# Food Law

Practice Guidance (Wales)

(Issued XXXX 20XX)

**Food Standards Agency** 

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# **Chapter 1** Introduction

The Food Law Practice Guidance (Wales) (the Practice Guidance) is:

- issued by the Food Standards Agency (FSA)
- directed at Local Authorities (Food Authorities) responsible for the delivery of official food controls and other official activities
- aimed at assisting Food Authorities with the discharge of their statutory duty to enforce food law
- aimed at supporting the quality, consistency, effectiveness and appropriateness of official food controls and other official activities

It complements the statutory Food Law Code of Practice (Wales) (the Code) and provides general advice on approach to enforcement of the law where its intention might be unclear. Food Authorities must have regard to the relevant Chapters of the Practice Guidance which are specifically referenced to within the Code.

The guidance contained in this document:

- is given in good faith and accords with the FSA's understanding of relevant legal requirements
- takes account of recommendations made by the Directorate-General for Health and Food Safety – Audit and Analysis (DGF) following any audit of the UK food control systems
- provides links to a range of guidance

The UK has left the European Union (EU). The European Union (Withdrawal) Act 2018 (the EUWA) provides that, from 1 January 2021, certain directly applicable legislation of the EU will be converted into UK law. Converted law is referred to as 'retained EU law'. The EUWA provides powers to make corrections to retained EU law to ensure it operates effectively as UK law. Examples of retained EU law relating to food and animal feed, include Regulation (EC) 178/2002 on General Food Law, Regulation (EC) No 852/2004 on the hygiene of foodstuffs. Food and feed safety law will therefore continue to apply in the UK in much the same way as it did before the UK exited the EU.

All references to legislation in the Practice Guidance are made on the basis that the legislation may be subject to amendment and/or revocation. When performing official food controls and enforcement activities, Food Authorities must ensure that they correctly refer to current versions of relevant legislation detailed in the Practice Guidance.

#### References to:

- chapters and sections are to the relevant parts of this document unless stated otherwise
- legislation must be considered a reference to that legislation in its current form (unless otherwise indicated)

If you are in any doubt whether a specific legal provision referred to in the Practice Guidance is still in force, you may wish to consult with your legal adviser before taking any action against a food business under that provision.

Any guidance on the law within the Practice Guidance should not 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.

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

There is a glossary with definitions of terms and abbreviations used throughout the Practice Guidance.

# Chapter 2 Administration, liaison, and co-ordination

#### 2.1 Introduction

Chapter 2 deals with:

- the administrative arrangements, including designation of Food Authorities, registration and approval of food business establishments
- liaison arrangements<sup>1</sup> to ensure the:
  - efficient and effective co-ordination between Food Authorities, delegated bodies and other government departments responsible for official controls and other official activities
  - consistency and effectiveness of official controls and other official activities across the UK
- avoidance of conflicts of interests<sup>2</sup>
- monitoring requirements to ensure consistent, appropriate and effective official controls and other official activities are being undertaken by Food Authorities

#### 2.2 Relevant dataset lists

Food Authorities must provide the FSA with relevant dataset lists, currently the list comprises:

- Food Hygiene (LAEMS)
- Food Standards (LAEMS)
- Imported Food (LAEMS)
- Approved Food Premises
- Imported Food Safeguard Measures
- Food Hygiene Rating Scheme (FHRS)

## 2.3 Departure from the Code

Circumstances might arise where the FSA requires Food Authorities to depart from the Food Authority's Interventions Programme that is based on the intervention ratings in the Code.

Such situations might include:

- those where there is evidence that:
  - an unsafe practice is occurring or has occurred which represents a significant hazard to public health;
  - a particular food handling or food preparation practice is found to entail a previously unsuspected hazard to public health;
  - a foodstuff previously thought to be safe is found to be hazardous to public health;

<sup>2</sup> Article 5(1)(c) of Regulation (EU) 2017/625

<sup>&</sup>lt;sup>1</sup> Article 4(2) of Regulation (EU) 2017/625

- a food with widespread distribution is found to be contaminated and thereby presents a significant hazard to public health;
- a food with widespread distribution is the subject of fraud in labelling or presentation; and
- in the case of primary production, an occurrence on-farm of a contagious animal disease (such as Blue Tongue) or a natural disaster (such as severe flooding) makes on-farm inspection impractical.
- in response to a state of emergency such as a pandemic or regional flooding

## 2.4 Requirements relating to documented procedures

# 2.4.1 Registration of food business establishments procedure and/or arrangements

Food Authorities must ensure their registration of food business establishments procedure and/or arrangements that they put in place:

- allows food business operators (FBOs) to submit a registration form that is complete and accurate at least 28 days before the business starts trading or food operations commence
- provides a registration form that is available to FBOs and requires them to provide full details of all activities undertaken
- details the actions to be taken on receipt of completed registration forms, including notifying other Food Authorities where activities fall outside the receiving Food Authorities enforcement remit or jurisdiction
- includes details on how the Food Authority will obtain information omitted from a registration form, where applicable, and circumstances where registration forms are returned or rejected to FBOs

#### 2.4.2 Approval of food business establishments procedure

Food Authorities must ensure their approval of food business establishments procedure:

- allows FBOs to submit an approval application form that is complete and accurate
- provides an approval application form that is readily available to FBOs and requires them to provide full details of all activities undertaken
- details the actions to be taken on receipt of completed approval application forms, including notifying other Food Authorities where activities fall outside the receiving Food Authorities enforcement remit or jurisdiction
- includes details on how the Food Authority will obtain information omitted from an approval application form, where applicable, and circumstances where approval application forms are returned or rejected to FBOs
- includes details on how approvals are to be determined (including approval numbers and notification), which take into account the Code, the Practice Guidance and other relevant legislation and/or guidance

### 2.4.3 Food business establishment database procedure

Food Authorities must ensure their food business establishments database procedure details:

- how their list of food business establishments registered with them or approved by them is maintained so that it is accurate, reliable and up to date
- the action taken on receipt of notifications of changes to food establishment operations, and how, where appropriate, these changes are made to the database

#### 2.4.4 Control verification procedure

Food Authorities must ensure their control verification procedure, more commonly referred to as internal monitoring procedure<sup>3</sup>:

- provides for the planned intervention programme being maintained and carried out competently
- includes details of the necessary steps to be taken to address any performance which does not meet expected standards
- demonstrates appropriate and consistent application of the food law riskrating systems, including where changes are made to an establishments riskrating score
- includes measures to establish:
  - that action taken by officers during and following an official control or other
    official activities, including at points of entry, is appropriate and consistent
    with the Food Authorities procedure(s) and policies and with the FSA,
     Welsh Local Government Association (WLGA) or other relevant guidance<sup>4</sup>
  - how the planned intervention programme can be amended to allow for inyear changes, for example new and closed food business establishments and food business establishments which have changed intervention rating
  - that officers are aware of and have access to other published industry codes of practice relevant to the businesses within the area of the Food Authority
  - that officers have due regard to published Guides to Good Practice
  - compliance with relevant legislation, the Code, the Practice Guidance, the Framework Agreement, the FSA Knowledge and skills for the effective delivery of official food and feed controls and other activities competency framework (The Competency Framework), other relevant FSA or relevant guidance
  - compliance with internal procedure(s) and policies, as required by the Code
  - appropriate use of relevant proforma forms (including enforcement notices)

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<sup>&</sup>lt;sup>3</sup> Article 12 (1) of Regulation (EU) 2017/625

<sup>&</sup>lt;sup>4</sup> Article 12 (3) (a) of Regulation (EU) 2017/625

- includes provisions to appropriately rectify any inaccuracies in the information made available to the public<sup>5</sup>
- provides measures to be taken where officers are found to be issuing false or misleading official certificates or abuse of official certificates<sup>6</sup>, which include:
  - temporary suspension of certifying officer from their duties
  - withdrawal of authorisation to sign official certificates
  - any other measure to prevent these issues re-occurring

Food Authorities should refer to the Framework Agreement and the FSA guidance document, <u>Every Inspection Counts</u> when developing and reviewing their internal monitoring procedures.

#### 2.4.4.1 Monitoring of service delivery

Food Authorities must carry out control verification checks to verify their conformance with legal duties, official guidance and their own procedure, policies, plans and programmes across the full range of service activities<sup>7</sup>.

#### Food Authorities must ensure:

- all relevant activities are subject to proportionate and routine quantitative and qualitative monitoring so that they can demonstrate its conformance with legislation, the Code, Framework Agreement and other relevant official guidance
- appropriate and proportionate records are maintained to verify management oversight of key service activities and actions, and measures are taken to address any identified problems
- that monitoring is flexible, proportionate, varied, targeted and tailored according to personnel or premises risks

#### Food Authorities should consider:

- consistency exercises within and across Food Authorities for example a range of business scenarios to enable a comparison of officer assessments, these might include:
  - risk scores
  - enforcement decisions
  - focusing on internal qualitative monitoring and improvements (rather than
    just quantitative checks on the numbers of activities carried out) for
    example monitoring trends in business risk profiles and the quality of
    officer interventions
- a 'risk-based' approach to internal qualitative monitoring for example greater emphasis on known problem areas (any issues with particular staff and a

<sup>&</sup>lt;sup>5</sup> Article 11(2) of Regulation (EU) 2017/625

<sup>&</sup>lt;sup>6</sup> Article 138(5) of Regulation (EU) 2017/625

<sup>&</sup>lt;sup>7</sup> Article 5 (1)(b) of Regulation (EU) 2017/625

- greater proportion of higher risk businesses) rather than an inflexible percentage check of all files approach
- running reports listing the recent risk-ratings so managers can quickly identify and investigate the reasons for any businesses remaining high risk over a series of interventions
- delegation of some routine monitoring activities encourages all staff to participate in self-monitoring and peer checking of each other's work for example letters, notices, file updating
- monitoring activities that may work well for some Food Authorities, which could include:
  - periodic accompanied inspections/audits
  - reviews of post-inspection/audit paperwork
  - post-inspection/audit visits to establishments by managers
  - manager reviews of all enforcement activities, including checks against the relevant guidance and enforcement policy
  - routine caseload meetings

### 2.4.4.2 Monitoring of interventions

Intervention programmes must be risk-based; central to this are the assessments of businesses food safety management and control arrangements.

Sufficiently detailed, accurate and retrievable documentation for key business operations and activities, interventions and assessment records, particularly in relation to food safety management systems, and any enforcement actions, are essential to:

- demonstrate that food businesses comply with relevant food law
- ensure that subsequent inspecting officers are aware of individual business compliance histories
- inform each step of a graduated enforcement approach
- provide the evidence base for formal enforcement
- permit effective internal qualitative monitoring, for example checking that:
  - lower risk businesses do not receive interventions ahead of known high risk, and/or at the expense of following up and addressing persistent problems with higher risk businesses
  - repeated or lengthy non-compliance is being tackled effectively and adequate monitoring by line managers
  - intervention records (electronic or hard copy) are sufficient to inform subsequent interventions and actions, especially where these fall to a different officer
  - the legibility of handwritten inspection/intervention reports
  - legal requirements are clearly distinguished from advice
  - any written correspondence specifies, where relevant the follow-up action and time allowed for remedial works
  - appropriate action has been taken in relation to imported food by inland Food Authorities including liaison between authorities

#### 2.4.4.3 Monitoring of follow-up action and enforcement

As part of effective internal monitoring in relation to follow-up action and enforcement action, Food Authorities must ensure that:

- instances of non-compliance are appropriately acted upon
- all significant non-compliance is addressed in a timely and effective manner
- any enforcement action taken, is in accordance with local enforcement policies, national guidance and appropriate to the severity and persistence of the offences
- any decisions to deviate from the approach prescribed in the enforcement policy are duly considered and the reasons documented (proposed officer action, or inaction, that does not conform with a Food Authorities enforcement policy should normally be referred for higher level agreement)
- the respective due legal process for each of the range of formal enforcement options is strictly observed
- formal notices are followed up in a timely manner (i.e. immediately following the date of expiry), with a presumption that enforcement will ensue in the event of continuing non-compliance
- identified instances of serious non-compliance and repeated poor risk-ratings are addressed
- they identify failure to take a graduated approach to enforcement and/or utilise the full range of enforcement tools
- they identify any lack of timely follow-up actions that would permit enforcement of the notice requirements for example checks at the time formal notices expire
- they identify where symptoms of non-compliance have been treated (i.e. a short-term fix) rather than addressing the root cause, resulting in repeated and continuing problems

#### Food Authorities should consider:

- regular case conferences between managers and staff, for example to discuss the compliance progress of all high-risk businesses in each officer's area
- including an 'enforcement review' section on 'inspection/audit forms/files for officers to provide brief reasons for any action taken/not taken, to inform subsequent inspecting/auditing officers and to facilitate manager checks of consistency against the local enforcement policy
- consulting with legal services early in formal enforcement actions to ensure that cases can meet all evidential and procedural criteria, and to avoid unnecessary technical challenge to well-founded cases
- developing formal enforcement checklists to ensure due process is checked prior to each step of formal actions (for example adapt the relevant Agency audit checklists to include local Enforcement Policy criteria, and use before a notice is served)

 officers' schedules and diarise follow-up visits/compliance checks against notices/formal actions to ensure they are carried out on time (and where appropriate, that these dates are notified to the business in the relevant 'inspection/audit report or notice covering letter)

#### 2.4.4.4 Monitoring of management information systems

Complete, up-to-date, accurate and reliable databases of local food businesses are essential to enable managers to know of all the relevant businesses located in their area and to provide the basis for comprehensive risk-based 'inspection/audit and intervention programmes. The databases need to be monitored and maintained to ensure that changes of business use and ownership, closures and new businesses can be tracked.

#### It is recommended that Food Authorities:

- have in place processes to monitor routinely both the accuracy of the premises database, and the action/information entries inputted and maintained for each business
- undertake occasional checks to identify any inconsistencies between file records and database entries of intervention details, enforcement activities and actions

#### Issues might include:

- businesses duplicated on the electronic database
- database records of inspections/interventions inconsistent with data held on hardcopy files (for example dates of actions, risk-ratings)
- no routine monitoring of data entries and/or anomalies and inaccuracies not picked up
- illegible handwritten 'inspection/audit reports scanned onto the system

#### Solutions might include:

- use of the database software manager reporting facility, or a simple spreadsheet, to monitor for consistency issues and to routinely check for anomalies and inaccuracies in electronic 'inspection/audit records
- routine cross-referencing checks of businesses held on the premises database against other listings of local businesses for example:
  - advertising on online search engines
  - social media pages
  - other internal Food Authorities databases for example Planning, Business Rates and Building Control
  - other relevant agencies for example the Veterinary Medicines Directorate (VMD) and the Animal and Plant Health Agency (APHA)
  - Red Tractor Assurance (RTA) website
  - other relevant Assurance schemes operated by industry

#### 2.4.5 Authorisation procedure

Food Authorities must ensure their authorisation procedure:

- details how competency will be assessed and recorded to complete the authorisation process
- covers the roles and responsibilities of staff in the authorisation process
- provides who is authorised to approve legal proceedings
- covers the process for authorising new appointments, newly qualified officers and those returning to food law enforcement
- details how the Food Authority ensures its lead food officer(s) and authorised officers are authorised in compliance with Chapter 3 of the Code

#### 2.4.6 Food incidents and alerts procedure

Food Authorities must ensure their food incidents and food alerts procedure8:

- is developed in consultation with:
- members of the relevant Food Liaison Group;
  - Public Health Wales (PHW);
  - Public Analyst;
  - Consultant in Communicable Disease Control (CCDC); and
  - relevant officers of the Food Authority, for example Emergency Planning Officer
- details how food incidents and food alerts identified within their area are dealt with
- includes provisions to:
  - call appropriate agencies together at short notice
  - implement urgent control measures whenever they are required
  - identify a lead authority, where necessary
- covers initiation and effective response to Food Alerts issued by the FSA
- includes details on effective response to pre-incident contact by the FSA

#### The procedure must include, as a minimum, the following:

- details, including contact details, of the lead food officer for such matters
- liaison arrangements between Trading Standards and Environmental Health Departments;
- any arrangements for out of hours reception and response to alerts and emergencies
- arrangements to ensure that food alerts and updates are brought to the attention of an officer with authority to initiate appropriate action without undue delay
- arrangements for the liaison with other relevant bodies, Food Authorities, both within and outside normal office hours
- arrangements to provide adequate staff resources to allow effective response to alerts

<sup>&</sup>lt;sup>8</sup> Article 12 (1) of Regulation (EU) 2017/625

 arrangements to provide adequate equipment, including access by the Food Authority out of hours, to allow an effective response to be made

When developing food incidents and food hazards procedures, Food Authorities should take into consideration the FSA guidance on <u>Food Safety, Traceability</u>, <u>Product Recall and Withdrawal</u>.

#### 2.4.7 Corporate complaints procedure

Food Authorities must ensure their complaints procedure:

- is readily available to the public and food businesses in its area
- leads to complaints received about the Food Authority being investigated in accordance with relevant centrally issued guidance
- requires a record to be made of all complaints received and actions taken in response to those complaints by the Food Authority

#### 2.4.8 Food complaints procedure

Food Authorities must ensure their food complaints procedure:

- covers complaints about food originating from inside and outside of the UK
- covers complaints about food and food business establishments
- includes procedures for any referral arrangements to inland authorities, or authorities with responsibility for import food controls at the point of entry
- leads to complaints received being investigated in accordance with the Code, centrally issued guidance and the Food Authority's policies and procedures
- details the mechanism(s)<sup>9</sup> for how complaints about actual or potential noncompliances can be made which include:
  - procedures for receipt of complaints and their follow-up
  - details on how persons reporting complaints will be protected from retaliation, discrimination or other types of unfair treatment as a result of their complaint (for example, whistle-blowers)
  - details on how personal data of persons reporting complaints will be protected

### 2.4.9 Sampling procedure

Food Authorities must ensure their sampling procedure 10.

