separate approval numbers needed for dispatch and purification centres operating from the same site?**

No. Where both exist on the same premises then the same number must be used for the dispatch centre and for the purification centre. The suffixes "DC, PC" must be used to identify the activities for which the establishment is approved.

### **What locations are considered suitable for dispatch centres and purification centres?**

Regulation 853/2004, Annex III, Section VII, Chapter III requires dispatch and purification centres to be located on land that is not subject to flooding by ordinary high tides or run-off from surrounding areas.

Does the dispatch centre working area need to be physically identifiable from the purification centre working area, when both activities are carried out on the same premises?

The need to separate clean from contaminated live shellfish would dictate this. It would also be in the interests of the business to have separate areas in the event of enforcement action on either the dispatch or purification centre. In small plants this is subject to a risk assessment by the Competent Authority.

## **Registration documents**

### **Can a Competent Authority issue registration documents to gatherers of shellfish in another Competent Authority's area?**

Registration documents should be issued by the Competent Authority with responsibility for the harvesting area. This ensures that up to date information about any public health issues relating to the harvesting area might be given to gatherers. A Competent Authority may allow gatherers to apply to it for registration documents for gathering in another Competent Authority's area as long as the two Competent Authorities liaise to ensure that arrangements operate effectively to assist industry and avoid potential misuse. Inter-authority arrangements of this kind must normally be restricted to adjoining Competent Authorities.

## **Identification marking**

**If a dispatch centre is selling live shellfish to individual consumers on a retail basis, does the identification mark need to be applied to each sale?**

Regulation 853/2004 does not, generally, apply to retail. Under this regulation there is only a requirement for identification marks to accompany consignments of live shellfish prior to retail sale. After live shellfish are sold the retailer must retain a copy of the registration document for at least 12 months, or for as long as the Competent Authority requires. Therefore, where a dispatch centre is acting as a retailer, record keeping of the dispatch of batches of live shellfish through the retail outlet might suffice. The position is similar for live shellfish sold by mail order.

**Seed Shellfish**

**What is the minimum period for on growing of seed mussels before they can be harvested for human consumption?**

The minimum period for growing on genuine seed mussels must be six months.

**A1.2 Q&A Fishery Products**

**A1.2.1 Approval of Establishments**

1. Which establishments are subject to approval under Regulation 853/2004?
2. What is 'retail'?
3. Who is the Final Consumer?
4. In what circumstances would auctions or wholesale markets need to be approved?
5. Should individual stalls in auction halls and wholesale markets be approved establishments?
6. Should retailers who also sell wholesale be approved establishments?
7. Are retailers engaged in processing of fish covered by Regulation 852/2004?
8. Do cold stores need to be approved establishments?
9. Do cash and carry's need to be approved?
10. Are sandwich makers covered by the Regulations and do they need to be approved?
11. Do fishmongers who also process fish (including smoking) and, if applicable, supply fish vans need to be approved?
12. Are fishmongers who sell retail, but who keep fish live covered by the Regulations?
13. If a retail outlet only has upright or chest freezer cabinets, does it need to be approved to comply with the requirements laid down for cold stores?
14. Do establishments storing only cans and jars of fishery products need to be approved?
15. Are airport caterers who supply fishery products to companies, which supply airlines, covered by the Regulations and do they need approval?
16. If a business supplies a company or a contractor, who then supplies the final consumer, would it be covered by the Regulations?



### **A1.2.2 Conditions of approval**

17. Do all the requirements of Regulation 853/2004 in relation to fishery products apply to all fishery products establishments?
18. Could such facilities as wash basins and lavatories be communal to a number of establishments?
19. When the Regulations refer to temperature recording devices, does this mean that readings can be taken and logged manually?
20. Are communal filleting premises permissible?
21. The Regulations require that operations such as filleting and slicing must be carried out in a place other than that used for heading and gutting operations. How should this be interpreted?
22. Is there a list of approved detergents and similar substances for maintaining general conditions of hygiene in establishments and on equipment?

### **A1.2.3 Fish farms**

23. Are fish farms covered by the Regulations?

### **A1.2.4 Identification marks**

24. Where should the identification mark appear in the case of fresh fish sold by an auction or wholesale market to a person who is not a retail customer?

### **A1.2.5 Landings of fishery products**

25. Do Competent Authorities have to carry out histamine checks on other compounds listed in Regulation 854/2004 on all consignments of fish?
26. Do quaysides where fish are landed need to comply with the Regulations?

## Approval of establishments – Questions and Answers

### 1. Which establishments handling fishery products are subject to approval under Regulation 853/2004?

Under Article 4 of Regulation 853/2004, establishments handling products of animal origin for which Annex III of that Regulation lays down requirements (including fishery products) require approval. There are however a number of exemptions from this requirement.

Article 1(2) of Regulation 853/2004 has the effect of exempting establishments engaged only in the production of food containing both products of plant origin and processed fishery products (e.g. sandwich makers) from approval, provided that the fishery products used enter the establishment as processed products. In such cases compliance with the relevant requirements of Regulation 852/2004 is required and the processed fishery products must be obtained and handled in accordance with the requirements of Regulation 853/2004.

Certain establishments such as those carrying out 'primary production' and 'retail' (as defined in Article 3(7) of Regulation 178/2002) establishments carrying out certain activities are also exempt from the requirement to be approved, although some provisions of Regulation 853/2004 are nonetheless applicable. Primary production establishments exempt from approval, including fishing vessels, are required to comply with Section VIII (Fishery Products) of Regulation 853/2004 as appropriate. Retailers exempt from approval are required to comply with Chapter III, Parts A, C and D, and Chapter IV and V of Section VIII (Fishery Products), of Regulation 853/2004. Section VIII Paragraphs 2 and 3 of Regulation 853/2004 refer respectively. Factory and freezer vessels are required to be approved and comply, as appropriate, with Chapters I – III of Regulation 853/2004, Annex III, Section VIII. Food Competent authorities may wish to use the checklists included in Appendix B, C and D of this section when carrying out official controls.

In order to decide whether a retail activity is or is not exempt from approval, Article 1(5) of Regulation 853/2004 must be considered. If a retail operation consists of transport and storage only then it will not require approval. Although the regulation generally applies to retail when food operations are conducted with the purpose of supplying another establishment, a retail establishment without approval may supply products of animal origin which would normally trigger the need for approval, but only to other retail establishments on a marginal, localised and restricted

Food businesses claiming exemptions from the requirement to be approved must be considered on a case by case basis.

### 2. What is retail?

The definition of 'retail', which is given in Article 3(7) of Regulation 178/2002, is as follows:

*'retail' means the handling and/or processing of food and its storage at the point of sale or delivery to the final consumer, and includes distribution terminals, catering*

*operations, factory canteens, institutional catering, restaurants and other similar food service operations, shops, supermarket distribution centres and wholesale outlets*

### **3. Who is the Final Consumer?**

The definition of 'final consumer', which is given in Article 3(18) of Regulation 178/2002, is as follows:

*'final consumer' means the ultimate consumer of a foodstuff who will not use the food as part of any food business operation or activity*

### **4. In what circumstances would auction halls or wholesale markets need to be approved?**

Under Article 2(1) (c) of Regulation 852/2004 an 'establishment' is defined as 'any unit of a food business'. Regulation 853/2002 defines 'wholesale market' as 'a food business that includes several separate units which share common installations and sections where foodstuffs are sold to food business operators'.

It is the case that wholesale outlets are included under the definition of 'retail' in Regulation 178/2002 (see Q&A 2, above). However, for such establishments to fall within this definition, an element of their sale or delivery of food must be to the final consumer. Auction halls and wholesale markets may fall under this definition.

Auction halls and any units within wholesale markets considered to be 'retail' under the definition would not require approval and would be subject to Regulation 852/2004 only. They would be permitted to supply the final consumer and other retail establishments on a marginal, localised and restricted basis. Auction halls and units within wholesale markets that do not sell, or deliver, to the 'final consumer' cannot be considered to be 'retail' as defined and as such would need to be approved and would be subject to the relevant requirements of both Regulation 852/2004 and Regulation 853/2004.

### **5. Should individual stalls / units within auction halls and wholesale markets be approved establishments?**

Individual stalls / units within auction halls and wholesale markets are classed as establishments. If the stall / unit can be considered to be 'retail' as defined (see Q&A 2 and 4, above) and is supplying only the final consumer and other retail establishments on a marginal, localised and restricted basis approval would not be required and Regulation 852/2004 only would be applicable. Otherwise, the stall / unit would require approval and would be subject to the relevant requirements of both Regulation 852/2004 and Regulation 853/2004.

### **6. Should retailers who also sell fishery products on a wholesale basis be approved?**

Establishments falling under the definition of 'retail' as defined (see Q&A 2 and 4, above) which also sell wholesale other than to the final consumer and/or other retail establishments on a marginal, localised and restricted basis would require approval.

Such establishments would be subject to the relevant requirements of both Regulation 852/2004 and Regulation 853/2004.

**7. Are retail establishments engaged in processing of fish covered by Regulation 853/2004?**

Unless they are only selling processed fish to the final consumer and to other retail establishments on a marginal, localised and restricted basis, retail establishments would require approval and would be subject to the relevant requirements of both Regulation 852/2004 and Regulation 853/2004.

**8. Do cold stores need to be approved?**

European Commission guidance advises that wholesale meat cold stores require approval on the basis that they are used in relation to activities for which Annex III of Regulation 853/2004 lays down requirements. It has been decided to apply this guidance across all products of animal origin. There is no requirement for veterinary control of cold stores and Competent Authorities are therefore responsible for approving fish cold stores and for enforcement in such establishments.

Stand-alone Cold stores supplying the final consumer exclusively or supplying retail establishments (including caterers) on a marginal, localised and restricted basis are not subject to approval and must therefore be registered under Regulation 852/2004.

**9. Do cash and carries need to be approved?**

The definition of 'retail' in Article 3(7) of Regulation 178/2002 (see Q&A 2, above) includes 'wholesale outlets'. Cash and carries may therefore fall into this category and could, depending on their specific activities, be exempt from the requirements of Regulation 853/2004. Although a wholesale outlet may be considered to be 'retail' as defined, if it is not supplying final consumers exclusively and/or other retail establishments on a marginal, localised and restricted basis approval would be required.

**10. Are sandwich makers covered by the Regulations and do they need to be approved establishments?**

Owing to the exemption provided by Article 1(2) of Regulation 853/2004, sandwich makers will not be subject to approval under that Regulation if the fishery products they use to make the sandwiches enter their establishment as processed products. However, the processed fishery products used in the production of the sandwiches must be obtained and handled in accordance with the requirements of Regulation 853/2004. Such sandwich makers will still need to comply with the relevant requirements of Regulation 852/2004.

**11. Do retail fishmongers who also process fish (including smoking) and, if applicable, supply retail fish vans need to be approved establishments?**

Retail fishmongers that sell their own processed products, but only to the final consumer would not be subject to approval under Regulation 853/2004. They would,

however, need to comply with Regulation 852/2004. If a retail fishmonger sells their own processed products to other establishments (including those in the same ownership) it will be subject to approval under Regulation 853/2004, unless the other establishments are retail establishments and the supply is marginal, localised and restricted

**12. Are retail fishmongers who keep fish live covered by the Regulation 853/2004?**

Regulation 853/2004 does not apply if they sell only to their final consumers. However, such establishments will still need to comply with the relevant requirements of Regulation 852/2004, as appropriate.