- includes measures for the procurement or purchase of samples, including those offered for sale by distance communications
- sets out how continuity of evidence is maintained
- includes action to be taken for unsatisfactory sampling results
- includes measures to prevent the deterioration or damage to samples whilst under control of the Food Authority<sup>11</sup>

<sup>10</sup> Article 12 (1) of Regulation (EU) 2017/625

<sup>&</sup>lt;sup>9</sup> Article 140 of Regulation (EU) 2017/625

<sup>&</sup>lt;sup>11</sup> Article 34(5) of Regulation (EU) 2017/625

#### 2.4.10 Equipment procedure

Food Authorities must ensure their equipment procedure:

- provides for the identification of equipment
- provides evidence of maintenance and calibration
- includes measures to demonstrate the results of any in service checks and the action taken where results are unsatisfactory

#### 2.4.11 Information procedure and/or arrangements

Food Authorities must ensure their information procedure and/or arrangements that they put in place:

- minimises the risk of corruption loss of information held on databases
- provides for reasonable security measures to prevent access and amendment of data held on databases by unauthorised persons
- leads to good data practices being kept and data quality maintained

#### 2.4.12 Official controls and other official activities procedure

Food Authorities must ensure their official controls and other official activities procedure 12.

- includes details on official controls and other official activities carried out on imported food
- leads to proportionate, consistent and risk-based controls being undertaken
- provides sufficient prompts to ensure official controls are effective and appropriate

#### 2.4.13 Enforcement procedure

Food Authorities must ensure their enforcement procedure<sup>13</sup>.

- leads to enforcement action being taken by their authorised officers which is reasonable, proportionate, risk based and consistent with good practice
- takes into account the following when determining appropriate action to take:
  - the hierarchy of enforcement
  - the Code for Crown Prosecutors
  - the Food Authorities enforcement policy
  - level of risks to consumer safety resulting from non-compliance
  - consumer sensitivities around the issue, leading to loss of consumer confidence or economic loss to industry
  - potential for non-compliant foods being distributed widely with large numbers of consumers affected
  - previous history of compliance
  - Primary Authority partnerships
  - Home Authority partnerships

<sup>&</sup>lt;sup>12</sup> Article 12 (1) of Regulation (EU) 2017/625

<sup>&</sup>lt;sup>13</sup> Article 12 (1) of Regulation (EU) 2017/625

### 2.4.14 Conflicts of interest procedure and/or arrangements

Food Authorities must ensure their conflicts of interest procedure and/or arrangements that they put in place, for example, a conflict of interest policy<sup>14</sup>:

Food Authorities must ensure their conflicts of interest procedure:

- means that authorised officers carrying out official controls and other official activities:
  - are free from any conflict of interest
  - are aware of the potential conflicts of interest that can arise through the promotion of the Food Authorities services
  - do not provide their own private services, to businesses, in their own time, within the area of the Food Authority that employs them or within the areas of other Food Authorities who liaise with the employing authority on enforcement matters
  - avoid the exclusive promotion of the Food Authorities services, if other providers of those services exist in the area, or the services are offered by a different organisation from outside the area
- means that potential or actual conflicts of interest do not arise as a result of Primary Authority responsibilities, chargeable discretionary services<sup>15</sup> or the contracting-out of services
- provides a clear and transparent separation between the provision of any discretionary services, such as advice or training (whether charged for or free) and the Food Authorities responsibility to perform official controls and other official activities
- includes processes so that enforcement decisions are free from any conflict of interest
- includes details on the action to take where a conflict of interest is identified, or provide a reference to other documentation where these details can be found

# 2.4.15 Control and investigation of outbreaks and food related infectious disease procedure

Food Authorities must ensure their control and investigation of outbreaks and food related infectious disease procedure:

- covers the control of outbreaks of food related infectious disease
- covers the investigation of notifications of food related infectious disease
- is developed in association with all relevant organisations
- is developed in accordance with centrally issued guidance
- requires all records relating to control and investigation of outbreaks and food related infectious disease are retained for 6 years

<sup>&</sup>lt;sup>14</sup> Article 5 (1)(c) of Regulation (EU) 2017/625

<sup>&</sup>lt;sup>15</sup> Section 93(1)(a) of the Local Government Act 2003

## 2.5 Requirements relating to documented policies

#### 2.5.1 Sampling policy

Food Authorities must ensure their sampling policy:

- is published and readily available to businesses and consumers
- sets out the Food Authorities general approach to food sampling, including unsatisfactory samples
- sets out the Food Authorities approach in specific situations such as:
  - surveillance
  - imported food monitoring
  - businesses with a Primary Authority inspection plan in place
  - interventions
  - complaints
  - special investigations
  - national, regional and local co-ordinated programmes
- covers all samples taken including those not taken in accordance with the Code
- details the factors taken into account when formulating their sampling programme, including any national or local consumer issues that will influence the level of sampling to be undertaken
- commits the Food Authority to providing the resources necessary to carry out their food sampling programme

#### 2.5.2 Enforcement policy

Food Authorities must ensure their enforcement policy:

- is readily available to FBOs and consumers
- covers all areas of food law that the Food Authority has a duty to enforce
- details the approach to enforcement, when and in what circumstances enforcement action is likely to be taken by the Food Authority, in respect of the range of enforcement actions that are available
- details the approach to revisits, except where this is already documented in another policy or procedure required under the Code
- has regard to any advice issued by the FSA and by WLGA
- does not use the number of improvement notices served or legal processes, such as prosecutions or simple cautions, as an indicator of performance
- is approved by the relevant Food Authority member forum or, where approval and management of service delivery plans has been delegated to senior officers, by the relevant senior officer
- details arrangements for ensuring compliance with food law in establishments where the Food Authority is itself the FBO, and that where any serious breach of food law is detected in such an establishment it is brought to the attention of the Food Authorities Chief Executive without delay

A Food Authorities Food Law Enforcement Policy may be part of a generic policy, or combined with other enforcement policies, providing the applicability of the policy to the enforcement of food law is clear.

The FSA may issue communications to Food Authorities on:

- new and/or revised enforcement policies
- information on food safety matters
- other issues connected with the effective enforcement of food law

Food Authorities must 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.

## 2.5.3 Complaints policy

Food Authorities must ensure their complaints policy:

- sets out the Food Authority's approach to receiving, handling and investigation of complaints about food and food business establishments
- covers complaints about food originating from inside and outside of the UK:
- leads to complaints received being investigated in accordance with the Code, centrally issued guidance and the Food Authority's policies and procedures

## 2.6 Requirements relating to documented plans

#### 2.6.1 Service plan

#### 2.6.1.1 Introduction

Service plans are seen as an important part of the process to ensure that national priorities and standards are addressed and delivered locally. Service plans also help Food Authorities to:

- follow the principles of good regulation
- focus on key delivery issues and outcomes
- provide an essential link with corporate and financial planning
- set objectives for the future, and identify major issues that cross service boundaries
- provide a means of managing performance and making performance comparisons
- provide information on an authority's service delivery to stakeholders, including businesses and consumers

When developing its service plan, a Food Authority should make it clear what period the plan covers, and what arrangements have been put in place for the regular review and updating of the plan.

#### 2.6.1.2 Format of service plan

Service plans are an expression of a Food Authorities' own commitment to the development of the food service. However, it is also important to consider the use made of the plans by the FSA, which will require information about official food

control activities in a common format to enable it to assess Food Authorities' delivery of the service.

In addition, service plans may be of use to other Food Authorities who will find analysis and comparison of their relative performance greatly facilitated by a common format. These guidelines are therefore structured in terms of a common format with chapter and subject headings specified, and a general description of the content that should form part of each. However, there is no intention to remove Food Authority flexibility to include additional items under particular headings.

It is recognised that Food Authorities have had service plans for many years and may have corporate style or templates that they wish to maintain. It is also recognised that some Food Authorities undertake the planning and review processes at separate times and issue the results of review as a separate document. Some include their plans for the food service as part of a larger plan of authority services. While there is flexibility for Food Authorities to continue with a corporate format, they must ensure that the information requirements in the Practice Guidance are included. Where food service plans form part of broader corporate plans, the food details must be separately identifiable in their planning documents.

Similarly, in those cases where several authorities are unifying as a single authority, they should ensure that the requirements of the Practice Guidance are included and are separately identifiable in the planning documents for the new unitary authority. Where an enforcement service is shared between authorities, the requirements of the Practice Guidance should be identifiable in the planning documents for each authority.

#### Food Authorities must:

- carry out, qualitative and quantitative, performance reviews of delivery against the plan, at least once per year, which must be documented<sup>16</sup>
- submit the plan for approval, whether that is at Member, Member forum or suitably delegated senior officer level, this plan can be tailored to suit their audience (for example a summary report for members) as long as a plan also exists that meets the requirements detailed in section 2.5.1.3 of the Practice Guidance
- keep records to show that plans have received appropriate approval
- ensure their service plan:
  - sets out how and at what level official food controls will be provided, in accordance with the Code
  - has regard to any advice issued by the FSA and WLGA
  - covers all stages of the food chain and sectors of the food industry, where relevant
  - is readily available to FBOs and consumers
  - clearly states the period of time during which the plan has effect

<sup>&</sup>lt;sup>16</sup> Chapter 2, Paragraph 3.2 of the Framework Agreement

- covers the following 6 areas in section 2.5.1.3<sup>17</sup>
- is drafted in accordance with the guidance, detailed at section 2.5.1.3 of the Practice Guidance, taking account of and making reference to, where relevant, the following:
  - all food law enforcement issues (including import controls) and considers resource demands and availability (including any shortfall) to deliver the planned intervention programme, including out of hours capacity and provision
  - the Food Authorities approach to enforcement
  - how new food business establishments are identified and how they are to be included in the Food Authorities planned intervention programme
  - the approach to revisits and enforcement (unless included in the Food Authorities enforcement policy)
  - how the quality of the Food Authorities Service is assessed and monitored including identification of database inaccuracies, review of annual targets, and identification of issues with consistency and competency
  - details of any variances in meeting the plan, from previous years, and how this is proposed to be addressed<sup>18</sup>
  - a statement in relation to the Food Authorities sampling policy including the basis of the sampling programme
  - details how sampling/intervention programmes and enforcement activities are developed and implemented with due consideration of the National Enforcement Priorities (NEPs), which must include information on any specific activities undertaken to implement them (this may be a simple bullet point list of planned activities)
  - what local and/or regional intelligence sources have the Food Authority considered when planning their official controls
  - details of the Food Authorities' plans for continuous improvement
  - details what arrangements have been put in place for the regular review and updating of the plan
  - what, if any, grant money available from the FSA the Food Authority has been allocated and used

The FSA may require Food Authorities to review their service plan, for example to accommodate the work of approved feasibility studies, pilots or pathfinder projects.

The FSA will communicate any relevant work that may impact on service plans to Food Authority so that they can be reviewed.

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<sup>&</sup>lt;sup>17</sup> However, each authority may choose its own way of formulating these plans – such as placing some aspects in management plans, and some in operational plans <sup>18</sup> Chapter 2, Paragraph 3.3 of the Framework Agreement

# 2.6.1.3 Template service plan

# 1. Service Aims and Objectives

1.1 Aims and objectives	A statement of the service's aims and objectives
1.2 Links to corporate objectives and plans	This section should identify how the service plan(s) fit into the Food Authority's corporate planning process and how it plays it's part in meeting the Food Authority's objectives. This should include meeting any relevant national indicator. It should also identify any cross linkage with other plans that have been adopted by the Food Authority.

# 2. Background

2.1 Profile of the Food Authority	This section should include details of the population, size and nature of the Food Authority
2.2 Organisational structure	A simple chart showing the council services and committee structure which shows where the food service fits in. The structure should identify the manager/s responsible for the delivery of official food controls and the officer/s with specialist responsibility for food hygiene and/or food standards if different, and the provision made for specialist services provided, for example, by public analysts and food examiners.
2.3 Scope of the food service	A brief statement that sets out the scope of the responsibilities and service provided. This should identify where areas of the food service are provided by another organisation for example contractors. Any other services that are delivered alongside the food service, for example health and safety inspections, can be described here.
2.4 Demands on the food service	This section should include a brief outline of:  the establishments profile the number of approved or registered establishments in the Authority's area any particular local requirements associated with specialist or complex processes

• the times at which the service is available from these points

This section also enables the Food Authority to describe any external factors that may impact on their service, for example:

- the percentage of business owners whose first language is not English
- the percentage of food establishments that are manufacturing foods
- imported food responsibilities
- seasonal activities

#### 2.5 Regulation policy

A brief reference statement to the Food Authority's documented enforcement policy

## 3. Service delivery

# 3.1 Interventions at food establishments

A statement in relation to the Food Authority's policy on interventions and how they will be selected in individual cases, including details of the programme of interventions at food establishments to be undertaken. This should include:

- the establishments profile
- the numbers of interventions programmed
- an estimation of the number of revisits that will be made
- an estimation of resources required for example staffing

The plan should also detail any targeted intervention activity that the Food Authority intends to carry out including any extra resources this may require; this could include specific project work.

The Food Authority should identify any priorities relating to nationally or locally driven outcomes, such as compliance with new legislation or improved compliance with existing legislation and other central government initiatives.

The section should include, where appropriate, the arrangements the Food Authority has made to ensure that they have access to adequate appropriate expertise to enable competent inspection of any specialised processes identified in Section 2.

3.2 Food complaints	A statement in relation to the Food Authority's policy regarding the investigation of food complaints
	including an estimation based on previous years' trends of the likely demand on the service and an estimation of the resources required.
3.3 Home Authority and Primary Authority	A statement in relation to the Food Authority's policy on the Home Authority principle and, where applicable, Primary Authority, including an estimation of the resources required in relation to meeting and advising those businesses for whom it acts, developing inspection plans for those businesses for whom it is the Primary Authority, and responding to notifications and enquiries from other enforcing authorities. The statement should also include details of how delivery will be resourced.
3.4 Advice to business	A statement in relation to the Food Authority's policy regarding advice to business (as part of the overall policy of interventions) including an estimation of the number of contacts from business and the resources necessary to provide the service. This section should include, where appropriate, any input the Food Authority has to business partnerships or forums.
3.5 Food sampling	A statement in relation to the Food Authority's sampling policy including the basis of the sampling programme and an estimate of the numbers of samples that will be taken from establishments, or submitted in relation to complaints, and any relevant resource allocation including staffing. It should also detail the arrangements that the Authority has made for the analysis and/or examination of the samples.
3.6 Food safety incidents	A statement in relation to the Food Authority's policy on handling food alerts to confirm that it complies with the relevant Codes of Practice; an estimation of the likely demand on the service and an estimation of the resources required.
3.7 Liaison with other organisations	The Food Authority should set out the arrangements it has made to ensure that enforcement action taken in its area is consistent with those of neighbouring Food Authorities. This section should include:
	<ul> <li>any liaison the Food Authority has with other Food Authorities</li> <li>any liaison, where appropriate, with the Department for Business, Energy &amp; Industrial Strategy (BEIS)</li> </ul>

3.8 Food safety and standards promotional work	<ul> <li>any arrangements with other official control bodies or government inspectorates to co-ordinate food controls</li> <li>any representation on Government working groups or committees</li> <li>liaison with professional body working groups</li> <li>liaison and involvement/participation with relevant food liaison advisory groups and similar or related bodies</li> <li>any formal liaison with voluntary groups and other public sector bodies</li> <li>any formalised liaison with other services within the Authority</li> <li>any commitment to local/regional groups</li> </ul> An estimation of the resource allocation should be included A statement of any food safety/standards promotional work, or information/intelligence gathering work, which the Food Authority intends to carry out in the year and the measures it will use to evaluate its effectiveness, with an estimate of the resource allocation including staffing to undertake this work.
3.9 Control and investigation of outbreaks and food related infectious disease	A statement in relation to the Food Authority's policy on the investigation of food poisoning notifications and outbreak control including an estimation based on previous years' trends of likely demand on the service and an estimation of the resources required.

## 4. Resources

4.1 Financial allocation	This section should set out the overall level of expenditure involved in providing the service and examine the trend of growth or reduction in real terms. Detail shall be provided in terms of the non-fixed costs including staffing, travel and subsistence, equipment including investment in IT, sampling budgets and the financial provision made by the Food Authority for any legal action necessary as part of their enforcement function.
4.2 Staffing allocation	A statement of the number of posts required to deliver the service, and of the number of staff working on food law enforcement and related matters (in terms of full-time equivalents); this should distinguish qualified staff from support staff. These figures should be expressed in terms of levels of competency

	with reference to the Code, including support staff.
4.3 Staff development plan	A statement in relation to any relevant ongoing training, including that to be provided in-house and externally for authorised and trainee officers in the year ahead.
5. Quality Assessment	

5.1 Quality assessment and internal monitoring	A statement specifying the measures to be taken to assess the quality of the Food Authority's service including any relevant monitoring arrangements developed by the Authority to assess performance against the Standard. This should include any agreed inter-authority audit or peer review arrangements. The Food Authority will also wish to include details of any externally accredited or self-assessment models used.
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# 6. Review

6.1 Review against the service plan	The Food Authority should set out the process for reviewing and reporting delivery of the service plan.  This should include information on the previous year's performance against the service plan and any specified performance targets and performance standards and targeted outcomes.
6.2 Identification of any variation from the service plan	The review should identify where the Food Authority was at variance from their service plan and, where appropriate, the reasons for that variance. The Food Authority may determine that additional work it has carried out in other areas of the enforcement mix has achieved the same objective. This should be clearly identified in this part of the plan.
6.3 Areas of improvement	The Food Authority should set out plans for any relevant improvement or service development identified as necessary by the review or the quality assessment.

# 2.6.2 Contingency plans

Food Authorities must ensure their contingency plan:

- provides details of Food Authorities and other agencies to be involved
- sets out the powers and responsibilities of those Food Authorities and agencies
- details the channels and procedures for sharing information between the Food Authorities and agencies involved
- covers arrangements for occasions where authorised officers are absent, for example, if only one officer is authorised to undertake particular controls, these arrangements could include officers in other Food Authorities being authorised temporarily to undertake these functions

# 2.7 Requirements relating to documented programmes and strategies

# 2.7.1 Intervention programme

Food Authorities must ensure their intervention programme:

- delivers an appropriate and effective<sup>19</sup>, risk-based programme of interventions<sup>20</sup> in line with the Code
- includes all registered and approved food business establishments
- is based on the relevant intervention rating scheme (food hygiene and/or food standards) determined in accordance with Chapter 4 of the Code
- applies official controls to exports with the same care as to the placing on the market within the United Kingdom provides mechanisms requiring authorised officers to:
  - have regard to Primary Authorities assured advice
  - follow inspection plans
- makes use of information supplied to them by FBOs in connection with the registration or application for approval of their food business establishments in order to determine when to carry out interventions
- is planned so that establishments receive an intervention no later than 28 days after the relevant date detailed in Chapter 4 of the Code
- is adequately resourced

# The FSA may:

 require Food Authorities to depart from their intervention programme, for example:

- to accommodate the work of approved feasibility studies, pilots, or pathfinder projects
- in response to an emerging incident or national programme of work

<sup>20</sup> Article 9(1) of Regulation (EU) 2017/625

<sup>&</sup>lt;sup>19</sup> Article 5(1)(a) of Regulation (EU) 2017/625

The FSA will communicate any relevant work that may impact on intervention programmes to Food Authorities so that intervention programmes can be reviewed. Food Authorities should contact the FSA if such direction presents a significant disruption to their ability to deliver a risk-based intervention programme.