**13. If a retail establishment only has upright or chest freezer cabinets, does it need to be approved?**

There is no need for a retail establishment to be approved where the only storage activity in respect of fishery products is their display, in upright or chest freezer cabinets, for retail sale to the final consumer. However, they will need to comply with Regulation 852/2004 as appropriate.

**14. Do establishments storing only cans and jars of fishery products need to be approved?**

No.

**15. Are airport caterers which supply fishery products to companies, which supply airlines, covered by Regulation 853/2004 and do they need approval?**

As they are not retail and are not supplying the final consumer exclusively, approval would be required for such industrial catering establishments unless all the products they make contain both products of plant origin and processed fishery products and the fishery products used enter the establishment as processed products (see Article 1(2) of Regulation 853/2004). In this case, the processed fishery products used must be obtained and handled in accordance with the requirements of Regulation 853/2004, and compliance with the relevant requirements of Regulation 852/2004 would be required.

**16. If a non-retail establishment supplies a company or a contractor, who then supplies the final consumer, would it be covered by the Regulation 853/2004?**

Yes. The establishment is not a retailer and is supplying other establishments.

## Conditions of Approval – Questions and Answers

### **17. Do all the requirements of Regulation 853/2004 in relation to fishery products apply to all fishery products establishments?**

No. In Regulation 852/2004 there are general requirements applicable to both businesses involved in primary production and manufacturing food businesses and indicates where separate conditions apply. Similarly, in Regulation 853/2004 there are specific requirements for establishments such as purification centres, fishing vessels, factory vessels and fishery product processing establishments.

### **18. Could such facilities as wash basins and lavatories be communal to a number of establishments?**

Regulation 852/2004 sets out the general hygiene requirements for food business establishments. As regards to wash basins and lavatories in wholesale markets (see Q&A 4), it is for the Competent Authority to decide whether separate facilities, for different units within the market (see Q&A 5) are necessary in the interests of public health or whether the communal facilities are sufficient for compliance with the Regulation.

### **19. When the Regulations refer to temperature recording devices, does this mean that readings can be taken and logged manually?**

Annex II, Chapter I (2) (d) of Regulation 852/2004 stipulates that, where necessary, it should be possible to monitor and record temperatures at which foodstuffs are maintained. The Regulation does not stipulate that the recording of temperatures should be done automatically, which implies that manual recording is allowed. However, for freezer vessels or establishments on land where the freezing of fishery products is undertaken, there is a requirement that a temperature recording-device is installed (see Regulation 853/2004 Annex III, Section VIII, Chapter I(C) (Requirements for Freezer Vessels) and Chapter III (B) (Requirements for Frozen Products (on land))).

### **20. Are communal filleting premises permissible?**

The Regulations do not specify whether or not communal filleting premises are permissible. Provided that control arrangements are adequate, ensuring that filleting is carried out to avoid contamination or spoilage then communal filleting premises would not be precluded. However, a separate establishment for communal filleting is likely to require approval and compliance with the relevant requirements of Regulation 852/2004 would be required.

### **21. The Regulations require that operations such as filleting and slicing must be carried out in a place other than that used for heading and gutting operations. How should this be interpreted?**

The main requirement under Regulation 853/2004 is to avoid contamination of fillets. There may be a number of ways in which this can be achieved, one of which is to separate operations by time rather than place. As long as the Competent

Authority is content that contamination of the fillets is prevented then this separation by time may be allowed. We would assume that filleting and slicing is carried out where necessary at a different time or a place other than that where heading and/or gutting is carried out.

**22. Is there a list of approved detergents and similar substances for maintaining general conditions of hygiene in establishments and in respect of equipment?**

No. Chemicals suitable for use in the food industry are governed by other legislation.

**Fish Farms – Questions and Answers**

**23. Are fish farms covered by the Regulations?**

Yes, farmed fish are classified as primary production, which is covered by Regulation 852/2004. Although fish farms are covered by other animal health legislation Annex 1 of that Regulation lays down hygiene provisions, which stipulate that primary products must be protected against contamination with respect to further processing. Various hygiene requirements to achieve this are laid down.

**Identification marks - Questions and Answers**

**24. Where should the identification mark appear in the case of fresh fish sold by an approved auction hall or wholesale market?**

Annex II(C) of Regulation 853/2004 allows for the identification mark to be applied in either of these ways; directly on the product, the wrapping or packaging, a label affixed to the product, its wrapping or packaging and be an irremovable tag of resistant material. Under these provisions approval number of the market (and the individual trader if applicable) can appear on the crate or whatever other container is being used as well as the accompanying documentation. The documentation may be in the form of a receipt or other proof of purchase e.g. some wholesale markets use a docket system to ensure that sold fish goes to the right buyer.

**Landings of fishery products - Questions and Answers**

**25. Do Competent Authorities have to carry out histamine checks on other compounds listed in Regulation 854/2004 on all consignments of fish?**

According to Regulation 854/2004, random checks for histamine are to be carried out to verify compliance with permitted levels. Competent Authorities will decide when these checks are necessary, but these are likely to take place should if the freshness of the product be in doubt.

Other checks are required under Annex III, Chapter II of Regulation 854/2004 and corresponding checks must also be carried out by food business operators.

## **26. Do quaysides where fish are landed need to comply with the Regulations?**

There are no structural requirements for quays laid down in the regulations. However Annex II of Regulation 852/2004 does lay down general hygiene requirements for establishments which will be applicable to auction and wholesale markets. Additionally, handling practices for the unloading and landing of fish and some requirements relating to equipment are specified in Annex III, Section VII, Chapter II of Regulation 853/2004.

Seafish Guidelines for Facilities and Equipment during Landing, Storage, Auction, and Dispatch from the Landing Area contain recommendations for quaysides and suggests that the following should be in place:

- Laboratory arrangements for the purpose of carrying out sampling in accordance with the Regulations;
- Documented cleaning schedules with details of any checks, including sampling, carried out by the occupier to establish the efficacy of proposed cleaning and disinfection methods;
- Documented maintenance schedules. These should specify the checks to be carried out and any reporting arrangements;
- Documented pest control arrangements, including copies of any contracts with external pest control companies;
- Details for calibrating and monitoring automatic temperature control equipment, where required by the Regulations;
- Staff hygiene training programme, including records of training undertaken to date;
- Written company policy on staff illness and exclusion from work;
- Medical certificates for all staff;
- Details of traceability system, including checks on incoming raw materials, arrangements for controlling application of the health mark and correct use of commercial documentation. Details should include arrangements for documenting these procedures. It may also be appropriate to request examples of identification marked labels;
- Emergency withdrawal procedure;
- Up to date list of suppliers;
- Up to date list of customers (National, EU, 3rd Country).



## ANNEX 2 Guidance for food law enforcement officers on Halal food issues

### A2.1 Background

*Halal* is an Arabic word which means 'permissible', a related word in the Qur'an is *Tayyab* which means wholesome and fit for human consumption. With regard to food described as *Halal*, it means food that Muslims are permitted to consume under Islamic law. The opposite of *Halal* is *Haram*, which means 'prohibited by God, unwholesome, foul'. It follows, for example, that any meat that has not been rendered *Halal* by Islamic slaughter or that is liable to cause ill health, e.g. meat that is contaminated and unfit for consumption, cannot be considered *Halal*. Meat also cannot be considered *Halal* if it is past its "minimum durability marking". If a Muslim is sold *Haram* food, it is viewed very seriously, as it causes them to eat food prohibited in Islam and, in addition, it may be a form of fraud or deception.

Muslims regard Al Qur'an as the very words of God as revealed to the last prophet Muhammed, and is the primary source of Islamic law. In Al Qur'an there are prohibitions on the consumption of pork, blood, carrion and alcohol, among other things. For a product to be *Halal* (lawful) for Muslim consumption, and described as such, all the ingredients should be *Halal*. The Muslim requirement for food to be *Halal* applies whether the food business operator is preparing, handling, processing, manufacturing, packaging, storing, importing, distributing, supplying, transporting or selling food, whether for profit or not, from a factory, warehouse, shop, restaurant, van, village hall, community centre or vending machine.

### A2.2 Examples of where the requirements of food law relate to Halal requirements

There are many similarities between aspects of *Halal* requirements and aspects of food law. A *Halal* food business operator must not only comply with food law but with the **Islamic Shariah (Law)** related to food. The requirements of the **Islamic** dietary laws are that:

- Meat, and other foods, including food ingredients, whether home-produced or imported, must be *Halal*.
- Meat must be obtained from *Halal* sources, e.g. an abattoir must have the facilities and personnel to undertake *Halal* slaughter. See 7.2.9.3 for further information on Islamic Shariah (Law) relating to *Halal* slaughter, previously provided by the FSA's then Muslim Organisations Working Group.
- Meat must be wholesome and meet food safety requirements - if meat is unfit for human consumption it cannot be considered *Halal*, even if slaughtered in the prescribed manner.

To be *Halal*:

- The animal should be alive or deemed to be alive at the actual time of slaughter and slaughter must be carried out in compliance with Islamic Shariah and the Welfare of Animals (Slaughter or Killing) Regulations 1995 (as amended)<sup>39</sup>. Animals/birds must be slaughtered by severance of neck arteries and jugular veins.
- No pork or pork ingredients must be present in the food.
- No alcohol or other intoxicants must be used.
- Any animal product, such as gelatine, must be produced from animals slaughtered in accordance with the Islamic Shariah.
- Any animal fat or meat must come from animals slaughtered in accordance with the Islamic Shariah.
- Any preparation area and the equipment used should be kept in such a manner as to prevent cross contact, contamination or mixing *Halal* food with non-*Halal* food.

Displaying *Halal* and non-*Halal* meat on the same premises does not in itself render *Halal* meat non-*Halal*. If open, unpackaged *Haram* food is stored and displayed alongside *Halal* meat, there would have to be clear separation and suitable labelling. However it should be noted that, as any direct or indirect contact between *Halal* and *Haram* food (e.g. use of the same knives or chopping boards etc) would render *Halal* meat and poultry as *Haram*, this could be difficult to achieve in practice.

There is no legal requirement to label food as being non-*Halal*. If a description “HALAL” is made, then it must be clear which product the description refers to, if the business is not to run the risk of committing offences of mis-describing the foods on sale.

At present there are few recognised systems of certifying that a particular food is *Halal*. However, certain Muslim organisations are collaborating to develop an umbrella certification board for *Halal* foods.

Officers carrying out routine inspections or following up complaints should whenever possible consider, apart from hygiene issues, checking whether food claiming to be *Halal* is actually *Halal*. This may be done, for example, in any informal food sampling programme, of canned meat, where the presence of pork in what is purported to be *Halal* meat would obviously be *Haram* to a Muslim and may well contravene food law in terms of composition and labelling.

Where officers suspect misdescription of fresh meat they should liaise with the Official Veterinarian (OV) – through the FSA’s relevant regional Field Operations FOenquiries@foodstandards.gsi.gov.uk.

In summary, officers are asked to consider action, where appropriate, against food business operators who sell and mis-describe *Halal* foods, in the same way as they would for any contravention of food law in food premises generally.

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<sup>39</sup> Under Regulation 22 “Schedule 5 (which relates to the stunning and killing of animals) shall not apply to any animal which is slaughtered in accordance with Schedule 12 (which relates to slaughter by a religious method)”.