Single-tier Food Authority areas may opt to base their planned intervention programme on the food hygiene risk assessment scheme under the Code. Food Authorities that exercise this option must ensure that:

- interventions consider both food hygiene and food standards
- interventions occur no less frequently than would have been the case had both schemes been used
- a food standards risk assessment is completed and recorded

#### 2.7.2 Sampling programme

Food Authorities must ensure their sampling programme<sup>21</sup>:

- details the intended food sampling priorities
- is risk based<sup>22</sup> and takes account of:
  - the number, type, size and intervention ratings of food business establishments in their area
  - the type of food produced in the area
  - the procedures adopted by the food business to ensure compliance
  - imported foods
  - the Food Authorities Primary Authority, Home Authority or originating authority responsibilities
  - the need to ensure that the provisions of food law are enforced
  - be planned to avoid foods that are already being looked at on a wider basis
- consider the main objectives of food sampling:
  - protecting health
  - detecting deceptive and fraudulent activities
  - compliance with labelling requirements
  - providing advice to FBOs
  - promoting fair trade and deterring bad practice
- consider the following to ensure the sampling programme is effective:
  - whether the Food Authority is the Primary Authority or originating authority for any food premises that deal in unusual food
  - are there food manufacturers in the area
  - are there any distribution centres which deliver food to a wide area
  - what type of food additives do FBOs (for example food manufacturers, and importers) use in the area

<sup>22</sup> Article 9(1) of Regulation (EU) 2017/625

- do national Sampling Programmes highlight any food types which relate to specific premises in the area
- national or regional imported food priorities/surveys and the UK's National Control Plan

With regards to imported food, the sampling programme should take account of:

- any statutory requirements for sampling laid down in Retained EU Law
- any agreed WLGA/FSA sampling programmes
- any sampling required following a Food Alert, Early Warning System (EWS) or relevant notification
- information from any WLGA, regional liaison group, local or other sampling survey
- any imported food where there is no known history or information on the product
- local priorities, including consumer complaints relating to imported food

Consideration must also be given to the following risk-related issues for all samples taken:

- the severity of the effect of any given fault with the food
- the likelihood of the occurrence of the fault
- the consumption pattern applicable to the food
- the degree and distribution
- the degree of control and monitoring exercised by the manufacturer for all potential faults
- the stage in the production and distribution chain at which the problem can occur or could be more easily detected
- the compliance history of a food business
- emerging national and international concerns
- local consumer and business concerns

### 2.7.3 Training programme

Food Authorities must ensure their training programme<sup>23</sup>

- sets out how authorised officers undertaking official controls and other official
  activities will receive appropriate training and on-going continuing professional
  development (CPD) to allow them to carry out their duties competently and
  which is appropriate to their level of authorisation
- sets out the process for reviewing CPD and training needs, so that authorised officers keep their areas of competence up to date and include process for identifying additional training needs
- includes training on subject matters set out in Chapter 1 of Annex II of Regulation (EU) 2017/625

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<sup>&</sup>lt;sup>23</sup> Article 5 (4) of Regulation (EU) 2017/625

- includes, where appropriate, training for staff carrying out physical checks on products of animal origin at Border Controls Posts (BCPs) on the subject matters as set out in Chapter 3 of the Practice Guidance
- provides how records of qualifications, training and on-going CPD are maintained

This training programme may be included within the authorisation procedure.

# 2.7.4 Alternative enforcement strategy

Food Authorities that decide to subject food business establishments to alternative enforcement strategies must ensure their alternative enforcement strategy:

- sets out their strategies for maintaining surveillance of these establishments in either their food service plan or enforcement policy, which could include making use of:
  - questionnaires
  - surveys
  - project based inspections (which would normally be combined with another type of intervention)
  - intelligence gathering visits
- does not permit alternative enforcement strategies to be used for food business establishments subject to approval under Regulation (EC) No 853/2004
- does not preclude full inspection, partial inspection or audit of these establishments, where these are the Food Authorities preferred intervention option
- includes measures to establish that food business establishments are subject to initial inspection and risk rated in accordance with Chapter 4 of the Code, before determining that alternative enforcement strategies are appropriate
- allows interventions to be carried out at establishments subject to alternative enforcement strategies where there has been:
  - a consumer complaint
  - planning or building regulation applications
  - an infectious disease notification
  - changes in activities or management
  - a non-return of a questionnaire
- includes measures to establish that a random percentage of these businesses are subject to inspection

# 2.8 Local, regional and national liaison

#### 2.8.1 Liaison

Chapter 2 of the Code provides that Food Authorities must respond to any reasonable communication from other Food Authorities requesting information or assistance. Examples of when Food Authorities may request information or assistance may include:

- referrals of cross boundary enforcement issues or concerns
- referrals of food complaints reported to a Food Authority
- information to help coordinate enforcement/infectious disease control activities
- information to help Food Authorities responsible for delivery of official feed controls ensure registers of feed business establishments are complete and accurate in respect of businesses who manufacture or place on the market products for use in feed

Upon receiving a request or referral, a Food Authority should take the following action:

- acknowledge receipt of the communication and advise the originating Food Authority that the matter is being dealt with
- investigate and/or take appropriate enforcement action, if necessary
- inform the originating Food Authority of any action taken
- ensure that responses to requests are open, transparent and provided without undue delay
- keep the originating Food Authority updated on progress, particularly when action is ongoing, and the outcome will not be known for some time

# 2.8.2 Liaison points of entry

Chapter 2 of the Code requires Food Authorities with points of entry or External Temporary Storage Facilities (ETSF) to liaise with relevant local organisations. These organisations include, where appropriate:

- neighbouring Food Authorities (particularly for joint boards and ports, which fall under the jurisdiction of more than one Food Authority, including County Councils for certain Trading Standards responsibilities)
- Her Majesty's Revenue and Customs (HMRC)
- Border Force
- Convention on International Trade in Endangered Species (CITES) teams
- Animal and Plant Health Agency (APHA)
- Public Health Wales (PHW)
- Food and Environment Research Agency (FERA)
- port operator
- import agents
- Internal Temporary Storage Facilities operators
- External Temporary Storage Facilities operators
- Maritime and Coastguard Agency (MCA)
- Medicines and Healthcare products Regulatory Agency (MHRA)
- relevant Primary Authorities

# 2.9 Primary Authority

# 2.9.1 Primary Authority Scheme

The principles of Primary Authority are set out in parts 1 and 2 of the Regulatory Enforcement and Sanctions Act (RESA) 2008 and are administered by the Office for Product Safety and Standards (OPSS) on behalf of the Secretary of State for the Department for Business, Energy and Industrial Strategy (BEIS). The FSA works with OPSS in its work to support the delivery of Primary Authority for food regulators to deliver consistency between Food Authorities and avoid unnecessary duplication of regulatory effort.

The scheme gives businesses the right to form a statutory partnership with a Food Authority, which then provides robust and reliable advice that other Food Authorities must respect. The scope of Primary Authority extends only to reserved matters so, for food and feed, the scheme operates only in England and Wales. Food businesses trading in both England and Wales that wish to benefit from Primary Authority in both nations will need to partner with both a Primary Authority in England and a Primary Authority in Wales.

A Primary Authority can support its partner business in complying with regulations by:

- issuing assured advice
- coordinating enforcement action
- developing an inspection plan

Food Authorities must have regard to Primary Authority and to the <u>BEIS Primary</u>
<u>Authority Statutory Guidance</u>, specifically to Part E, which provides guidance on their responsibilities as 'enforcing authorities' within Primary Authority.

#### 2.9.2 Identifying businesses in Primary Authority

Food Authorities must have regard to Primary Authority in their planning and delivery of official controls; for example, by routinely accessing the scheme's secure IT system to determine whether businesses with whom they are dealing have Primary Authority partnerships. Food Authorities should use the information held on the <a href="Primary Authority Register">Primary Authority Register</a> to determine whether businesses with whom they are dealing have Primary Authority partnerships.

The Primary Authority Register should also be used to identify whether Primary Authority advice has been issued by the Primary Authority to businesses and whether an inspection plan in place.

#### 2.9.3 Inspection plans

Primary Authorities can produce an inspection plan for the business(es) in their partnership. An inspection plan helps guide enforcing authorities through their inspection process and other checks, such as sampling visits and test purchases, focusing activity to where it is most needed.

An inspection plan must be approved by the Secretary of State before being published in the secure area of the Primary Authority Register for regulators to view. Authorised Officers should check the <a href="Primary Authority Register">Primary Authority Register</a> to identify whether an inspection plan exists for a business before they carry out an official control.

Where there is a Primary Authority inspection plan in place Authorised Officers must follow it and provide feedback to the Primary Authority if required, except in circumstances where:

- a request to follow an alternative approach has been made to the Primary Authority, and the Primary Authority has either agreed or has failed to respond within the required period of 5 working days
- a possible non- compliance is identified during the course of a proactive intervention that need to be addressed

# 2.9.4 Compliance issues and enforcement action

Where a Food Authority is considering its response to possible non-compliance by a business that has a Primary Authority, it should take account of any Primary Authority advice issued and consider appropriate communication with the Primary Authority at an early stage.

If enforcement action<sup>24</sup> is envisaged the Food Authority must notify the Primary Authority, in accordance with the Primary Authority statutory requirements. Notification should be made via the <u>Primary Authority Register</u>.

In most cases this should be done before action is taken, except where there is an urgent need to avoid significant risk of harm to human health, the environment or financial interests of consumers, where the enforcement action must be notified retrospectively.

Notification allows the Primary Authority to review the proposed enforcement action and to decide whether it is inconsistent with the Primary Authority advice issued. A Primary Authority can direct against any enforcement action if the action is considered inconsistent with advice that has been issued.

Where there is disagreement between any of the three parties – the Primary Authority, the enforcing authority, and the business – as to whether the proposed enforcement action is inconsistent with Primary Authority advice and whether that advice was correct and properly given by the Primary Authority, the Secretary of State is consulted and makes a determination.

Further details are set out in the BEIS Primary Authority Statutory Guidance.

#### 2.9.5 Supporting regulator

The FSA became a Primary Authority supporting regulator on 1 October 2017 following changes introduced by the <a href="Enterprise Act 2016">Enterprise Act 2016</a>. Primary Authorities can

<sup>&</sup>lt;sup>24</sup> Defined in Regulation 5 of the Coordination of Regulatory Enforcement Regulations 2017 (CORE)

seek support from supporting regulators in relation to the provision of Primary Authority Advice or the development and management of an inspection plan.

Further <u>guidance and request template</u> are available on the FSA Smarter Communications Platform (Smarter Comms).

# 2.10 Facilities and equipment

#### Food Authorities should:

- provide officers with the equipment and facilities necessary to enable them to carry out the full range of food controls:
  - competently
  - in accordance with food law
  - in accordance with the requirements of the Code
  - provide officers who carry out interventions with clean protective clothing, including headgear, consistent with good industry practice
- require officers, when inspecting businesses to:
  - wear protective clothing
  - give any relevant information on their health status when requested
  - adhere to any reasonable precautions that are required by the business

The Code requires that appropriate equipment is available, which means that it may be shared with other Food Authorities, provided they will be readily available for use, when required, so as not to impede the effective delivery of official controls.

# 2.11 Enforcement e-mail addresses

As required by Chapter 2 of the Code, Food Authorities must notify the FSA of the email address to which communications can be sent to <a href="mailto:lasupportwales@food.gov.uk">lasupportwales@food.gov.uk</a>.

# 2.12 Registration of food establishments

### 2.12.1 What is a food business establishment?

Article 2(c) of Regulation (EC) No 852/2004 defines 'establishment' as any unit of a food business.

A 'food business' as defined in Article 3(2) of Regulation (EC) No 178/2002 means any undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to any stage of production, processing and distribution of food.

A food business establishment may include units where food may not be handled, but where decisions are made on relevant aspects of the food business such as the food's movement/ transportation and/or labelling.

# 2.12.2 Who is a Food Business Operator (FBO)?

Article 3(3) of Regulation (EC) No 178/2002 defines a 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.

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 (EC) No 852/2004, Food 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 a charity, limited company, organisation or trust that operates it, partnerships and sole traders.

# 2.12.3 Requirement to register a food business establishment

Under Article 6(2) of Regulation (EC) No 852/2004, FBOs must register the establishment(s) under their control with the appropriate Food Authority.

Food Authorities should advise FBOs to submit a registration of a food establishment at least 28 days before the business starts trading or the food operations commence.

Food Authorities are encouraged to make information available to businesses on the requirements relating to registration.

There may be situations when a 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 Food 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.).

# 2.12.4 Channels of registration

Food Authorities should require FBOs to register to provide them with full details of the activities undertaken at the establishment(s) under their control.

Under the Regulation 32(1) of the Provision of Services Regulations 2009, Food Authorities must have an electronic means for FBOs to register food business

establishments. Digital registration is the preferred method for registration and FBOs should, where possible, be encouraged to complete their registration online.

The Register a Food Business (RAFB) online service is a tool for FBOs to register their food business with the Food Authority responsible for food safety in their area. This service can be accessed via the <u>FSA website</u>, or through the participating Food Authorities' website.

Food Authorities are encouraged to help those FBOs requiring support to complete their registration online. Support can be given in person at the establishment, over the phone or by inviting a FBO into the office.

#### 2.12.5 Use of Information from other sources

Where information about the address of the establishment and the activity carried out is already available for other sources as provided below, that information may be used for registrations purpose<sup>25</sup>.

## 2.12.5.1 Primary production

Establishments at the level of primary production that have been registered with the Rural Payments Wales (RPW) prior to 1 December 2006 are considered registered for the purposes of Article 6(2) of Regulation (EC) No 852/2004.

## 2.12.5.2 Fishing vessels

Fishing vessels at the level of primary production that have been registered with the Marine Management Organisation (MMO) are considered registered for the purposes of Article 6(2) of Regulation (EC) No 852/2004. This list is published online by the MMO.

# 2.12.6 Exemptions from registration

# 2.12.6.1 Degree of organisation and continuity of activities

Establishments which undertake food activities that do not involve a certain degree of organisation and a continuity of activities<sup>26</sup> do not meet the definition of a food business establishment, so fall outside the scope of Regulation (EC) No 852/2004. Therefore, registration is not required for establishments who occasionally handle food.

The FSA guidance on the application of EU food hygiene law to community and charity food provision, has been published to provide clarity on Recital 9<sup>27</sup>.

Furthermore, the European Commission 'guidance document on the implementation of certain provisions of Regulation (EC) No 852/2004 on the hygiene of foodstuffs' states that 'somebody who handles, prepares, stores or serves food occasionally and on a small scale cannot be considered as an 'undertaking'.

<sup>&</sup>lt;sup>25</sup> Article 10(2) of Regulation (EU) 2017/625

<sup>&</sup>lt;sup>26</sup> Recital 9 of Regulation (EC) No 852/2004

<sup>&</sup>lt;sup>27</sup> Article 3(2) of Regulation (EC) No 178/2002

Although such establishments are exempt from registration requirements, they do, however, remain subject to certain provisions of the Food Safety Act 1990 and Regulation (EC) No 178/2002.

An example would be in respect of a charitable or community event where a private person prepared cakes for a bake sale, but inadvertently substituted a dangerous substance for a food ingredient.

Further advice as to which food suppliers or sellers might not count as undertakings can be found in the FSA guidance document <u>Guidance on the application of EU food hygiene law to community and charity food provision</u>.

## 2.12.6.2 Approved establishments

Article 4(1)(b) of Regulation (EC) No 853/2004 stipulates that food establishments that are subject to approval under Regulation (EC) No 853/2004 are not required to also register with the Food Authority under Regulation (EC) No 852/2004.

#### 2.12.6.3 Other exemptions

Article 1(2) of Regulation (EC) No 852/2004 set out the circumstances under which the requirement to register under Article 6(2), would not apply, namely:

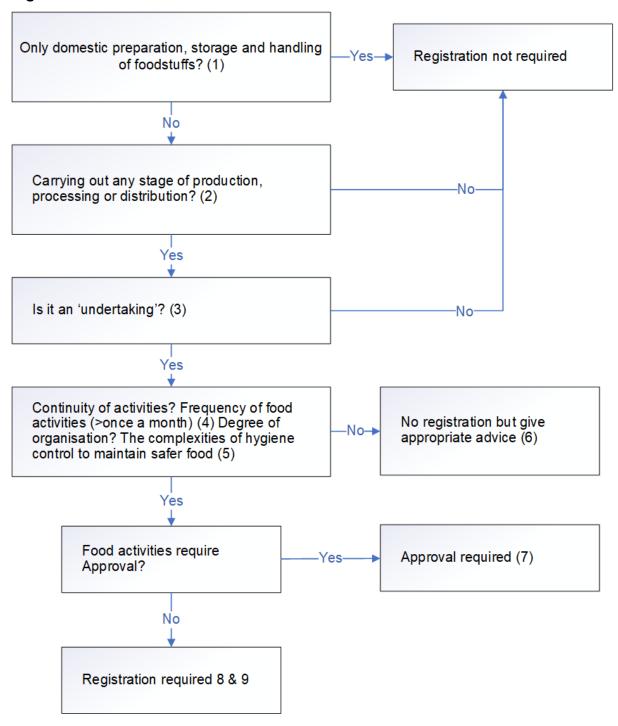
- primary production for private domestic use
- the domestic preparation, handling or storage of food for private domestic consumption
- small quantities<sup>28</sup> of primary products supplied directly by the producer to the final consumer or to local retail establishments directly supplying the final consumer
- 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

<sup>&</sup>lt;sup>28</sup> For further information see <u>guidance</u> on approval of food establishments.

# 2.12.6.4 Registration flow chart

Figure 1 provides a decision tree to help determine which food activities require registration with the Food Authority.