### **A2.3 Islamic Shariah (law) relating to slaughter of animals or poultry**

- Animal and birds should have preferably been raised in a natural environment.
- Their feed should not contain animal-based products.
- Animals and poultry at farms or lairages must be cared for properly. They must be fed and watered before slaughter.
- They must receive ante-mortem inspection so that only healthy animals are brought in for slaughter.
- In the slaughterhouse animals must not be able to see other animals being slaughtered, nor must they have sight of blood. This requires cleaning the area before the next slaughter.
- There must be no cruelty to animals or poultry at any time.
- The slaughter man must be a Muslim, who has been properly trained and licensed.
- All slaughtering must be carried out in a licensed slaughterhouse.
- Places where pigs are slaughtered should be avoided.
- The slaughter man must use a sharp knife (which must not be sharpened in front of the animal). He must sever the jugular veins and carotid arteries as well as the oesophagus and trachea, but not the spinal cord as this restricts convulsion, which in turn restricts the pumping out of blood.
- At the time of slaughter he must pronounce *Bismillah Allahu Akbar* (In the name of God, God is the Greatest) on each animal or bird.
- At all times the meat and general hygiene regulations must be complied with.
- Any carcasses found unfit on post mortem inspection must not be used for food for human consumption.

NB: This is included for information

Acknowledgement: The FSA is grateful for the help and advice received from members of the FSA's Muslim Organisations Working Group.

## **ANNEX 3 Links to legislation, guidance and forms (food hygiene)**

### **A3.1 Food Law Code of Practice (England) /Practice Guidance (England)**

<http://food.gov.uk/enforcement/enforcework/foodlawcop/copengland/>

### **A3.2 Regulations relating to England**

The Food Safety and Hygiene (England) Regulations 2013 (SI 2013 No. 2996):  
<http://www.legislation.gov.uk/ukxi/2013/2996/made>

Official Feed and Food Controls (England) Regulations 2009 (SI 2009 No. 3255):  
<http://www.legislation.gov.uk/ukxi/2009/3255/contents/made>

### **A3.3 EU Regulations**

The following links below are to the Commission's consolidated versions of the legislation which are intended, for ease of reference, to reflect the various amendments to the legislation over time. *Please note that these consolidated versions do not constitute official texts for legal purposes.*

Regulation (EC) No. 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2002R0178:20090807:EN:HTML>

Regulation (EC) No. 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2004R0882:20090807:EN:HTML>

Regulation (EC) No. 852/2004 on the hygiene of foodstuffs:

<http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02004R0852-20090420>

Regulation (EC) No. 853/2004 laying down specific hygiene rules for food of animal origin:

<http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02004R0853-20141117>

Regulation (EC) No. 854/2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2004R0854:20100705:EN:HTML>

Regulation (EC) No 1688/2005 implementing Regulation (EC) No 853/2004 of the European Parliament and of the Council as regards special guarantees concerning salmonella for consignments to Finland and Sweden of certain meat and eggs:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2005:271:0017:0028:EN:PDF>

Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2005R2073:20100519:EN:HTML>

Commission Regulation (EC) No 2074/2005 laying down implementing measures for certain products under Regulation (EC) No 853/2004 of the European Parliament and of the Council and for the organisation of official controls under Regulation (EC) No 854/2004 of the European Parliament and of the Council and Regulation (EC) No 882/2004 of the European Parliament and of the Council, derogating from Regulation (EC) No 852/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2005R2074:20090101:EN:HTML>

Commission Regulation (EC) No 2076/2005 laying down transitional arrangements for the implementation of Regulations (EC) No 853/2004, (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2005R2076:20090224:EN:HTML>

#### **A3.4 European Commission guidance documents**

European Commission Guidance Document on Regulation (EC) No. 852/2004 on the hygiene of foodstuffs:

[http://ec.europa.eu/food/food/biosafety/hygienelegislation/guidance\\_doc\\_852-2004\\_en.pdf](http://ec.europa.eu/food/food/biosafety/hygienelegislation/guidance_doc_852-2004_en.pdf)

European Commission Guidance Document on Regulation (EC) No. 853/2004 on the hygiene of food of animal origin:

[http://ec.europa.eu/food/food/biosafety/hygienelegislation/guidance\\_doc\\_853-2004\\_en.pdf](http://ec.europa.eu/food/food/biosafety/hygienelegislation/guidance_doc_853-2004_en.pdf)

European Commission Guidance Documents on the implementation of procedures based on HACCP principles and facilitation of the implementation of the HACCP principles in certain food businesses:

[http://ec.europa.eu/food/food/biosafety/hygienelegislation/guidance\\_doc\\_haccp\\_en.pdf](http://ec.europa.eu/food/food/biosafety/hygienelegislation/guidance_doc_haccp_en.pdf)

### **A3.5 FSA guidance documents**

For Model template forms see the documentation section of this Practice Guidance.

### **A3.6 Central register of letters sent by the FSA to Competent authorities**

<http://www.food.gov.uk/enforcement/workwithenforcers/centralref/>

### **A3.7 Government Guidance**

Regulators' Code: <https://www.gov.uk/government/publications/regulators-code>

### **A3.8 FSA allergens guidance**

- Training: The FSA has worked with the relevant professional bodies (TSI and CIEH) to develop training to support effective enforcement of the new arrangements.
- Industry developed guidance: British Retail Consortium and Food and Drink Federation in partnership with the FSA have also provided allergen guidance for pre-packed food on:

<http://www.brc.org.uk/downloads/Guidance%20on%20Allergen%20Labelling.pdf>

- E-learning: The FSA has updated its E-learning module to provide training and advice for caterers, enforcement officers and consumers about allergen labelling and the new Regulation. This is freely accessible at: <http://allergytraining.food.gov.uk>
- Consumer advice: The new food allergen labels are already coming onto the market. To inform consumers of the changes, we updated our advice for consumers to include details of the new Regulation. <http://multimedia.food.gov.uk/multimedia/pdfs/publication/allergy-leaflet.pdf>

- Enforcement officer and SME's Advice: The Agency will update our online advice to include details of the new Regulation: <http://www.food.gov.uk/business-industry/guidancenotes/allergy-guide/>
- Training is available on the details of the EU FIC <http://www.food.gov.uk/enforcement/enforcetrainfund/>
- The Food Standards Agency offers training for officers on issuing Food Standards IN's <http://www.food.gov.uk/enforcement/enforcetrainfund/>.
- Allergy and Intolerance – Guidance for Food businesses <http://www.food.gov.uk/sites/default/files/fir-2014-guidance.pdf>