Figure 1



## 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<sup>29</sup>.
- 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<sup>30</sup>.
- 3. 'Undertaking' is not defined in food law but the <u>EU Commission document</u> suggests that an undertaking is not somebody who handles, prepares, stores or serves food occasionally and on a small scale.
- 4. Continuity of activities<sup>31</sup> 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.
- 5. Degree of organisation<sup>32</sup> 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 <u>guidance</u> on the application of EU food hygiene law to community and charity food provision.
- 6. Food Authorities should advise that if food operations change, they should contact the relevant Food Authority to check whether registration is subsequently required.
- 7. Approvals guidance available on Smarter Comms.
- 8. Guidance and online registration on the FSA website.

#### 2.12.7 Action on receipt of a completed registration

On receipt of a completed registration form, Food Authorities should record the date of receipt on the submission. Where any activities indicated on the form fall outside of their enforcement remit, the relevant Food Authority should be notified as soon as practicable.

For LAs on the RAFB service this will be recorded automatically by the system.

Food Authorities should enter relevant information from the registration form onto their database of registered food business establishments. The registration form should then be placed on a file (electronic or otherwise) prepared in respect of each food business establishment.

If an establishment is undertaking any activity which could be deemed high risk, this should be taken into account when prioritising initial inspections.

<sup>&</sup>lt;sup>29</sup> Article 1(3) of Regulation (EC) No 178/2002 and Article 1(2)(b) of Regulation (EC) 852/2004

<sup>&</sup>lt;sup>30</sup> Article 3(16) of Regulation (EC) No 178/2002

<sup>31</sup> Recital 9 of Regulation (EC) No 852/2004

<sup>32</sup> Recital 9 of Regulation (EC) No 852/2004

Food Authorities should keep application forms relating to establishments in a format that maintains their admissibility as evidence if required.

If any information is omitted from a registration form submitted by a FBO, the Food Authority should either make contact with the FBO to obtain the missing information or, if a substantial amount of information is missing, return the submission to the FBO for full completion.

On receipt of a completed application form, Food Authorities should have regard to Chapter 4 of the Code with respect to carrying out any inspection, if required.

# 2.12.8 Acknowledgement of registration

Food Authorities should acknowledge receipt of a submitted food business registration.

The confirmation of registration will include a reminder to the FBO to advise the Food Authority of any subsequent changes to the business, in accordance with Article 6(2) of Regulation (EC) No 852/2004.

Where a Food Authority is connected to the RAFB service, acknowledgement of an application to register by an FBO is sent automatically by the service. The Food Authority may wish to send their own acknowledgement in addition.

# 2.12.9 Changes to food establishment operations

Under Article 6(2) of Regulation (EC) No 852/2004, FBOs must ensure that the appropriate Food Authority always has up-to-date information on their food establishment(s) and must notify their registering Food Authority of any significant changes to the operation and closure.

This requirement includes changes to both the operation and the operator.

Significant changes are considered to include changes in, or ceasing of:

- food activities
- ownership
- changes to the details previously supplied

#### 2.12.10 Change of ownership following registration

Food Authorities may come across changes of ownership during interventions at food business establishments. The FBO by virtue of Article 6(2) of Regulation (EC) No 852/2004 is required to notify the Food Authority of any significant changes, which includes change of ownership. Not complying with this requirement is an offence under Regulation 17 of the Food Hygiene (Wales) Regulations 2006.

The table below 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 in registration document)	Change of FBO (assuming no other changes to the business)	Comments	New registration required?
Sole trader, partnership or incorporated company (for example Ltd, PLC, etc.)	Different sole trader, partnership or incorporated company takes over ownership	Discontinuation of operator/s	Yes
Sole trader or Partnership	Company incorporated (and registered), sole trader or partner/s become Director/s	Creation of a company changes the legal matrix of FBOs	Yes
Sole trader	Creation of a partnership where the sole trader is one of the partners	Continuation of operator	No
Partnership	Dissolved and one of the partners takes over sole ownership as a sole trader	Continuation of operator	No
Partnership	New partner joins or a partner leaves, as long as there is a continuation of at least one partner  Continuation of operator  No		No
Incorporated company	Company goes into administration and run as a going concern by administrators	Discontinuation of operator/s	No

Existing FBO (as stated in registration document)	Change of FBO (assuming no other changes to the business)	Comments	New registration required?
Incorporated company in administration	Company taken over from administrators by a different sole trader, partnership or incorporated company	Discontinuation of operator/s, registration expires	Yes
Sole trader, Partnership or Incorporated Company	Bankruptcy, insolvency or in liquidation (wound up/dissolved)		Not applicable

Other business types such as co-operatives, registered charities and other specialised types of organisation (for example 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 ensure that food law is complied with within the food business under their control.

# 2.12.11 Multisite and satellite operations

# 2.12.11.1 Multiple premises constituting a single food business establishment

There are circumstances where a single registration, under the same FBO, is permissible of a food business operating at multiple sites. In these circumstances, authorised officers may prefer to consider separate sites and/or locations as part of a wider establishment for the purposes of registration under Article 6 of Regulation (EC) No 852/2004 and for intervention rating in accordance with Chapter 4.

In these situations, 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 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 Hazard Analysis Critical Control Points (HACCP) based procedures from the production site through their own retail outlet/s to the final consumer.

This flexibility may only be applied where the main focus of the establishment's activities is that of a retail business, i.e. when supply of food is direct to the final consumer.

Food Authorities should consider such businesses on a case by case basis to ensure that all three of the following criteria are satisfied:

- the operation is under a single 'controlling mind', that is, the natural or legal person or persons, is responsible for the implementation of 'HACCP based procedures', is the same between all sites
- one set of 'HACCP based procedures' covers all stages and units of the operation across the wider establishment
- all the activities undertaken at the various units within the linked establishment are within close enough proximity that it can be reasonably expected that the single 'controlling mind' can effectively manage the food safety management controls at all sites

Where all three criteria are met, but the main activity of the establishment is the supply of POAO to other businesses, then approval is required (unless it meets the permitted exemptions in Article 1(3) of Regulation (EC) No 853/2004). Food Authorities should refer to and consider the guidance document on the <a href="mailto:implementation">implementation of certain provisions of Regulation (EC) No 853/2004 on the hygiene of food of animal origin.</a>

Where one or more of the criteria laid out above cannot be met, the Food Authority should require a food registration for each individual food establishment identified in the operation (unless the establishment is subject to approval).

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'.

# 2.12.11.2 Enforcement and oversight of multi-sites operating under a single registration

Due to the practicalities of an officer maintaining the necessary ongoing oversight and assessment of such set-ups operating as a registration, it is recommended that this flexibility is only applied to establishments within the same Food Authority area. However, there will be occasions where businesses meeting the criteria set out in section 2.11.1 of the Practice Guidance operate across Food Authority boundaries.

It is recommended that the relevant Food Authorities consider together whether it is practical to put in place a procedure that allows this flexibility. 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 registration may or may not be appropriate. These are in no way prescriptive or exhaustive and are for illustrative purposes only.

# 2.12.11.3 Examples of when single food establishment registration would apply

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

A catering establishment or 'hub kitchen' that 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.

# **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'.

# 2.12.11.4 Examples of when single food establishment registration would not apply

# **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 registration criteria are not fulfilled, and the single registration flexibility should not be applied.

### Example 2 - Supply to retail outlet

A bakery supplies freshly baked food products 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.

#### 2.12.12 Movable food business establishments

The following sections refer to food establishments which move between fixed locations and usually via scheduled routes.

Although ocean-going ships, aircraft, trains and long-distance coaches are subject to the provisions of Regulation (EC) No 852/2004; their movable nature generally means that there is little practical value in the registration of individual vehicles with UK Food Authorities, as they are not always present in the same area of jurisdiction. The following sections outline the arrangements for registration of movable establishments:

## 2.12.12.1 Ships and vessels

FBOs must register vessels under their control which meet the definition of a food business establishment, unless they require approval (i.e. freezer and factory vessels). This includes:

- vessels which are permanently moored in the UK (floating restaurants)
- vessels which are engaged for the purposes of catching, gathering and distribution of food
- passenger vessels which ply their trade on inland water ways and travel the same routes, never leaving territorial waters for example cross channel ferries, river ferries and pleasure craft.

If the vessel routinely calls at more than one UK port, the 'registering authority' should usually be the Port Health Authority where the vessel has its 'home port' as a registered vessel with the Maritime and Coastguard Agency (MCA).

#### 2.12.12.2 Aircraft

Airlines and in-flight caterers that are food businesses should register with the most appropriate Food Authority. This is usually the Food Authority or Port Health Authority within which company policy and management decisions on food safety are made.

### 2.12.12.3 Trains and coaches

Train and coach operating companies that are food businesses should register with the most appropriate Food Authority. This is usually the Food Authority within which company policy and management decisions on food safety are made.

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 Food 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 operations (which provide food) are co-located, the registering Food Authority itself can undertake these inspections.

#### 2.12.12.4 Markets

In the case of vehicles and stalls (whether or not these facilities are provided by the market controller) used for transporting, preparing or selling of food to consumers within the area of a market, the FBO should register the establishment with the Food Authority in which their food stocks are ordinarily stored.

#### 2.12.13 Mobile food establishments

The following sections refer to food establishments that have the mobility to trade in more than one location, other than those movable food establishments described in section 2.10.12 of the Practice Guidance.

# 2.12.13.1 Registration requirements

Mobile food establishments are required to be registered by the FBO with the Food Authority (the registering Food Authority) within which the establishment is ordinarily kept or returns to between trading. For example, the private residence house of the owner of the mobile food establishment.

Following registration, the FBO should not be asked to register with any other Food Authority in whose area it trades.

# 2.12.13.2 Food Authority responsibilities

Food Authorities are responsible for carrying out official controls of the activities undertaken by a mobile establishment that operates in their area.

Inspecting Food Authorities should contact the registering Food Authority before any intervention to:

- seek up to date information regarding the establishment
- determine whether an inspection is due
- if an intervention is due, the type of intervention that may be appropriate in the circumstances (for example full inspection, partial inspection or audit)

The registering Food Authority has the discretion to decide whether it needs to undertake any specific intervention, for example in circumstances, where full inspection has been carried out by the inspecting Food Authority in whose area the mobile establishment operates.

To ensure consistency and to avoid 'over inspection', the inspecting Food Authority must provide the registering Food Authority with information relating to interventions undertaken of mobile establishments operating in their area.

Details of interventions and enforcement action should be passed to the registering Food Authority as soon as possible, following an intervention. The registering Food Authority should take account of information supplied in determining the intervention rating, when this should be revised in accordance with Chapter 4 of the Code and be recorded on the Food Authorities database of food establishments.

#### 2.12.13.3 Mobile food business with multiple units

Where a food business operates more than one mobile establishment, consideration should be given as to whether it is appropriate to register the business as one single establishment (i.e. where there is a single 'controlling mind') or register each individual mobile establishment. In making this decision, Food Authorities should determine whether the food business satisfies the criteria in section 2.10.11.1 of the Practice Guidance. Only when all three criteria are met, should a single food business registration be accepted.

# 2.12.13.4 Risk rating of mobile establishments

Food Authorities should carry out risk rating for mobile establishments registered with them when due. This should be based on their own inspection and a consideration of information provided by inspecting Food Authorities where an appropriate intervention has taken place. The risk rating should result from an intervention that has included observations of a business in operation where possible.

#### 2.12.13.5 Sources of information on mobile food establishments

The Nationwide Caterers Association (NCASS) has developed <u>NCASS Connect</u>, 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.

Food Authorities can access NCASS Connect for free to view documents uploaded 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 has a Primary Authority Partnership with Monmouthshire County Council in Wales and in England, the Royal Borough of Greenwich. See the <u>Primary Authority register</u> for further information on this partnership, including details of any inspection plans.

#### 2.12.13.6 Other types of establishments

# 2.12.13.7 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 Food Authority where the undertaking takes place.

# 2.12.13.8 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.

#### 2.12.13.9 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 may be exempt from registration if they do not meet the definition of an 'undertaking' given in Recital 9 of Regulation (EC) No 852/2004 and Article 3(2) of Regulation (EC) No 178/2002. The FSA's guidance on the application of EU food hygiene law to community and charity food provision should help determine this.

#### 2.12.13.10 Food brokers

Food brokers are food businesses that operate as intermediaries in the supply chain, operating at various stages between other food businesses and the final consumer or caterer.

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 'FBO', then the registration requirement applies, and they must be registered with the Food Authority in which they undertake the work.

In respect of products of animal origin, Article 3 of Regulation (EC) No 931/2011 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 Food Authority.

<u>Guidance</u> for authorised officers on food brokers includes information on the distinction between food brokers and food agents, who act as a representative of a FBO without any authority to trade in their own name and do not take legal or physical possession or custody of the food at any time.

#### 2.12.13.11 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. If such businesses fall within the definition of a food business as outlined in Regulation (EC) No 178/2002 then relevant requirements of food law will be applicable to them.

Such businesses must register with the most appropriate Food Authority. This may be where they live, where their office is located or where the food stocks are stored.

Food businesses such as those who set up websites providing caterers' menus to consumers, which facilitate sale of the food and arrangement of its delivery from caterer to consumer, should also be registered as food businesses.

<u>Guidance</u> for Food Authorities regarding foods sold online can be found on Smarter Comms.

#### 2.12.13.12 Temporary food business establishments

Temporary food businesses or 'pop-up' food businesses are establishments that are only open for a limited period of time. The time they are open for can range from a few hours, to a few months, depending on the nature of the food business. These

businesses should be treated in the same way as mobile food establishments for the purposes of registration.

Food Authorities should prioritise initial inspections of these businesses based on risk and in accordance with their service plan and intervention programme.

## 2.12.13.13 Vending machines

Vending machines are subject to the relevant provisions of Annex II 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 Food Authority. The delivery vehicles used for the transport of food for stocking vending machines should be covered in the interventions at such establishments.

#### 2.12.13.14 Non-commercial establishments

Food activities which do not operate from primarily commercial premises but meet the definition of a 'food business', must be registered as a food business establishment. This may include, for example, a food business operating from a domestic premises primarily used as a dwelling.

# 2.13 Approval of establishments

# 2.13.1 Division of responsibilities between Food Authorities and FSA

Responsibility rests with Food Authorities for the approval and enforcement of establishments subject to approval under Regulation (EC) No 853/2004 in respect of which control does **not** fall to an Official Veterinarian.

These 'product-specific' establishments will be producing any, or any combination, of the following:

- minced meat
- meat preparations
- mechanically separated meat
- meat products
- live bivalve molluscs
- fishery products
- raw milk other than raw cows' milk
- dairy products
- eggs (not primary production) and egg products
- frogs' legs and snails
- rendered animal fats and greaves
- treated stomachs
- bladders and intestines
- gelatine and collagen

This will include certain re-wrapping/re-packing establishments, cold stores and some wholesale markets.

Food Authorities are also responsible for enforcement in respect of collection centres and tanneries supplying raw material for the production of gelatine or collagen intended for human consumption.

The FSA is responsible for the approval of establishments subject to approval under Regulation (EC) No 853/2004 where control falls to an Official Veterinarian, and for enforcement in such establishments once approved. Such establishments include:

- slaughterhouses
- game handling establishments
- cutting plants placing fresh meat on the market

The FSA is also responsible for establishments co-located with these establishments which also produce:

- minced meat
- meat preparations
- mechanically separated meat
- meat products
- rendered animal fats and greaves
- treated stomachs
- bladders and intestines
- gelatine
- collagen

Where a slaughterhouse, game handling establishment, or cutting plant is co-located with an establishment carrying out any other food business operation, to which either Regulation (EC) No 852/2004 or non-meat Regulation (EC) No 853/2004 applies, the FSA may on a case-by-case basis, with the agreement of the Food Authority, take over responsibility for enforcement in the co-located establishment, except where retail activity exists. This includes any other product of animal origin and products not of animal origin.

Requests for the FSA to take on enforcement responsibilities need to be referred to the FSA for agreement and decision before a transfer can take place.

The FSA is also responsible for enforcement in relation to the matters regulated by Schedule 6 of the Food Hygiene (Wales) Regulations 2006, in so far as it applies in relation to raw cows' milk intended for direct human consumption.

Where a food business is carrying out any activity that is subject to approval under Regulation (EC) No 853/2004 (including those that require approval by the FSA, but is not yet approved) without the required conditional or full approval, an offence is committed under Regulation 17 of the Food Hygiene (Wales) Regulations 2006, and enforcement action is the responsibility of the relevant Food Authority.

## 2.13.2 Exemptions from approval

On receipt of an application for approval or when providing advice to FBOs, Food Authorities will need to consider whether the activities proposed require approval, or whether the FBO might be exempt.

The relevant exemptions from the requirements for approval under Regulation (EC) No 853/2004 fall into three categories:

- direct supply of small quantities of primary products<sup>33</sup>
- retail exemption<sup>34</sup>
- food containing both products of plant origin and processed products of animal origin (composite products)<sup>35</sup>

Food Authorities must be aware that establishments which are exempt from approval because they assemble, manufacture or handle composite products only, must demonstrate that the POAO used to make the composite products were produced and handled in accordance with the specific requirements in Regulation (EC) No 853/2004 as well as the requirements in Regulation (EC) No 852/2004. This is specified in Article 1(2) of Regulation (EC) No 853/2004.

Further information on these exemptions is provided in the FSA guidance, '<u>Approval</u> of establishments - Guidance for local authority authorised officers'.

# 2.13.3 Applications for approval

Under the Provision of Services Regulations 2009, Food Authorities must have an electronic means for FBOs to seek approval for food establishments.

Applications for approval may be electronically completed and submitted to the relevant Food Authority online using the <u>Gov.uk website</u>.

# 2.13.4 More than one type of product

When considering an application for the approval of an establishment, Food Authorities must take into consideration all activities carried out in the establishment.

There will be establishments where two or more products of animal origin subject to requirements of Regulation (EC) No 853/2004 are applicable, for example an establishment producing both meat products and fishery products. In such cases the relevant provisions will apply to areas of the establishment where each type of product is produced. All relevant provisions of the Regulation will apply to those areas of the establishment where facilities are shared.

# 2.13.5 Determination of approval

Before reaching a decision on an application for approval, the Food Authority must ensure that an on-site visit<sup>36</sup> is made in the form of an inspection of the

<sup>&</sup>lt;sup>33</sup> Article 1(3)(c) to (e) of Regulation (EC) No 853/2004

<sup>34</sup> Article 1(5)(b)(ii) of Regulation (EC) No 853/2004

<sup>&</sup>lt;sup>35</sup> Article 1(2) of Regulation (EC) No 853/2004

<sup>&</sup>lt;sup>36</sup> Article 148 (2) of Regulation (EU) 2017/625

establishment, to verify that, where necessary, all systems, procedures and documentation meet the relevant requirements of Regulation (EC) No 852/2004 and Regulation (EC) No 853/2004.

The inspection must be conducted in accordance with, and cover, all aspects of the relevant inspection form for the business concerned, and consider all issues identified by Regulation (EC) No 853/2004, as requiring Food Authority consent.

As per Article 148(3) of Regulation (EU) 2017/625 the relevant requirements of food law must be fully complied with prior to full approval being granted.

# 2.13.6 Conditional approval

Article 148(4) of Regulation (EU) 2017/625 permits the granting of conditional approval to an establishment, following an onsite visit, which does not fully comply with the requirements of food law, but only if the establishment meets all the infrastructure and equipment requirements. It is for Food Authorities to decide whether to grant conditional approval to a food business establishment which does not fully comply.

If conditional approval is granted, a new official control visit must be carried out within three months of the conditional approval being granted.

In appropriate circumstances conditional approval may be extended, but it must not be extended to more than six months<sup>37</sup> from the date of the initial granting of conditional approval.

In the case of factory and freezer vessels, conditional approval shall not exceed 12 months.

Professional judgement must be used in deciding whether it would be appropriate to extend conditional approval on a case by case basis, but Food Authorities should note that Article 148(4) of Regulation (EU) 2017/625 requires clear progress to have been made towards compliance.

# 2.13.7 Refusal of approval and appeals

Food Authorities must bear in mind that the FBO has the right to appeal to a relevant Court against decisions on approval. Rights of appeal are subject to Regulation 12 of the Official Feed and Food Controls (Wales) Regulations 2009.

From the date on which the notice of the decision is served on the relevant person the establishment cannot continue operating whilst the appeal is being determined.

# 2.13.8 Change of activities, ownership or details

For guidance on the action required where there has been a change in activities, ownership or details, see the FSA document, 'Approval of establishments - Guidance for local authority authorised officers'

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<sup>&</sup>lt;sup>37</sup> Article 148(4) of Regulation (EU) 2017/625

# 2.13.9 Notification to the FSA regarding approval status

Chapter 2 of the Code sets out the circumstances where Food Authorities are required to notify the FSA of approved establishment details.

Food Authorities must as soon as practicable notify the FSA of these details by email to <a href="mailto:lasupportwales@food.gov.uk">lasupportwales@food.gov.uk</a>

This information will then be used to update the <u>lists of approved food</u> <u>establishments</u> published on the FSA's website.

# 2.13.10 Food Authority files

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

A properly structured file, in hard copy or held electronically, containing all the relevant information is important to the Food Authority. It provides:

- a history of the establishment and how it has developed
- continuity for new officers
- for the facilitation of monitoring exercises
- assistance to the Food Authority in demonstrating competence

An example of what an approval file may contain, as relevant and appropriate for the establishment includes:

- the application form
- a plan(s) of the establishment indicating:
  - layout of the establishment
  - location of equipment
  - workflows for each product line
  - water distribution system within the establishment including all outlets and sampling points
  - drainage layout
  - pest control baiting and/or trapping points within the establishment and external areas
- a synopsis of the establishment (no more than one side of an A4 sheet) which briefly describes what type of establishment it is, products produced, volume of product, type of trade, number of employees, approval number, what it is approved for, details of other businesses that produce or import for the business
- a pre-approval inspection report
- a planned programme of works to achieve approval
- an approval notification document specifying:
  - details of activities to which the approval relates
  - approval number
  - classification

- special hygiene direction(s)
- any establishment-specific derogations that have been granted
- any other conditions or limitations specified by the Food Authority
- any arrangements acceptable to the Food Authority
- all relevant information and documentation, including
- labels and commercial documents bearing the identification mark
- letter indicating the Food Authorities involvement in the planning and implementation of the establishment's hygiene training of staff
- intervention reports in chronological order
- correspondence with establishment in chronological order
- copies of notices or other formal action taken, in chronological order
- a copy of company's emergency recall and withdrawal plan and traceability system including names, telephone numbers, etc. of key personnel within the company
- results of all samples taken by the Food Authority
- location of any off-site facilities
- copies of any other documents that have been provided by, or copied at, the approved premises, including:
  - HACCP documentation
  - supplier information
  - product list
  - raw material, product and water sampling plans and test results\*
  - other sampling plans and results for example environmental sampling\*
  - process records
  - management and key contact names and contact details
  - photographs and digital images, as appropriate

# 2.13.11 Identification mark (including approval code)

Chapter 2 of the Code requires Food Authorities to give a unique approval number to each food business establishment it approves, or conditionally approves, in accordance with Article 148 of Regulation (EU) 2017/625.

This approval number must be a three-digit number unique to that authority, which should form part of an approval code consisting of the Food Authorities two-letter code followed by the approval number.

The Food Authority must agree an identification mark with each establishment it approves which:

- incorporates the approval code it has allocated
- meets the requirements of Annex II, Section I B of Regulation (EC) No 853/2004 including the need for the mark to be within an oval shape

<sup>\*</sup> Where FBOs are using alternative sampling plans or methods in accordance with Article 5 of Regulation (EC) No 2073/2005 on the microbiological criteria for foodstuffs, the Food Authorities verification of the proposed alternative approach should be held on file.

Approved establishments are required to apply the identification mark to their products, as appropriate. The requirements for the application and form of the identification mark as well as the method of marking are set out in Annex II, Section I, A, B and C of Regulation (EC) No 853/2004.

Guidance on the health and identification marks that must be applied to food products of animal origin (POAO), such as meat, egg products, fish, cheese and milk, after the end of the EU Transition Period is available on the FSA website.

# 2.13.12 Template forms

A series of <u>template forms</u> to assist Food Authorities in the administration of approvals can be found on Smarter Comms.

This includes the following forms:

- Application for Approval
- Notification of Grant of Full Approval/Conditional Approval
- Notice of Decision Not to Grant Approval
- Notice of Decision to Withdraw Approval/Conditional Approval
- Notice of Decision to Suspend Approval/Conditional Approval
- Notification of Refusal to Grant Full Approval to an Establishment which was Conditionally Approved

Note: these forms are all included in the same composite document.

Whilst the content of these documents must be regarded as the minimum required, Food Authorities can adapt them as necessary to meet local requirements.

#### 2.13.13 Further guidance

For further guidance on the approval of food business establishments that handle POAO, see the FSA document entitled, 'Approval of establishments - Guidance for local authority authorised officers'.

The <u>Operational Policy</u> for the approval of meat establishments by the FSA is available on the FSA website.

#### 2.14 Food Business Establishment records

# 2.14.1 List of registered Food Business Establishments

Chapter 2 of the Code requires Food Authorities to maintain an up-to-date list of food business establishments registered with them. This list should contain the following information about each food business establishment:

- name of the FBO
- name of the food establishment
- address of the food establishment
- nature of the food business

## 2.14.2 Freedom of Information and data protection

This section contains information about the Data Protection Act 2018 and the Freedom of Information Act 2000 as they relate to food business records.

Food Authorities must 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 Food Authorities have any doubts about the release of data or information they should seek legal advice and/or contact the <u>Information Commissioner's Office</u>.

## 2.14.3 Information requirement

The Food Authorities establishment record files, which may be computer based, must be updated after each intervention and include:

- information on the size and scale of the business and its customer base
- information on the type of food activities undertaken by the business, including any special equipment, processes or features
- copies of any correspondence with the business, including documentation associated with approvals or registration
- copies of food sample analysis/examination results
- a system of flagging for significant issues, including details of any noncompliance to be reviewed at future interventions
- in respect of establishments inspected for food hygiene purposes, an assessment of the businesses compliance with procedures based on HACCP principles, where appropriate
- information on hygiene training undertaken and qualifications held by employees; including any training on the implementation and operation of the food safety management system
- information as to whether the business imports food and/or is the first destination inland after import and, additionally in respect of premises inspected for food standards purposes:
  - the existence and assessment of any documented quality system
  - details of other businesses that produce or import for the business

# 2.14.3.1 Retention of HACCP plans

The public inquiry into the 2005 outbreak of E. coli O157 in South Wales, recommended that, 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 regards to this recommendation, 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.

The FSA has produced <u>guidance</u> highlighting the recommendation made by the Public Inquiry to assist Food Authorities in effectively managing their establishment records.

# 2.15 Escalating technical queries to the FSA or other Government Agency

Food Authorities, before escalating a query to the FSA, must consider and follow the agreed hierarchy for escalating queries which is endorsed by the Food Hygiene Focus group and Food Standards and Information group, which liaise:

- 1. within your Food Authority
- 2. with your county or regional food liaison group
- 3. with your local Food Hygiene or Food Standards Groups representative

For consistency we also advise posting information on the Knowledge Hub.

# Chapter 3 Authorisations, competence, and qualifications

# 3.1 Introduction

This Chapter provides advice on:

- the qualifications and competence required for officers undertaking official food controls, other official activities, and any other activities related to these; and
- assessing an officer's competency for undertaking activities.

#### 3.2 Authorisations

# 3.2.1 Appointment of staff

The Code requires Food Authorities to appoint a sufficient number of suitably qualified and competent officers so that official food controls and other official activities can be performed efficiently and effectively, as part of their statutory obligations<sup>38</sup>.

# This may involve:

- establishing regional or cross-regional arrangements so other Food Authorities' may undertake official controls and/or official activities on behalf of the Food Authority; and
- employing temporary staff or contractors.

The advantage of regional or cross-regional arrangements is that it supports resilience and sustainability in respect of knowledge transfer between and within Food Authorities and regions.

#### 3.2.2 Lead food officer

There may be separate Lead Officers with responsibility for food hygiene, food standards and/or food hygiene at the level of primary production enforcement, and for specific tasks, for example:

- developing, implementing, monitoring, and reviewing documented policies, procedures, and plans;
- management of the response to an incident and alert; and
- collating and reporting data

Food Authorities must provide the FSA with the name and contact details of their appointed lead food officer(s) and provide details of any changes as soon as practicable to <a href="mailto:lasupportwales@food.gov.uk">lasupportwales@food.gov.uk</a>.

<sup>&</sup>lt;sup>38</sup> Article 5(1)(e) of Regulation (EU) 2017/625 and Chapter 2, Paragraph 5.3 of the Framework Agreement

# 3.2.3 Authorisation procedure

Food Authorities must have a documented authorisation procedure that sets out the process to be followed in assessing the competence of the officer to undertake specific official controls, other official activities, and assurance activities prior to their authorisation. This applies equally to officers who are directly employed, agency staff, temporary staff, and to those employed by or as contractors.

#### 3.2.4 Authorisation of officers

All Food Authorities must ensure they have a sufficient number of properly authorised officers to undertake imported food controls, food hygiene and/or standards control work and related enforcement action.

Food Authorities are not required to authorise officers to undertake all food enforcement activities. An officer's authorisation can be extended as the officer gains the necessary competency and qualifications where these are required.

Officers must be authorised to enforce relevant food law regulations that include specific enforcement powers within the regulations themselves.

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 it. However, for example, officers performing duties under the Food Hygiene (Wales) Regulations 2006 and the Official Feed and Food Controls (Wales) Regulations 2009, need to be separately authorised in writing to deal with matters arising under these Regulations, because they are not made under the Food Safety Act 1990 and contain specific enforcement powers within the regulations.

These regulations therefore must be specifically referred to in authorisation documents, including officers' credentials.

The FSA 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 (Wales) Regulations 2009 if already authorised under these Regulations.

Food Authorities might also wish to consult their legal advisors on this matter.

# 3.3 Qualification requirements

### 3.3.1 Qualifications with restrictions

# 3.3.1.1 Food Hygiene

Food Authorities must ensure officers have their authorisation of legal powers and duties restricted, until they can demonstrate the competency<sup>39</sup> requirements relevant to the activities they will undertake, as detailed below.

Higher Certificate in Food Premises Inspection awarded by EHRB, IFST or SFSORB

Higher Certificate in Food Premises Inspection with the Food Standards Endorsement awarded by EHRB, IFST or SFSORB

Higher Certificate in Food Premises with the Food Inspection Endorsement Inspection awarded by EHRB, IFST or SFSORB

Ordinary Certificate in Food Premises Inspection awarded by EHRB, IFST or SFSORB

Activity restriction	Competency requirements to undertake restricted activity
Undertake inspection of food to determine fitness	Activity A: Common competencies.  Activity B6: Assessing products, labelling and other information.  Sub-activity B6.1: Assessing whether food products are safe and fit for human consumption.
Seize and detain food	Activity A: Common competencies.  Activity D2: Formal enforcement action.  Sub-activity D2.2 Detaining, seizing and voluntary surrender of food.
Serve Remedial Action Notices	Activity A: Common competencies.  Activity D2: Formal enforcement action.
Serve Hygiene Emergency Prohibition Notices	Activity A: Common competencies.  Activity D2: Formal enforcement action.  Sub-activity D2.1: Emergency prohibition procedures
Undertake import control functions for fishery products	Activity A: Common competencies.  Activity E2: Import controls.  Sub-activity E2.1: Import controls at point of entry.  Sub-activity E2.2 Import controls fishery products.

<sup>&</sup>lt;sup>39</sup> Competency is a combination of the knowledge and skills required to effectively deliver official food control activities, other official controls.

#### 3.3.1.2 Food Standards

Food Authorities must ensure officers holding one or more of the following qualifications are not authorised to undertake food standards enforcement unless they hold a suitable qualification as listed in section 3.4.2 of the Code.

- Higher Certificate in Food Premises Inspection awarded by EHRB, IFST or SFSORB
- Higher Certificate in Food Premises Inspection with the Food Inspection Endorsement awarded by EHRB, IFST or SFSORB
- Ordinary Certificate in Food Premises Inspection awarded by EHRB, IFST or SFSORB

#### 3.3.2 Equivalency of qualifications

The relevant awarding bodies are the Chartered Institute of Environmental Health (CIEH), the Chartered Institute of Trading Standards (CTSI) and the Institute of Food Science & Technology (IFST), and the Scottish Food Safety Officers' Registration Board (SFSORB).

The FSA is informed by these bodies of any determination concerning the assessment of qualifications.

Food Authorities must consider and recognise <u>European Economic Area</u> and Swiss qualifications which are of an equivalent standard to UK qualifications in scope, content and level<sup>40</sup>. This situation may arise if an individual seeks employment in the UK as a Public Analyst, Food Examiner, or food law enforcement officer, having acquired relevant qualifications and work experience in their home country.

The equivalence of non-UK qualifications can be determined by the United Kingdom National Academic Recognition Information Centre (UK NARIC) on the recognition of professional qualifications.

#### 3.4 Competency requirements

#### 3.4.1 Introduction

Competency is a combination of the knowledge and skills required to effectively deliver official food control activities, other official activities and assurance activities.

The Competency Framework is activity-based and describes the competencies required to undertake an activity. The Competency Framework is activity-based and describes the competencies required to undertake an activity.

Each activity stands alone, which means an individual can be authorised to undertake one or multiple activities within the framework depending on their role. There is no expectation that an individual must be competent for all activities within the framework.

Food Authorities may have existing competency assessment tools that meet the requirements laid down in the Code. These can continue to be used provided they meet the objectives of the Competency Framework in this Chapter.

Food Authorities should satisfy themselves through appraisal and assessment that an officer can provide evidence that they meet the relevant competency requirements set out in this Chapter.

Competency recognises that an officer's authorisation can be broadened as the person gains knowledge and develops new skills.

<sup>40</sup> Recognition of Professional Qualifications (Amendment etc.) (EU Exit) Regulations 2019

In the Competency Framework, authorised officer competencies, are those relevant to the activities the officer will be authorised to undertake.

#### 3.4.2 Lead food officer competency requirements

Lead food officer specific activities, in the Competency Framework, are E1.1 to E1.3 'Operational Management':

- E1.1: Developing, implementing, monitoring, and reviewing documented policies, procedures, and plans;
- E1.2: Management of the response to an incident and alert; and
- E1.3: Collating and reporting data.

In addition, lead food officers must meet the competencies required for an authorised officer as detailed in the Competency Framework, relevant to the activities they will be authorised to undertake.

An appropriate manager (such as a service manager or senior officer with responsibility for the Food Authority's food service) should work with the lead food officer to assess their competency. Alternatively, this could be done by another lead food officer from another Food Authority.

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

The Code recognises that more than one person may perform the lead food officer role. Competencies relevant to an individual's role should be considered when conducting assessments.

#### 3.4.3 Regulatory support officer competency requirements

Regulatory support officer specific activities, in the Competency Framework, are:

- alternative interventions B11
- education, advice, and coaching B7
- information gathering B8 excluding the sub-activity B8.1: Gathering, processing, and sharing intelligence
- shellfish environmental monitoring E6

## 3.4.4 Officers performing official controls or certain tasks related to other official activities at BCPs

Food Authorities need to determine which of the activities within the Competency Framework the officers performing official controls or certain tasks related to other official activities at BCPs need to be competent to undertake.

As a minimum those officers performing official controls and/or other official activities at BCPs must be able to demonstrate the competencies for the following activities:

- Activity A: Common competencies
- Activity E2: Import controls
- Sub-activity E2.1: Import controls at point of entry
- Activity B5 Sampling

- Sub-activity B5.1 Taking formal samples
- Sub-activity B5.2 Taking informal samples
- Sub-activity E2.2: Import Controls for fishery products (only for official fish inspectors)

Where a Food Authority chooses to authorise an officer to undertake enforcement those officers must be able to demonstrate the competencies for the relevant enforcement activities, for example:

- Activity D1: Informal enforcement action
- Activity D2: Formal enforcement action
- Sub-activity D2.2: Detaining, seizing and voluntary surrender of food

#### 3.4.5 Competency assessment

Food Authorities should ensure the following approach to the assessment of competency of its officers.

- Step 1: identify the activities and sub-activities within the competency framework relevant to the:
  - officer's role; and
  - activities the officer will be authorised to undertake.
- Step 2: conduct a competency assessment to determine whether the officer can satisfy all the competency requirements for each activity they will undertake;
- Step 3: following the competency assessment, the lead food officer, in consultation with the individual officer, should identify development needs which can be used to inform an officer's personal development plan and Continuing Professional Development (CPD) priorities;
- Step 4: provide the necessary training that is supervised by a lead food officer(s) or another competent authorised officer to address any deficiencies highlighted in the competency assessment;
- Step 5: authorise or restrict the officer's authorisation until they can demonstrate they meet all the competencies for an activity or sub-activity; and
- Step 6: keep a record, in writing, or by electronic means, of details of the competency assessment, qualifications and training.