## ANNEX 4

### ANNEX 4 - Glossary

|                               |  |
|-------------------------------|--|
| Advanced electronic signature | Has the meaning set out in Regulation 2, The Electronic Signatures Regulation 2002.  |
| APHA                          | Association of Port Health Authorities   |
| Approved establishment        | A premises approved under Regulation (EC) No. 853/2004 for handling, preparing and/or producing products of animal origin.   |
| Audit                         | A systematic and independent examination to determine whether activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.   |
| Authorised Officers           | Has the meaning set out in Section 5 (6) Food Safety Act 1990.   |
| Awarding bodies               | In relation to the Code, the awarding bodies are: The Chartered Institute of Environmental Health (CIEH); Trading Standards Institute (TSI) and; The Institute of Food Science and Technology (IFST).  |
| BIS                           | Department for Business, Innovation and Skills.  |
| BRDO                          | Better Regulation Delivery Office  |
| Broadly compliant(Hygiene)    | An establishment that has an intervention rating score of not more than 10 points under each of the following three parts of Section 5.6.1: Part 2: Level of (Current) Compliance - Hygiene and Level of (Current) Compliance – Structure; and Part 3: Confidence in Management. |
| Broadly compliant(Standards)  | An establishment that has an intervention rating score of not more than ten points under each of the following parts of Chapter 5.6.2, Part 2: Level of (Current) Compliance; and Part 3, Confidence in Management/Control Systems.  |
| Cefas                         | Centre for Environment, Fisheries and Aquaculture Science  |
| CEN                           | The European Committee for Standardisation.  |
| CCDC                          | Consultant in Communicable Disease Control   |
| CCP                           | Critical Control Point   |



|                             |   |
|-----------------------------|---|
| Central Competent Authority | Has the meaning set out in Regulation 882/2004 <sup>40</sup> and is the Food Standards Agency.  |
| CIEH                        | Chartered Institute of Environmental Health   |
| CIM                         | Confidence in Management  |
| Competent Authority         | Has the meaning set out in Regulation 2 (1) The Official Feed and Food Controls (England) Regulations 2009 <sup>41</sup> . For the purposes of the Code this would, normally, mean Food Authorities; but it could also include Official Veterinarian, where applicable. |
| Competent person            | Meeting the requirements of the competency framework set out in Chapter 4.  |
| Complaint                   | Conformity with the requirements of the law.  |
| Compliance notice           | Has the meaning set out in The Food Additives, Flavourings, Enzymes and Extraction Solvents (England) Regulations 2013  |
| Compliance risk elements    | These are defined within the Hygiene Risk Rating System as structure compliance, hygiene compliance, confidence in management and significant risk.   |
| Conditional Approval        | Has the meaning set out in Article 31(2)(d) of Regulation (EC) No. 882/2004.  |
| Could                       | Is generally used to indicate those provisions which are for guidance only.   |
| CPD                         | Continuing Professional Development.  |
| CPHM/EH                     | Consultant in Public Health Medicine (Communicable Disease/Environmental Health)  |
| DCA                         | Diploma in Consumer Affairs   |
| DCATS                       | Diploma in Consumer Affairs and Trading Standards   |
| DTS                         | Diploma in Trading Standards  |
| Designated regulator        | Has the meaning set out in section 37(1) as read with Schedule 37 Regulatory Sanctions and Enforcement Act 2008. The FSA is the Designated Regulator for food.  |
| Detention Notice            | Has the meaning set out in Regulation 10 The Food Safety and Hygiene (England) Regulations 2013.  |

<sup>40</sup> <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:226:0003:0021:EN:PDF>

<sup>41</sup> <http://www.legislation.gov.uk/ukxi/2009/3255/contents/made>

|                             |  |
|-----------------------------|--|
| Domestic premises           | A dwelling house or other building used principally, but not exclusively as a dwelling and its curtilage.  |
| Earned Recognition          | A framework for reducing wherever possible the frequency and type of official controls on businesses that demonstrate sustainable compliance.  |
| <i>E.coli</i> O157          | Escherichia coli O157  |
| EEA                         | European Economic Area   |
| EHRB                        | Environmental Health Registration Board  |
| Electronic communication    | Has the meaning set out in Section 15(1) Electronic Communications Act 2000  |
| Electronic records          | Information captured through electronic means, and which may or may not have a paper records to back it up. Also called machine readable record.   |
| Electronic signature        | Has the meaning set out in Regulation 2 of the Electronic Signatures Regulation 2002   |
| Emergency Control Order     | Has the meaning set out in Section 13 Food Safety Act 1990   |
| Emergency Prohibition Order | Has the meaning set out in Section 12 Food Safety Act 1990   |
| Enforcement Authority       | Has the meaning set out in Regulation 2 (1) The Food Safety and Hygiene (England) Regulations 2013   |
| Establishment               | “Establishment” does not simply mean “premises”, but is directly linked to the business occupying the establishment (“establishment denotes both premises and the manner in which those premises are being used by the food business operator”). |
| Evidence                    | The measure and conditions necessary to control hazards and to ensure fitness for human consumption of a foodstuff taking into account its intended use.   |
| Export                      | The action of sending or transporting a commodity abroad, especially for trade or sale outside the EU.   |
| EU                          | European Union   |
| FBO                         | Food Business Operator   |
| FCATS                       | Foundation Certificate in Consumer Affairs and Trading Standards.  |
| FHIS                        | Food Hygiene Information Scheme  |

|                        |   |
|------------------------|---|
| FHRS                   | Food Hygiene Rating Scheme  |
| Food Authority         | Has the meaning set out in Section 5 (1) Food Safety Act 1990 <sup>42</sup>   |
| Food Examiner          | Has the meaning set out in Section 30 (9) Food Safety Act 1990 and Regulation 45 Food Safety (Sampling and Qualifications) Regulations 2013.  |
| FSA                    | Food Standards Agency   |
| Food Business          | Has the meaning set out in Regulation (EC) 178/2002 – Article 3.2 <sup>43</sup>   |
| Food Business Operator | Has the meaning set out in Regulation (EC) 178/2002 – Article 3.3   |
| Framework              | Framework Agreement on Local Authority Food Law Enforcement <sup>44</sup>   |
| Full Approval          | Has the meaning set out in Article 31(2)(d) of Regulation (EC) No. 882/2004.  |
| Food Incident          | Has the meaning set out in Section 2.2.1 of this Code   |
| Food Alert             | Has the meaning set out in Section 2.2.2 of this Code   |
| Food Hazard            | Has the meaning set out in Section 2.3.1 of this Code   |
| Formal Action          | The taking of action against a food business operator as set out in the legislation including the service of a statutory notice to remedy non-compliance with legal requirements, the issuing of a Simple Caution or the institution of legal proceedings for breaches of legal requirements. |
| Formal Notice          | Means a notice as defined in the various Acts of Parliament or statutory instruments relating to food law.  |
| HACCP                  | Hazard Analysis and Critical Control Point  |
| HCATS                  | Higher Diploma in Consumer Affairs and Trading Standards  |
| Hazard                 | Anything that has the potential to cause harm.  |

<sup>42</sup> <http://www.legislation.gov.uk/ukpga/1990/16/contents>

<sup>43</sup> <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:031:0001:0024:EN:PDF>

<sup>44</sup> <http://food.gov.uk/multimedia/pdfs/enforcement/frameworkagreementno5.pdf>

|                                      |  |
|--------------------------------------|--|
| Home Authority                       | The authority where the relevant decision making base of an enterprise is located.   |
| Hygiene                              | The measure and conditions necessary to control hazards and to ensure fitness for human consumption of a foodstuff taking into account its intended use.   |
| Hygiene Emergency Prohibition Notice | Has the meaning set out in Regulation 8 of the Food Safety and Hygiene (England) Regulations 2013.   |
| Hygiene Improvement Notice           | Has the meaning set out in Regulation 6 of the Food Safety and Hygiene (England) Regulations 2013.   |
| Hygiene Prohibition Order            | Has the meaning set out in Regulation 7 of the Food Safety and Hygiene (England) Regulations 2013.   |
| IFST                                 | Institute of Food Science and Technology   |
| Import                               | The action of bringing in goods and/or services from another country outside of the EU.  |
| Improvement Notice                   | Has the meaning set out in Section 10 of the Food Safety Act 1990  |
| IMS                                  | Information Management Scheme  |
| Inherent Risk Elements               | These are defined within the Hygiene Risk Rating System as Potential Hazard, Method of Processing, Consumers at Risk and Vulnerable Groups.  |
| Informal Action                      | Bringing to the attention of a food business operator and giving advice on non-compliances with food safety law in order that any non-compliance can be quickly remedied.  |
| Inspection                           | The examination of any aspect of feed, food animal health and animal welfare in order to verify that such aspect(s) comply with the legal requirements of feed and food law and animal health and welfare rules.                               |
| Inspecting Authority                 | The food authority that carries out the official control intervention in respect of any establishment.   |
| Intervention                         | Regulatory <u>actions</u> taken by a <u>government</u> in <u>order</u> to affect or interfere with <u>decisions</u> made by <u>individuals</u> , <u>groups</u> , or <u>organizations</u> <u>regarding</u> social and economic <u>matters</u> . |
| Investigation                        | The action taken by the competent authority to gather evidence where it believes an offence has been committed.  |
| LAEMS                                | Local Authority Enforcement Monitoring System  |
| LBRO                                 | Local Better Regulation Office (now BRDO)  |

|                                 |   |
|---------------------------------|---|
| LGA                             | Local Government Group Association.   |
| Live bivalve molluscs           | References to live bivalve molluscs also include live echinoderms, live tunicates and live marine gastropods, in line with Annex III, Section VII(1) of Regulation (EC) No. 853/2004 laying down specific hygiene rules for food of animal origin (Regulation 853/2004), with the exception of parts of the Code which deal with purification of live bivalve molluscs  |
| Local Authority                 | Has the meaning set out in Section 270 Local Government Act 1972 <sup>45</sup>  |
| MCA                             | Maritime and Coastguard Agency  |
| Mobile Establishment            | Premises other than permanent premises, and “relevant moveable premises” means moveable premises, used for the transport or preparation of food or the retail sale of food on five or more days, whether consecutive or not, in any period of five consecutive weeks, other than –<br>(a) motor vehicles which are constructed solely for the purpose of carrying no more than 8 passengers (including the driver) and their personal effects,<br>(b) tents, or<br>(c) moveable premises which are ordinarily kept outside Great Britain. |
| Monitoring                      | Conducting a planned sequence of observations or measurements with a view to obtaining an overview of the state of compliance with feed or food law, animal health and animal welfare rules.  |
| MoU                             | Memorandum of Understanding   |
| Must                            | Is used to confirm an obligation.   |
| May                             | On its own indicates an optional exercise of a power or function.   |
| May not                         | Indicates a prohibition.  |
| NHS                             | National Health Service   |
| Non-compliant                   | A failure to comply with the one or more requirements of a food law.  |
| Official controls               | Has the meaning set out in Article 2 (1) of Regulation (EC) No. 882/2004.   |
| Official controls Interventions | Inspections, monitoring, surveillance, verification, auditing and sampling (where the analysis/examination is to be carried out by  |