Competency should be reviewed on an ongoing basis, for example as part of a Food Authority's appraisal process.

#### 3.4.6 Evidence of competency

The following, are ways in which a Food Authority can demonstrate competency of their officers, and Food Authorities should consider maintaining a portfolio of evidence for each of their officers to demonstrate their knowledge and skills which may include:

- academic and professional qualifications;
- post qualifications courses that lead to an additional relevant qualification;

- details of employment history detailing functions undertaken, responsibility exercised, and experience gained;
- details of official food controls and other official activities carried out under the supervision of an appropriately authorised officer;
- successful completion of training courses, including short courses and elearning, for example, on matters related to official food controls, HACCP, enforcement sanctions;
- accompanied inspections/visits under the supervision of an appropriately authorised officer;
- having conducted a specific piece of work, for example drafting of notices, production of witness statements, gathering evidence, building elements of a prosecution file, conducting sampling to a specified protocol;
- satisfactory performance of activities as part of internal performance appraisal/monitoring procedures; and
- doing any of the things suggested in section 3.6.3.

#### 3.5 Training

#### 3.5.1 Training Programme

The Food Authority's training programme may be included in the authorisation procedure.

The FSA recognises the need for all officers to update or refresh their knowledge and competency to adapt to the changing circumstances they work in, and for officers who are starting out in food law enforcement for the first time, or officers returning to food law enforcement after a break who need to develop their knowledge and competency.

#### There are several FSA e-learning courses available.

3.5.2 Training for staff on import controls on aquatic animals, products of animal origin, animals, germinal products or animal byproducts at Border Control Posts

The content of the training programme at Border Control Posts must:

- be determined according to the animals and goods for which the border control posts are designated and the tasks and responsibilities to which the staff are assigned
- cover the following subjects<sup>41</sup>, as appropriate
  - applicable legislation concerning the importation into the UK of animals and goods, including procedures and activities to be carried out during and after physical checks;
  - general principles of examination of animals;
  - examination of the fitness to travel of animals;

<sup>&</sup>lt;sup>41</sup> Article 3 of Regulation (EU) 2019/1081

- practical aspects of the handling of animals in line with legislation, including arrangements to prevent or reduce delays at BCPs and, where necessary, to feed, water, unload and accommodate the animals;
- sensorial examination of goods;
- examination of the means of transport and the transport conditions,
   including the management of temperature-sensitive goods (cold chain)
   and the transport of animals;
- identification of animal species, including, when appropriate, identification of invasive alien species<sup>42</sup> introduced via animals and goods;
- control procedures, concerning the use of equipment, the implementation
  of monitoring plans and sampling procedures and laboratory analysis with
  regard to animals and animal and public health aspects
- methods for the interpretation of laboratory test results and related decisions in accordance with the requirements of applicable legislation;
- risk assessment, including data gathering in relation to animal and public health in order to carry out appropriately targeted physical checks;
- prevention of cross-contamination and compliance with relevant biosecurity standards;
- labelling requirements for POAO; and
- investigations and control techniques aimed at detecting fraudulent or deceptive practices in trade.

#### 3.6 Continuing Professional Development (CPD)

#### 3.6.1 Introduction

CPD is how authorised officers maintain, improve, and broaden their knowledge and skills, and develop the personal qualities and competencies required to undertake their food law enforcement role. Many professions define CPD as a structured approach to learning to help ensure competence to practice, taking in knowledge, skills, and practical experience. CPD can involve any relevant learning activity, whether formal and structured or informal and self-directed.

Fundamental to a CPD scheme is the need for individuals to take ownership of their career progression.

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

Food Authorities employing officers who are not members of professional bodies should still maintain a record of their CPD, which should be countersigned by a lead food officer.

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<sup>&</sup>lt;sup>42</sup> Point (2) of Article 3 of Regulation (EU) No 1143/2014

#### 3.6.2 CPD requirements

Other than where unavoidable (for example because of an extended absence), those carrying out official food controls and other official activities must undertake a minimum of 20 hours CPD each year.

While the Code sets a minimum level, extra hours may be required depending on the experience of individual officers and their area(s) of authorisation, any specific training needs or deficiency in competency identified at their annual reviews.

The Code requires that at least 10 hours CPD must be spent on subject matters set out in Chapter 1 of Annex II of Regulation (EU) 2017/625 and on the obligations of the Food Authority resulting from this Regulation, relevant to the activities officers are authorised to undertake.

Examples may include, but are not limited to:

- risk rating consistency exercises;
- different control techniques, such as inspection, verification, screening, targeted screening, sampling, laboratory analysis, testing, and diagnosis;
- control procedures;
- requirements of food law;
- assessment of non-compliance with food law;
- hazards in production, processing, and distribution of food;
- different stages of production, processing and distribution and the possible risks to human health, and where appropriate for the health of animals and plants, the welfare of animals and the environment;
- the evaluation of the application of HACCP procedures;
- management systems such as quality assurance programmes that FBOs manage and their assessment insofar as these are relevant to food law requirements;
- official certification systems;
- contingency arrangements for emergencies;
- legal proceedings and the implication of official food controls;
- examination of written, documentary material and other records, including those related to inter-laboratory comparative testing, accreditation, and risk assessment, which may be relevant to the assessment of compliance with food law; this may include financial and commercial aspects;
- control procedures and requirements for food entering the UK; and
- any other area necessary to ensure that official food controls are carried out in accordance with Regulation (EU) 2017/625.

The remaining 10 hours can be made up from learning related to 'other professional matters' i.e. CPD that will support an officer's profession and not necessarily food related.

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;
- attendance at court;
- participation in scenario-based case studies;
- drafting relevant articles for peer-reviewed journals/papers;
- undertaking relevant distance learning or e-learning activities for example, on evidence gathering; and
- making presentations to colleagues on new or changes to legislation.

#### 3.6.3 Ways of attaining CPD

The examples below are all ways in which authorised officers can undertake and attain CPD. Examples include:

- relevant training courses including distance learning or e-learning activities;
- coaching from other experienced authorised officers;
- review of case studies and literature;
- conferences or meetings which involve an element of learning;
- reading to understand the legal, regulatory framework for professional work;
- maintaining or developing specialist skills;
- shadowing of an authorised officer who meets the competency requirements;
- attending training courses/conferences not linked to official food controls but supporting professional development;
- taking part in a DGF audit or fact-finding mission;
- shadowing experienced (internal or external) colleagues to develop knowledge of a specialist process, such as cheese-making; meat products; shellfish/fishery products;
- participation in scenario-based case studies (for example notice drafting, risk-rating);
- authoring relevant articles for peer-reviewed journals/papers;
- writing guidance on food law or other legislative requirements;
- undertaking relevant distance learning or e-learning activities;
- preparing and delivering presentations to colleagues or businesses on legislative requirements, particularly new changes to legislation; and
- appropriate discussions with colleagues and/or FBOs on legal requirements/enforcement action which involve an element of learning.

#### 3.6.4 Evidencing and recording CPD

Most CPD is likely to be evidenced by the established practice of certification from a training provider. However, other means of supportive evidence may demonstrate it, for example, publication in a peer-reviewed journal.

Food Authorities should keep a record of their authorised officers' CPD which should be used as part of their annual review of training and CPD needs. Such reviews might be combined with annual staff appraisals where appropriate.

The record, which can be electronic should include the following information as a minimum:

- date(s) of activity;
- type of activity/activity description;
- hours spent on an activity; and
- copy of certification or countersignature from an authorised officer who meets the competency requirements for the stated activity which took place.

#### **Chapter 4** Delivery of interventions

#### 4.1 Introduction

Chapter 4 covers delivery of official controls (their methods and techniques<sup>43</sup>), other official activities, and alternative enforcement strategies.

#### 4.2 Interventions

When selecting the type of intervention to use, the authorised officer must have regard to the limitations as laid down in the Code and the Food Authority's own enforcement policy. The officer must choose the intervention that will be most effective in maintaining or improving compliance with food law.

#### 4.2.1 Intervention types

Tasks relating to official controls must, in general, be carried out using appropriate control methods and techniques, such as monitoring, surveillance, verification, audit, inspection and sampling for analysis (which can include a combination of such control methods and techniques), known as intervention types. For an intervention to constitute an official control, the officer must be satisfied that a single, or a combination of, control methods and techniques, will verify compliance with food law.

Examples of official control methods and techniques, non-official controls and other official activities are detailed in the below table.

Official control methods and techniques	Non-official controls	Other official activities
<ul> <li>Inspection</li> <li>Audit</li> <li>Sampling for analysis</li> <li>Monitoring</li> <li>Surveillance</li> <li>Verification</li> </ul>	<ul> <li>Education</li> <li>Advice</li> <li>Coaching</li> <li>Information and intelligence gathering</li> </ul>	<ul> <li>Enforcement         measures and/or         remedial actions         following non-         compliance</li> <li>Management of lists         of         registered/approved         FBOs</li> <li>The act of issuing         official certificates or         official attestations</li> </ul>

#### 4.2.2 Inspections and audits

Inspections should be based on the relevant inspection form, where one has been developed, for the business concerned.

<sup>&</sup>lt;sup>43</sup> Article 14 of Regulation (EU) 2017/625

The inspection form is intended to assist officers and businesses by introducing a structured approach to the inspection process consistent with quality assurance practice. It is not necessary to inspect every aspect of a food business at every inspection, for example a supermarket's in-store bakery or restaurant operated by that supermarket might not always need to be inspected during an inspection of a supermarket.

The inspection process should begin with a review of the information held on record by the Food Authority in relation to the food business establishment to be inspected.

At the beginning of the inspection, the officer should discuss with the FBO or representative:

- the purpose and scope of the inspection
- whether there have been any changes in activities since the last visit
- what the officer intends to do

An inspection should include:

- assessment of the food safety management system, as applicable
- the identification of all the food related activities undertaken by the business
- the areas of the establishment used for the preparation, production, storage and transport of foodstuffs
- any processes used and the staff involved

Where an inspection form has been developed, officers should:

- complete it fully, to ensure that they have a sufficient record to show how the business is complying with relevant food law
- clearly record on the inspection forms any areas that were not inspected or assessed
- record any information on which decisions were based when determining the risk rating

Staff of food businesses who have been given specific responsibilities for ensuring compliance with relevant legal requirements may be questioned in order to verify that they understand their duties and are carrying them out effectively.

An assessment of whether to take samples, and if so what to sample, should be an integral part of an inspection, but particularly in food manufacturing, packing and catering businesses.

Inspections may also be for purposes connected with Primary Authority, for example, advising FBOs on the law and ways in which they can comply with it.

Officers should offer advice where it is appropriate or is requested and should encourage FBOs through an educative approach to adopt good practice.

At the conclusion of every inspection, the officer should discuss any contravention of food law discovered and set out:

- any corrective action necessary
- the timescale for corrective action

• any further action the officer intends to take and any recommendations of good practice that the officer considers appropriate

In this closing discussion, and in subsequent reports or correspondence, officers should clearly differentiate between action required to comply with legal requirements and recommendations of good practice.

The officer should, on request, advise and discuss with the FBO, the intervention and/or the risk rating applied to the business.

The officer may wish to consider if further intervention strategies may be appropriate for example education or training.

#### 4.2.3 Factory and fishing vessels – hygiene inspections

In addition to the planned intervention programme of land-based establishments, Food 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 Food 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.

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

#### 4.2.4 Verification

The circumstances below are examples of, but not limited to, when an intervention should be recorded as a verification visit.

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
- remote assessment of the adequacy of HACCP plan and pre-requisites (not necessarily necessitating an actual physical visit to the establishment)
- validation of food labelling (including advertising materials and websites) with food labelling marketing and use rules. Checking, by examination and the consideration of objective evidence, whether specified requirements of food law have been fulfilled
- 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

#### 4.2.5 Monitoring and surveillance

The circumstances below are examples of, but not limited to, when an intervention should be recorded as monitoring or surveillance. These include:

- information gathering if it includes verification of information collected on site by an appropriately qualified officer
- a visit to check the information supplied as part of an alternative enforcement strategy

#### 4.2.6 Sampling visits

A visit to an establishment to obtain 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 visits:

- 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)
- 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

#### 4.2.7 Education and advisory work

Providing education, advice and training delivered at the business establishment, or remotely can be a key part of a Food 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 a visit to:

- premises to give advice and/or training
- give advice on Safe Catering Pack or Safer Food Better Business (SFBB) or equivalent schemes
- 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.

Food Authorities that undertake advisory visits to new and existing food businesses for both hygiene and standards must ensure that the delivery of the official control intervention programme is not compromised and in the case of food hygiene these advisory visits do not undermine delivery of FHRS.

The purpose of advisory visits is to provide guidance to businesses on achieving compliance with food law requirements.

If during an advisory visit to a business that is trading, significant non-compliances are identified that present a risk to public health, a full inspection should be undertaken, and appropriate enforcement action taken in line with the Food Authority's Enforcement Policy. In such circumstances the use of formal enforcement powers may be necessary.

Advisory visits should not be carried out to the detriment of the planned intervention programme, in particular, that relating to higher risk establishments.

#### 4.2.8 Information and intelligence gathering

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 who will assess whether further action is appropriate.

The circumstances below are examples of, but not limited to, when the intervention should be recorded as information and intelligence gathering for that visit to the food establishment. These include a 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
- by a regulator other than the Food Authority to gather intelligence/information on a food establishment

#### 4.2.9 Revisits

Revisits may focus on the significant statutory requirements that were found to be contravened at the previous intervention.

#### 4.3 Delivery of official food controls

#### 4.3.1 Notification of official controls

Prior notification must be the exception<sup>44</sup>.

Examples, but not limited to, where notification may be appropriate are:

- when the purpose of an intervention is to see a particular process in operation
- to examine records which are only available if the proprietor of the food business is present

Authorised officers must exercise discretion in this area guided by the overriding aim of ensuring compliance with food law.

<sup>44</sup> Requirement as per Article 9(4) of Regulation (EU) 2017/625

#### 4.3.2 Initial inspection of new establishments

The Code of Practice requires that all food establishments must receive an initial inspection. This should as a rule take place within 28 days of registration or from when the Food 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.

Prioritisation of initial inspections within the Food 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.

#### 4.3.2.1 Deciding when to undertake the initial inspection

The Food Authority should consider the following factors when determining when to undertake an initial inspection:

- where the new establishment is believed to be undertaking high risk food activities the Food 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 4 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.

#### 4.3.3 Undertaking inspections and audits

#### 4.3.3.1 Food hygiene inspections

In general, an officer conducting a food hygiene inspection should:

- establish whether food is being handled and produced hygienically, and is safe
  to eat, having regard to any subsequent processing; assess the hazards posed
  by the activities of the business and the FBO's understanding of those hazards
- confirm that the FBO is carrying out their own controls and checks, based on HACCP principles (other than in the case of primary production) and these are being operated effectively and appropriate corrective action is being taken where necessary
- assess the efficacy of the controls in place to manage the risk of crosscontamination between ready-to-eat foods and foods requiring further processing
- assess the risk of the food business failing to meet food hygiene requirements; in respect of primary production, establish that FBOs and their employees have an understanding of the hazards posed by the activities of the business, and assess

- and verify that preventative/corrective actions necessary to protect the safety of food entering the human food chain take place
- recommend good food hygiene practice in accordance with relevant Good Practice Guidance and UK Industry Guides, relevant sector specific codes, and other relevant technical standards, and promote continued improvements in hygiene standards through the adoption of good practice
- check the source and any health or identification marking of raw materials, and the identification marking and destination of finished products. Where deficiencies in health or identification marking are identified
- check compliance with product specific legislation, for example in relation to retail and catering businesses that sell or use live bivalve molluscs, ensure that where parcels of live bivalve molluscs are split before sale to the ultimate consumer, that information on identification marks is retained for at least 60 days

In addition to the general requirements detailed above, a food hygiene inspection should include, if appropriate:

- a discussion with any staff responsible for monitoring and corrective action at critical control points to confirm that control is effective
- a physical inspection to determine whether critical controls have been identified and whether the controls are in place, and to assess compliance with relevant food law
- an assessment of compliance with the traceability requirements of Article 18 of Regulation (EC) No 178/2002
- a discussion regarding any hazards that have been identified by the officer that have not been covered by the business's systems
- a discussion regarding any failure to implement or monitor any critical controls that have been identified by the business

Published UK Industry Guides to Good Hygiene Practice (Industry Guides) may be particularly relevant to certain establishments subject to food law as will other published recommended industry codes of practice. Officers may draw these to the attention of FBOs in appropriate circumstances.

The full scope of the food hygiene inspection is detailed in the relevant inspection form, where one has been developed, for the business concerned.

# 4.3.3.2 Food hygiene intervention frequencies (Impact of food information (Wales) Regulations 2014 on the Food Law Code of Practice food hygiene scoring system and FHRS ratings)

The purpose of the food hygiene scoring system in Chapter 4 the Code is to determine planned intervention frequencies at all food establishments on the basis of assessment of compliance with food hygiene law. The system forms the basis of the Food Hygiene Rating Scheme (FHRS), which is operated by all Food Authorities in Wales with responsibility for food hygiene. The scheme helps consumers choose where to eat out or shop for food by giving them information about the hygiene standards in restaurants, takeaways, other places you eat away from home and food shops, based on a rating scheme of 0-5. The FSA has produced <u>Guidance for Food Authorities</u>. Regulation 5 on

allergens in the Food Information (Wales) Regulations 2014 relate to food labelling and information so should not form part of this assessment since these are food standards requirements.

#### 4.3.3.3 Food standards inspections

An officer conducting a food standards inspection should:

- consider the existence and effectiveness of management systems designed to ensure that food standards requirements are met and, where they exist, test their effectiveness
- assess compliance with composition, presentation and labelling requirements by examining advertisements, labels, descriptions, menus, claims, recipes and other records
- assess compliance with the traceability requirements of Article 18 of Regulation (EC) No 178/2002 as read with Regulation (EU) No 931/2011 on the traceability requirements set by Regulation (EC) No 178/2002 for food of animal origin
- assess compliance with supplier specifications
- assess the risk of the food business failing to meet food standards requirements
- recommend good practice in accordance with relevant industry codes and other relevant technical standards

The full scope of the food standards inspection is detailed in the relevant inspection form where one has been developed, for the business concerned.