<sup>45</sup> <http://www.legislation.gov.uk/ukpga/1972/70/contents>

|                             |  |
|-----------------------------|--|
|                             | an Official Laboratory).   |
| Official Control Laboratory | A laboratory accredited for the purposes of analysis, and which appears on the list of official food control laboratories.   |
| Originating authority       | Means the authority in whose area final food production takes place.   |
| Other interventions         | Education, advice and coaching provided at a food establishment and information and intelligence gathering (including sampling where the analysis and examination is NOT to be carried out by an Official Laboratory).                                 |
| Penalty                     | The punishment imposed by a court on conviction for an offence under food legislation.   |
| PARNUTS                     | Foodstuffs intended for particular nutritional uses  |
| Port Health Authority       | Has the meaning set out in Section 2 Public Health (Control of Diseases) Act 1984 <sup>46</sup> .  |
| Primary Authority           | Has the meaning set out in Section 25 Regulatory Enforcement and Sanctions Act 2008 <sup>47</sup>  |
| Primary Production (Food)   | The production, rearing or growing of primary products including harvesting, milking and farmed animal production prior to slaughter. It also includes hunting and fishing and harvesting of wild products as defined in Regulation (EC) No. 852/2004. |
| Prohibition Order           | Has the meaning set out in Section 11 Food Safety Act 1990   |
| Prohibited Person           | Has the meaning set out in Regulation 7 (4) The Food Safety and Hygiene (England) Regulations 2013   |
| PTA                         | Permanent transport authorisation.   |
| Public Analyst              | Has the meaning set out in Section 27 Food Safety Act 1990 and Regulation 4 Food Safety (Sampling and Qualifications) Regulations 2013.  |
| RAF                         | Royal Air Force  |
| RPA                         | Rural Payments Agency  |
| Records                     | Means information preserved in writing or the like.  |

<sup>46</sup> <http://www.legislation.gov.uk/ukpga/1984/22/contents>

<sup>47</sup> <http://www.legislation.gov.uk/ukpga/2008/13/contents>

|                           |   |
|---------------------------|---|
| REHIS                     | Royal Environmental Health Institute of Scotland.   |
| Remedial Action Notice    | Has the meaning set out in Regulation 9 (1) The Food Safety and Hygiene (England) Regulations 2013.   |
| Registering authority     | The competent authority responsible for registering an establishment under Regulation (EC) No. 852/2004.<br>In relation to a mobile establishment, the registering authority will be where it is ordinarily kept.   |
| Regulation 29 Certificate | A Certificate issued under Regulation 29 Food Safety Hygiene (England) Regulations 2013 that food has not been produced, processed or distributed in compliance with the hygiene regulations.                       |
| Regulated Person          | Has the meaning set out in Section 22 (2) Regulatory Enforcement and Sanctions Act 2008   |
| Regulatory Function       | Has the meaning set out in Section 32 (2) Legislative and Regulatory Reform Act 2006 <sup>48</sup>  |
| Regulatory Services       | Environmental Health, Trading Standards and Licensing as set out in “National Enforcement Priorities for Local Authority Regulatory Services”. March 2007 (Rogers Review) <sup>49</sup>                             |
| Risk                      | The chance or probability that a person will be harmed or experience an adverse health effect if exposed to a hazard.   |
| Risk Analysis             | A process consisting of three interconnected components: risk assessment, risk management and risk communication.   |
| Risk Rating Category      | The Risk Category attributed to a premises following an inspection and scoring of the premises in accordance with the Intervention Rating Scheme and used to determine the frequency of inspection of the premises. |
| Risk Rating Element       | One of the three elements i.e. Potential Risk, Level of Current Compliance and Confidence in Management that make up the Risk Rating Scheme set out at section 5.6 to the Code                                      |
| RN                        | Royal Navy  |
| Safety                    | The quality of averting or not causing injury, danger, or loss.   |
| Sanction                  | The provision within a statute to take punitive action for failure to comply with the provisions of the statute.  |

<sup>49</sup>

[http://webarchive.nationalarchives.gov.uk/+/bre.berr.gov.uk/regulation/reviewing\\_regulation/rogers\\_review/index.asp](http://webarchive.nationalarchives.gov.uk/+/bre.berr.gov.uk/regulation/reviewing_regulation/rogers_review/index.asp)

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| Sampling              | Taking feed or food or any other substance (including from the environment) relevant to the production, processing and distribution of feed or food or to the health of animals, in order to verify through analysis compliance with feed or food law or animal health rules. |
| SFBB                  | Safer Food Better Business  |
| SFSORB                | Scottish Food Safety Officers' Registration Board   |
| SIMS                  | Ships Inspection Management System.   |
| Signed                | Means having a signature affixed either in writing or by electronic means.  |
| Simple Caution        | Has the meaning set out in Ministry of Justice guidance note : "Simple Cautions for Adult Offenders" <sup>50</sup>  |
| Standards             | Rules or principles defined in food safety law that are used as the basis for judgment against.   |
| Surveillance          | Means a careful observation of one or more food businesses, or food business operators or their activities.   |
| Third Country         | Has the meaning set out in Chapter V of Regulation (EC) No 882/2004.  |
| TSI                   | Trading Standards Institute   |
| Third Party Assurance | Independent verification of business compliance against a predetermined standard which has been endorsed by the FSA as being equivalent to /complying with the requirements for food law.   |
| UK                    | United Kingdom  |
| UKAS                  | United Kingdom Accreditation Service  |
| UKFSS                 | United Kingdom Food Surveillance Scheme   |
| Validation            | Means confirmation that requirements have been complied with.   |
| Verification          | Means the checking, by examination and the consideration of objective evidence, whether specified requirements have been fulfilled.   |

<sup>50</sup> [http://www.xact.org.uk/information/downloads/Pace/HOC\\_16-2008.pdf](http://www.xact.org.uk/information/downloads/Pace/HOC_16-2008.pdf)



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|------|---|
| VTEC | Verocytotoxin-producing <i>Escherichia coli</i> |
|------|---|