#### 4.3.4 Reports following official controls

The information to be included in the report is:

- a description of the purpose of the official food controls
- the control methods applied
- the outcome of the official food controls and non-compliances identified
- where appropriate, action that the Food Authority requires the operator concerned to take
- a clear distinction between legal requirements and recommendations
- timescales for addressing any non-compliances
- trading name and address of the business, and registered address if different
- name of the food business operator/food business proprietor
- type of business
- name(s) of person(s) seen and/or interviewed
- date and time of inspection
- specific food law under which intervention conducted
- areas inspected/audited (to be specified)
- documents and/or other records examined (to be specified)
- samples taken (to be specified)
- key points discussed during the visit (to be specified)
- action to be taken by the Food Authority (to be specified)
- signed by the officer

- name of officer
- designation of inspecting officer
- contact details of inspecting officer
- contact details of senior officer in case of dispute
- date
- Food Authority name and address

Communications between Food Authorities and multi-site food businesses should be in accordance with Primary Authority requirements and, or Home Authority Principle. The inspection plan produced by a Primary Authority may require particular feedback from Food Authorities and this must be given, where requested.

Direct communications between Food Authorities and multi-site food businesses should normally be with the head office of the business concerned, unless the business has given a different address for communications to be sent.

Documents that are left with on-site personnel and those that are sent by electronic means should also be copied to the relevant head office or other address, unless the head office indicates otherwise.

Food Authorities should ensure their management information systems (databases) are updated as soon as practicable.

## 4.4 Requirement for food safety management procedures based on HACCP principles

Article 5 of Regulation (EC) No 852/2004 requires all food businesses, (except primary producers, with the exception of establishments approved for sprouting seeds) 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.

Regulation (EC) No 852/2004 requires food businesses to put in place, implement and maintain food safety management procedures based on HACCP principles. The FSA has produced the Safe Catering Pack and the Safer Food, Better Business (SFBB) package to help businesses comply with Regulation (EC) No 852/2004, which are available through FSA's website.

Food establishments 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 establishments 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 so FBOs adopt good practice to improve compliance with food law.

In following an educative approach, authorised officers 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 authorised 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.

#### 4.4.1 HACCP flexibility

Article 5 of Regulation (EC) No 852/2004 is flexible, in that it 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. In particular, it is necessary to recognise that, in certain food businesses, it is not possible to identify critical control points and that, in some cases, good hygienic practices can replace the monitoring of critical control points.

The European Commission has published a <u>Commission Notice on HACCP</u> and flexibility and which relates HACCP to Prerequisite programmes. Commission guidance on flexibility, in particular for traditional products/methods and other specific manufacturing is available for FBOs and for Food Authorities.

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 the flexibility to put in place procedures based on the HACCP principles. This section describes this flexibility for small businesses.

For enforcement, in practice, compliance means:

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

#### 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
  - follow the food safety procedures in the business
  - have proportionate training (formal training may not be necessary to achieve the required competencies)

- have on the job training where appropriate
- 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 authorised officer might judge progress towards complying with it in small businesses.

The table below breaks down the components of the legislation into the standard seven principles of HACCP, some of the flexibility in the legislation is identified. Although guidance materials may use the seven-principle framework, it is not necessary for this approach to be used. Provided the same outcome is achieved and safe food is produced. This is clarified in Annex III of the Commission guidance on flexibility.

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.

#### 4.4.1.1 Seven principles of HACCP Table

#### 1) Identify any hazards that must be prevented eliminated or reduced.

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.

The traditional HACCP approach of controlling some hazards through pre- requisite 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.

For enforcement, in practice, this means:

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.

### 2) Identify the critical control points (CCPs) at the steps at which control is essential

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.

#### 3) Establish critical limits at CCPs;

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.

#### For enforcement, in practice, this means:

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.

#### 4) Establish procedures to monitor the CCPs;

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.

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.

#### For enforcement, in practice, this means:

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.

#### 5) Establish corrective actions to be taken if a CCP is not under control;

It is also important that the business knows what to do when things go wrong – the corrective action that needs to be taken.

#### For enforcement, in practice, this means:

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.

## 6) Establish procedures to verify whether the above procedures are working effectively;

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.

#### For enforcement, in practice, this means:

Seeing sufficient evidence that the procedures in a business are reviewed to ensure they continue to be appropriate and reflect changes in the business.

## 7) Establish documents and records to demonstrate the effective application of the above measures:

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.

#### For enforcement, in practice, this means:

- Seeing documentation that is up to date and describes the main procedures or methods used in the business to control the most important hazards;
- 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.

However, for simple small businesses following good hygienic practice, guides, documentation and record keeping might not be necessary.

#### 4.4.1.2 Role of the Food Authority

Larger businesses and manufacturers may continue to develop and use traditional HACCP systems. The approaches developed by the FSA, Safe Catering Pack and Safer food, better business (SFBB) are approaches considered suitable for use by caterers.

Small food manufacturers represent a specific banding of businesses falling between those businesses where a SFBB type approach is suitable and larger manufacturing businesses with technical competence on the traditional seven principle HACCP approach.

To support small food manufacturing businesses, the FSA has developed 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. Online guidance is available for authorised officers.

Proper implementation of the appropriate support model constitutes compliance with the HACCP requirements of Article 5 of Regulation (EC) No 852/2004.

Businesses should either have in place or be seen to be making progress towards having effective food safety management systems. 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:

- cooking
- cleaning
- chilling
- cross-contamination

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.

#### 4.4.2 FSA Approved Assurance Schemes

Details of those assurance schemes which currently have FSA approved status, together with a link to the relevant Memorandum of Understanding (MoU), can be found on the FSA website.

Details on the criteria, the process for scheme approval, governance arrangements, and exchange of information with enforcement authorities can be found in the

<u>guidance</u> on approved assurance schemes in the food hygiene at the level of primary production sector.

#### 4.4.3 Model forms

The following model forms may be used to record official controls carried out at food business establishments at the level of primary production:

- Primary production food hygiene fresh fruit and vegetable inspection report (Ready to Eat) – long form
- Primary producers: crops grown for food or feed long form

Officers are reminded that these are model forms and they are encouraged to assess the food business establishment ahead of the inspection to determine what areas are applicable to the business.

#### 4.5 Import controls

## 4.5.1 Guidance for Food Authorities on food imported from outside the UK

Significant volumes of food are routinely imported into the UK and it is important that effective arrangements are in place in Food Authorities to check imported food both at the BCP and inland. Food 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 Food Authorities have responsibilities for imported food controls. The purpose of the Practice Guidance is to set out and assist Food 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 (EU) 2017/625 which became Retained EU Law, and Regulation (EU) 2019/1793 which sets out FNAO products that are subject to increased levels of official controls. The provisions of this Regulation are directly applicable but are given effect at national level by the Official Feed and Food Controls (Wales) Regulations 2009, and parallel legislation in Scotland, England, and Northern Ireland.

#### 4.5.1.1 Scope

The scope of the Practice Guidance extends to imported FNAO and illegally imported products of animal origin (POAO) but does not cover control activities for POAO at BCPs.

Please note: BCPs may be situated at seaports, airports or international rail links, and are for POAO from outside the UK.

Except where a specific distinction is made, the Practice Guidance applies to all Food Authorities, both inland and at points of entry, including Port Health Authorities (PHAs). For the purpose of the Practice Guidance 'imported food' means food

imported into the UK from outside the UK; and 'point of entry' means a seaport, airport or international rail link at which imported food is introduced into the UK.

Food 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 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 Food Authority.

For further details of the roles and responsibilities of PHAs, Food Authorities and other Government Agencies and Departments it is recommended that officers view the <u>FSA's Resource Pack</u> for Inland Enforcement of Imported Food Controls, which has been developed for Competent Authorities in England.

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

Food Authorities should put risk-based planned arrangements in place and review and analyse the information gathered, acting where necessary. It is recommended that Food Authorities should carry out quarterly checks at infrequent points of entry. This might include a visit or questionnaire being sent, liaison with port operators and manifest checks.

<u>Guidance</u> 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.

Food Authorities responsible for imported Products of Animal Origin (POAO) at BCPs must refer to central guidance produced by the Department for Environment, Food and Rural Affairs (Defra), available in the BCP Manual.

- 4.5.2 Imported food legislation Food Not of Animal Origin (FNAO)
- 4.5.2.1 The Official Feed and Food Controls (Wales) Regulations 2009

The Official Feed and Food Controls (Wales) (Miscellaneous Amendments)
Regulations 2019 give effect to the import provisions of Regulation (EU) 2017/625 in Wales only.

The Official Feed and Food Controls (Wales) Regulations 2009 <sup>45</sup> also 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. It does so by giving the FSA powers to make declarations regarding import conditions for particular products. These conditions can apply with immediate effect.

#### 4.5.2.2 Other legislation

For certain areas, for example, contaminants, there are specific requirements for foods which can be applied at points of entry as well as inland. These requirements are implemented in the UK by separate legislation but the powers to deal with non-conforming food to import are those contained in the Official Feed and Food Controls (Wales) Regulations 2009. Guidance on the contaminant's legislation is available.

#### 4.5.2.3 Food of 'known or emerging risk'

The Welsh Ministers by virtue of Article 47(2)(b) of Regulation (EU) 2017/625 may issue a <u>list</u> of imported FNAO of 'known or emerging risk' regarding the increased level of official controls.

Article 47(1)(d) provides for the types of animals and goods that official controls are required to be performed on when entering the UK at a BCP.

The frequency and nature of such checks are specified by the Secretary of State when products with a risk from particular countries outside the UK are identified.

Such products usually require prior notification by means of a Common Health Entry Document (CHED), import through BCPs (that must have particular facilities available and be approved by the FSA), and will be subject to documentary, identity and physical checks.

The UK has an Early Warning System (EWS) for risks associated with imported FNAO. This is an emerging risk detection tool which aims to protect UK consumers from the risks that may be associated with imported foods. It does this in two main ways:

- by predicting hazards including Salmonella, mycotoxins, pesticide residues, sulphites, etc.) for specific food and feed from specific 3rd countries for inclusion in legislation, for example Annex I of Regulation (EU) 2019/1793 or other safeguard measures
- alerts Port Health Authorities and inland Food Authorities to newly identified imported food issues, primarily FNAO (foods not of animal origin) but increasingly POAO (products of animal origin).

Intelligence from the EWS is disseminated monthly to facilitate local targeted enforcement and authorised officers who deal with imported food are recommended to take note of its proposals.

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<sup>&</sup>lt;sup>45</sup> Official Feed and Food Controls (Wales) Regulations 2009

#### 4.5.2.4 **UK** safeguard measures

The European Commission imposes special conditions governing the import of certain FNAO from particular outside the UK 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 (usually BCPs or Import) following prior notification and may require that they must be accompanied by a health certificate and results of sampling and analysis.

#### 4.5.2.5 Non-UK country pre-export checks

Regulation (EU) 2017/625 Articles 73 (1), (2) and 74 include provisions for the Secretary of State to grant outside the UK reduced import checks on imported goods. Such arrangements will be restricted to those countries where the Secretary of State is satisfied that effective official controls are in place to carry out the appropriate pre-export checks immediately prior to export to the UK. Details of relevant products and countries outside the UK will be notified to Food Authorities, as appropriate.

This status can be repealed by the Secretary of State in the light of information or experience. Where such arrangements are in place, Food 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 Food Authorities have concerns relating to any such arrangements based on checks carried out, they must notify the FSA as soon as possible.

#### 4.5.3 Information

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

- the port operator
- stakeholders, including importers and import agents in addition to airlines/shipping operators
- Internal Temporary Storage Facilities (ITSF) and External Temporary Storage Facilities (ETSF)
- trade type (volume, nature, frequency and trade routes)
- port health and safety requirements
- security requirements including access to port/Customs areas

Points of entry that are designated as BCPs 'authorised' for certain higher risk commodities should also:

- have access to 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 BCPs in their BCP Manual
- maintain equipment for carrying out inspections and sampling of imported food

 maintain 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 timescale of analysis/examination and issuing of the results

See Chapter 2 of the Food Law Code of Practice for information on the communication between Food Authorities for Food 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 <u>FSA's</u>
Resource Pack for Inland Enforcement of Imported Food Controls.

Where relevant, Food 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.

#### 4.5.4 Records

#### 4.5.4.1 Identifying and recording food importers

All Food 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, Food Authorities/PHAs should refer to the scope of Article's 44, 45 and 47 within Regulation (EU) 2017/625. 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, Food 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 FBOs and other local government departments as part of outline programmed activities.

#### 4.5.4.2 Records of consignments and examinations

Food 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 outside the UK.

## 4.5.4.3 Arrangements for points of entry without a permanent Food Authority presence

The <u>Import controls at smaller seaports and airports guidance</u> provides further advice on imported food control at points of entry through which occasional and/or low levels of consignments of FNAO are received.

#### 4.5.5 Reporting, notification and prohibition

#### 4.5.5.1 Nominated officer for imported food controls

The details of the nominated officer or changes to the nominated officer should be notified to the FSA, who can be contacted by e-mail: lasupportwales@food.gov.uk.

#### 4.5.5.2 Monitoring returns

All Food 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. <u>Guidance on the completion of imported food returns on LAEMS</u> is now on Smarter Comms.

Food 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 Secretary of State in connection with emerging animal/public health issues or for inclusion in the Multi-Annual National Control Plan (MANCP) or annual reports that GB produces in accordance with the requirements of Articles 110 and 111 of Regulation (EU) 2017/625.

#### 4.5.5.3 Notification of food hazards or incidents

The FSA's Consumer Protection Team can be contacted by e-mail: <a href="mailto:wales.foodincidents@food.gov.uk">wales.foodincidents@food.gov.uk</a> or on 029 2067 8961 during office hours and on 07789 926 573 out of hours.

All Food 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 Chapter 5 of the Code and any subsequent documents.

#### 4.5.5.4 Notification of illegal imports of POAO

The Food Authority should notify Defra whenever illegally imported POAO are seized under Regulation 19 of the Trade in Animals and Related Products (Wales)

Regulations 2011 (TARP). Food Authorities should report the seizures to Defra using the IIT1 form. The reporting of seizures by Food 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 Food Authorities will need to obtain the necessary password permission in order to access these areas from.

- The Association of Port Health Authorities
- CIFH

The information provided in this form is also shared with the FSA's Food Crime team, please email: <a href="mailto:foodcrime@food.gov.uk">foodcrime@food.gov.uk</a>.

Please note: Where illegally imported POAO is found at a point of entry, this is dealt with there by the Food Authority. If illegally imported POAO is found outside of the BCP it is instead referred to Border Force for their action and should also be reported to the FSA.

#### 4.5.5.5 Prohibition

It is an offence<sup>46</sup> for any person to import a product that does not comply with the food safety requirements as set out in 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 direct from outside the UK.

#### 4.5.6 Liaison/referrals

Whenever inland Food 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 Food 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 Food Authorities covering points of entry to refer imported food matters to inland Food 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 Food Authority.

- Examples include where:
- a consignment of FNAO, which is subject to emergency controls or other restrictions, has been illegally imported for example without being presented to the Food Authority at the point of entry for the required checks to be carried out

<sup>46</sup> Regulation 28 as read with Regulation 41 of The Official Feed and Food Controls (Wales) Regulations 2009

- the Food 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 (Wales) Regulations 2009 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
- 'Higher risk' FNAO transferred under detention to an inland ETSF facility to be supervised pending the outcome of laboratory tests.

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

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

#### 4.5.7 Inland inspection of imported food

When considering specific imported food inspection programmes local Food 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 or sell food from outside the UK, in particular those premises that are the first destination after import. Such premises are likely to include:

- specialist supermarkets/retailers
- manufacturers
- 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 country outside the UK. The FSA's Resource Pack for Inland Enforcement of Imported Feed and Food Control 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 the FSA website.

#### 4.5.7.1 Deferred examination of FNAO – Inland controls

Regulation 27 of the Official Feed and Food Controls (Wales) Regulations 2009 allows for (in exceptional circumstances and where the PHA/Food Authority have valid reasons) import controls for the examination of consignments of FNAO to be deferred and undertaken by the inland Food Authority covering the ETSF or international rail terminal or at any other place of destination in the UK.

#### 4.5.8 Sampling of imported food

#### 4.5.8.1 Considerations for sampling

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

- any statutory requirements for sampling laid down by the Secretary of State in emergency control Regulations (usually this will occur at a point of entry)
- any agreed WLGA/FSA sampling programmes
- any sampling required following a Food Alert, EWS or RASFF notification
- information from any EU, WLGA, regional liaison group, local or other sampling survey
- any imported food where there is no known history or information on the product

Food Authorities should also take into account local priorities, including consumer complaints relating to imported food, and their local business profile when considering sampling priorities, 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.

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

#### 4.5.9 Official Controls on FNAO

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

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 Article 49 of Regulation (EU) 2017/625.

#### 4.5.9.1 Identification

It is important that Food Authorities with a point of entry are aware of the volume and nature of foods entering the port. Food 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.

Food Authorities overseeing airports, ETSFs and international rail terminals must set up, implement and maintain documented procedures on the arrangements in place to identify imported food. Where appropriate, arrangements should be put in place to obtained/gain access to airline manifest documents should be checked and these should be checked frequently.

This might be carried out through:

- liaison with HMRC regarding food imported directly from outside the UK or ports under T1 arrangements (a transit declaration made to HMRC. T1 signifies those goods that are not in free circulation i.e. still subject to Customs control)
- liaison with ITSF 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.

#### 4.5.9.2 Examination

Imported food should be subjected to risk-based checks. Article 44(1) and (2) of Regulation (EU) 2017/625 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 retained EU law. Food Authorities with points of entry which are not designated to handle certain 'higher risk' FNAO products subject to safeguard measures 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 safeguard measures, are subject to 100% checking. At the BCP the documentation that would be checked, would consist of for example, health certification and non-UK country results of sampling and analysis. However, inland documentary checks may involve, for example, checking the CHED 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 BCP the checks would be to ensure the

product tallies up with all of the documentation provided, for example, checking batch/consignment codes for the products against the accompanying health certification. An identity check conducted inland would be closely linked with the documentary check but may include verifying that the <a href="CHED">CHED</a> corresponds with the product. 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 and condition of the product, temperature checks, organoleptic testing, and chemical or microbiological examination, or any other check necessary to verify compliance with <a href="UK">UK</a> food safety requirements. Such checks may also take into account any guarantees that the Food Authority of the non-UK country has given. 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 (Wales) Regulations 2009 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 safeguard legislation
- the risk associated with different types of food safety issues
- local knowledge of the product for example new or unusual
- any requirements following a Food Alert, EWS or RASFF notification
- the history of compliance for the product, country of origin and exporter/importer
- the controls that the FBO importing the food has carried out
- any guarantees that the Food Authority of the non-UK country of origin has given under the non-UK country pre-export checks provisions in Regulation (EU) 2017/625
- any existing co-ordinated programmes for example at the request of or under the direction of other food control/advisory bodies
- adequacy or sufficiency of documentation for example discrepancies which need further investigation
- suspicion of non-compliance

Checks might also be influenced by information received from inland Food 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) (Wales) 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.

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

#### 4.5.9.3 Deferred examinations of FNAO

Deferred examinations may be considered where the Food Authority at the BCP 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 Food 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 Food Authority covering the point of entry. In coming to any decision, liaison with the receiving Food Authority should be carried out to ensure that appropriate checks will take place and deferral should therefore be based on full cooperation and agreement between the two Food Authorities.

Where products are subject to a safeguard measure which requires entry through a BCP, 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 there is a known or emerging risk, food should 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 (Wales) Regulations 2009 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 Food Authority. This process should be supervised by the authorities involved. The Food Authority at the point of entry should notify the receiving Food Authority forthwith and in writing that the food has not been examined and forward to the Food Authority a copy of any written undertaking given by the importer.

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

#### 4.5.10 Onward transportation

Article 51 of Regulation (EU) 2017/625 and some other safeguard measures permit the authorisation by the Food Authority at a BCP for onward transportation of a consignment(s) of foods of non-animal origin that may have been sampled at the BCP pending results of tests/analysis. The Food Authority at the BCP may authorise

these arrangements; however, where authorisation is given, the Food Authority at the point of destination must be consulted. Appropriate arrangements must be put in place to ensure that the consignment remains under the continuous control of these Food 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 BCP to an inland authority's remit) s.

## 4.5.11 Fees

Article 79(2) of Regulation (EU) 2017/625 and the other safeguard measures provide that mandatory fees for FNAO imports of a 'known or emerging risk' are determined and calculated in accordance with the criteria laid down in article 81 and 82 Regulation (EU) 2017/625.

## 4.5.12 Retention of import documentation

Food Authorities with a point of entry for imported food must 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 External Temporary Storage Facilities or international rail terminals) and deferred examinations must provide consignment traceability and permit effective internal monitoring.

This information must 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 must be held for three years.

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 country outside the UK.

Copies of the following information should be retained:

- the Common Health Entry Document (CHED) for a period of three years
- the original of each non-UK country's health certificate or any document required to accompany a consignment and subject to checking for example results of analysis, for a period of three years
- all submission forms with which samples are sent to laboratories for examination/analysis and a record of the results of all such examinations, for a period of one year

## 4.5.13 Enforcement at points of entry and inland

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, 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.

## 4.5.14 Products of Animal Origin (POAO) enforcement

#### 4.5.14.1 Imported food legislation - POAO

Defra is the Government Department designated as the Central Competent Authority for controls at BCPs 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 has provided <u>guidance on importing and exporting live animals or animal products</u>.

The FSA has also provided a <u>resource pack</u> (see pages 29-31) for Food Authorities within Wales that are responsible for enforcement of imported food inland to explain key elements of the Trade in Animals and Related Products (Wales) Regulations 2011 SI No 2379 (W. 252) ('TARP'), how those Regulations are applied and fit with other existing domestic legislation.

# 4.5.14.2 The Trade in Animals and Related Products (Wales) Regulations 2011 SI No 2379 (W. 252)

Under Regulation 19 of the Trade in Animals and Related Products (Wales) Regulations 2011, the Food Authority must seize any consignment that is either: brought into Wales other than through a BCP approved for that animal or product, removed from a BCP without a Common Health Entry Document (CHED) or the authority of the Official Veterinary Surgeon (OVS) (or official fish inspector (OFI) in relation to fish and fishery products) at the BCP, or transported from a BCP to a destination other than that specified on the CHED. Regulation 20(3) – If a consignment of products is seized outside a BCP under Regulation 19 the Food 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 Regulation 20(1)(b) or 20(1)(c).

## 4.5.14.3 Illegally introduced POAO

POAO must be imported in accordance with the relevant provisions of the Trade in Animals and Related Products (TARP) (Wales) Regulations 2011. These require that POAO are imported through a designated BCP and are subject to veterinary checks<sup>47</sup>. A CHED must be issued for consignments which pass the veterinary checks, and this should accompany the consignment to the first premises after

 <sup>&</sup>lt;sup>47</sup> Regulation 13 and 15 of the Trade in Animals and Related Products (TARP)
 (Wales) Regulations 2011

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 BCP of entry, for clearance or have not received a correctly completed CHED from the BCP.

Border Force are responsible for detecting smuggled POAO in Customs controlled areas including ETSF. However, Food Authorities have responsibilities relating to goods presented at BCPs and also inland where officers come across illegal POAO in the course of their routine enforcement activities.

The FSA's Operations Group is responsible for illegal POAO found at premises under its control. Where FSA Operations staff discover meat in approved cutting plants that they suspect is illegally imported, they have the primary responsibility and enforcement powers to deal with it.

All Food 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 (Wales) Regulations 2011. This should be done as soon as possible.

## 4.5.14.4 Reporting

A notification to Defra should be made when illegally imported POAO is seized under Regulation 19 of the TARP (Wales) 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.

## 4.6 Sampling and analysis

This section concerns the procedures that must be followed when food samples are procured under Regulation 12 of the Food Hygiene (Wales) Regulations 2006 or Section 29 of the Food Safety Act 1990, and the associated requirements of the Food Safety (Sampling and Qualifications) (Wales) Regulations 2013.

The Food Hygiene (Wales) Regulations 2006 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 Food Authority. Where the quantity or frequency of sampling gives rise to significant financial consequences for the owner of the food, the Food 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 should purchase the sample.

Legislation provides a framework for Food Authority sampling, which is carried out with a view to taking formal enforcement action if results are unsatisfactory.

All samples that are taken by authorised officers that are sent to an Official Laboratory constitute official control samples.

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 sampling provisions of this section do not apply to samples of food:

- that are the subject of complaint and are brought to the Food Authority by consumers or other agencies
- that are submitted to the Public Analyst for monitoring or surveillance purposes alone, i.e. there is no intention at the time of sampling that any formal enforcement action will ensue from the result
- procured in accordance with food law which are not taken for analysis or examination, for example samples submitted for the opinion of other experts for example pest identification etc
- that are taken as evidence for example use-by dates

## 4.6.1 Certificate issued by Public Analyst or Food Examiner

Regulation 13 of the Food Hygiene (Wales) Regulations 2006 require a Public Analyst or Food Examiner to give the officer who submitted the sample, a certificate specifying the result. Food 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.

The Certificates of Analysis or Examination (as specified in Schedule 3 of the Food Safety (Sampling and Qualifications) (Wales) Regulation 2013 are available for formal samples on request from either a Public Analyst or Food Examiner. The laboratory issuing the test report and Certificate of Analysis or Examination must use test methods that are accredited to ISO/IEC 17025:2017 (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 (EU) 2017/625. The test report and Certificate of Analysis or 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.

## 4.6.2 Division of samples for analysis

The sample must, as soon as possible, be divided into three representative parts. Unless the sample meets the criteria for submission for analysis without division.

The resultant parts of the sample are referred to in the Code as final parts. Where practicable, the division should be carried out in the establishment of the FBO, who, if present, should be given the opportunity to observe the sampling and division before being invited to choose one of the parts for retention.

The sampling of imported foods at the port of entry may pose difficulties. In the special circumstances found by Port Health Authorities, a sample need not be divided on the premises or in the presence of any representative of the seller/owner or importer, unless the legislation under which the sample is taken specifically requires otherwise.

The sampling of foods procured through distance sales such as online or mail order need not be divided in the presence of the FBO or any representative of the FBO, unless the legislation under which the sample is taken specifically requires otherwise.

## 4.6.3 Samples for analysis – Quantity

The nature and quantity of any sample must be such as to enable the required analysis to be made, and that should be the case after it is divided into three parts. 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.

All samples for analysis, taken under section 29 of the Food Safety Act 1990 in accordance with the Food Safety (Sampling and Qualifications) (Wales) Regulations 2013 and with the requirements of the Code, must be submitted to the appointed Public Analyst at a laboratory accredited for the purposes of analysis, and which appears on the <u>list of official food control laboratories</u>.

Samples procured under section 29 of the Food Safety Act 1990 can be subject to examination if considered appropriate.

## 4.6.4 Samples for analysis – Containers for samples

Samples of non-prepacked 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. 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 Food Authority, the place, date and time of sampling and an identification number. Where necessary, they 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.

## 4.6.5 Samples for analysis – Transport of samples

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 in accordance with Regulation 8(2) of the Food Safety (Sampling and Qualifications) (Wales) Regulation 2013.

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 (for example 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.

# 4.6.6 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 Safety (Sampling and Qualifications) (Wales) 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) of the Food Safety (Sampling and Qualifications) (Wales) Regulations 2013
- 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, for example 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) of the Food Safety (Sampling and Qualifications) (Wales) Regulations 2013 the owner must be notified of its submission for analysis.

Regulation 7(2) of the Food Safety (Sampling and Qualifications) (Wales) Regulations 2013 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.

### 4.6.7 Notification of formal sampling activity (analysis)

The owner of the food must be notified of any formal sampling activity.

The notice must be given as soon as practicable after sampling has taken place and should include the name of the food.

If the identity of other interested parties such as the manufacturer, packer or importer, agent, etc. is available on the packaging of the sample, with a United Kingdom address, the officer should notify that person of the procurement, in writing.

#### 4.6.8 Certificate of analysis

Certificates of analysis must be in the format set out in Schedule 3 of the Food Safety (Sampling and Qualification) (Wales) Regulations 2013 but may be subject to adaptation as circumstances reasonably require).

### 4.6.9 Notification of results (analysis)

In accordance with Regulation 10 of the Food Safety (Sampling and Qualifications) (Wales) Regulations 2013, a copy of the certificate of analysis must be supplied, on request, to the owner of the food which has been analysed.

If the alleged offence is thought to be related to the manufacturer, they should be informed at the earliest opportunity by the fastest possible means (for example telephone, subsequently confirmed in writing) along with the relevant Food Authority.

The packer or, in the case of imported food, the importer, or their agent, may also be notified.

However, where the Food Authority is undertaking an investigation the release of the certificate may be delayed if its early release might compromise the investigation.

#### 4.6.10 Samples for examination

All samples for examination, taken in accordance with Regulation 12 of the Food Hygiene (Wales) Regulations 2006 and the requirements of the Code, must be submitted to the Food Examiner at a laboratory accredited for the purposes of examination, and which appears on the list of official food control laboratories.

The Food Safety (Sampling and Qualifications) (Wales) Regulations 2013 apply in relation to samples procured by an authorised officer of a Food Authority under

regulation 13 of the Food Hygiene (Wales) Regulations 2006, as if it were a sample procured by an authorised officer under section 29 of the Food Safety Act 1990.

## 4.6.11 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 (for example alcohol).

## 4.6.12 Samples for examination – Continuity of evidence/traceability

Food samples are normally dealt with in a food laboratory and faecal specimens in a clinical laboratory, operating independently of the Food 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
- sample details (for example temp, batch no.)

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. An individual in the laboratory must be capable of making a sworn statement and of providing sworn oral testimony on these points.

#### 4.6.13 Samples for examination - Organisation

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.

## 4.6.14 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.

## 4.6.15 Samples for examination – Handling

Samples of non-prepacked 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 (for example 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, for example food handling techniques/storage methods observed in respect of the food sampled.

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.

# 4.6.16 Samples for examination - Handling, transport and storage of faecal specimens

When required to investigate reported or suspected cases of foodborne illness and obtain faecal specimens, officers must have a supply of appropriate leak-proof containers.

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.

## 4.6.17 Notification of formal sampling activity (examination)

The owner of the food must be notified of any formal sampling activity. The notice should be given as soon as practicable after sampling has taken place and should include the name of the food.

If the identity of other interested parties such as the manufacturer, packer or importer, or his or her agent etc. of food that has been procured by an officer for examination is available on the food packaging, and the address is in the United Kingdom, the officer should notify that person of the procurement, in writing.

#### 4.6.18 Certificates of examination

Certificates of examination must be in the format set out in Schedule 3 to the Food Safety (Sampling and Qualifications) (Wales) Regulations 2013.

#### 4.6.19 Notification of results

In accordance with Regulation 10 of the Food Safety (Sampling and Qualifications) (Wales) Regulations 2013, a copy of the certificate of examination must be supplied, on request, to the owner of the food which has been examined.

If the alleged offence is thought to be related to the manufacturer, they should be informed at the earliest opportunity by the fastest possible means (for example telephone, subsequently confirmed in writing), along with the relevant Food Authority.

The packer or, in the case of imported food, the importer, or their agent, may also be notified.

However, where the Food Authority is undertaking an investigation the release of the certificate may be delayed if its early release might compromise the investigation.

### 4.6.20 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.

## 4.6.21 Requests for information from manufacturers or importers

Food Authorities should meet all reasonable requests to provide information on the selection of the sample, sampling method and method of microbiological examination or chemical analysis, to enable the manufacturer or importer of the food to assess the result or repeat the examination or analysis.

## 4.6.22 Sampling of goods attained via distance communication

Sampling of goods ordered via distance communication<sup>48</sup> (i.e. on-line) by the Food Authority without identifying themselves can be validly used for the purposes of an official control. Food Authorities must inform the food or feed business operator that such a sample has been taken and, where appropriate, is being analysed in the context of an official control.

#### 4.6.23 Right to second opinion

Food Authorities must ensure that operators, whose animals or goods are subject to sampling, analysis, test or diagnosis in the context of official controls, have the right to a second expert opinion, at the operator's own expense.<sup>49</sup>

Guidance on how to submit for a second expert opinion may be found here.

Guidance on how to submit a referee sample to the government chemist can be found here.

## 4.7 Inspection of ships and aircraft

#### 4.7.1 Introduction

Officers to consider additional aspects relating to the inspection of ships and aircraft. An inspection template for airlines named 'Airline Food Safety Questionnaire', which may be adapted, where appropriate, provided that the procedures outlined in the Code are not overlooked, can be found in the Port Health at Airports Group (which you would need to join) on the Knowledge Hub (https://khub.net).

Food Authorities must have regard to:

- The Food Hygiene (Wales) Regulations 2006 include any ship or aircraft in the definition of premises
- Schedule 4 to these Regulations which sets out specific temperature control requirements does not apply to these means of transport
- The relevant temperature requirements for these means are stated in Chapter IV of Annex II of Regulation (EC) No 852/2004

#### 4.7.2 General

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

<sup>&</sup>lt;sup>48</sup> Article 36 of Regulation (EU) 2017/625

<sup>&</sup>lt;sup>49</sup> Article 35(1) of Regulation (EU) 2017/625

#### 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 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, sometimes 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 (for example some cruise liners over 3,000 passengers and 1,200 crew) to smaller vessels crewed by 10 to 15 personnel.

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 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 FBO/food business proprietor is in each case.

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

#### 4.7.3 Catering waste

There are requirements for FBOs in Chapter VI of Annex II of Regulation (EC) No 852/2004 for disposal of food waste and non-edible products. These require FBOs to ensure there is no accumulation of waste, that waste is stored in suitable containers and are free of pests, etc (further advice regarding the inspection is available at 8.10.2.). Waste must be disposed of hygienically and in an environmentally friendly way in accordance with other legislation.

For FBOs operating from establishments to which the rules of Chapter III of Annex II of Regulation (EC) No 852/2004, (for example B&Bs, stalls and temporary premises) apply, point 2(f) of Chapter III requires adequate arrangements or facilities for the hygienic storage or disposal of waste to be available.

## 4.7.4 International catering waste

The disposal of international catering waste to landfill is regulated by the Animal By-Products (Enforcement) (Wales) Regulations 2014. 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.

## 4.7.5 Inspections and enforcement

Authorised officers should bear in mind that other parts of the Code and Practice Guidance are primarily designed for the inspection of fixed premises, and that there are significant differences between these and ships and aircraft.

Food Authorities should ensure:

- they obtain appropriate security clearance prior to inspection
- they consider the range and variety of vessels is an important factor when
  planning ship inspection activities. In respect of aircraft, primary consideration
  should be given to the origin of the food on board, including water and other
  drinks, and the transport to, and loading of, the aircraft
- they consider that food hygiene standards on ships and aircraft meet the relevant requirements of Regulation (EC) No 852/2004
- any procedures be commensurate with the size and type of the vessel and the nature of activities undertaken on board
- enforcement action is carried out in accordance with a written enforcement policy
- when serving notice, the authorised officer contacts the Management Company or the Handling/Shipping Agent. If considered necessary, in respect of ships, the officer should also contact the Maritime and Coastguard
- a strategy for frequency of inspection is adopted, based on knowledge about different types of craft, their origin and history
- before they consider a ship or aircraft inspection, all relevant information is obtained from the other relevant authorities, the shipping operator, airline, or shipping agent as appropriate chapters of the Framework Agreement

Article 5 of Regulation (EC) No 852/2004 requires the development and implementation of food safety procedures based on HACCP principles.

An officer may serve a Hygiene Improvement Notice, Hygiene Emergency Prohibition Notice or a Remedial Action Notice in relation to any ship or aircraft. The conditions that must be met before such a notice can be served are the same as apply in relation to fixed premises.

## 4.7.6 Craft registered outside the UK

Communications with other countries outside the UK regarding incidents will be via the FSA. If the ship or aircraft is registered in a non-UK country, the FSA should be given full details to allow the matter(s) to be raised with the Food Authorities in the relevant country.

## 4.7.7 UK military ships and aircraft

Authorised officers should contact Portsmouth City Council, the Royal Navy Primary Authority for procedural guidance prior to any proposed visit to a Royal Navy ship or submarine. Wycombe District Council, the Royal Air Force Primary Authority, should be contacted for guidance prior to any proposed visit to RAF aircraft. Similarly, Rushmoor Borough Council, the Army Primary Authority should be contacted prior to any proposed visit to an army base.

Only military aircraft used for 'Air Trooping' should be included in inspection programmes. No food business activities take place on armed forces' yachts.

#### Authorised officers:

- should refer to Chapter 6 (Categories of Crown Premises) in relation to security considerations when visiting UK military ships and aircraft, which must be regarded as Group 3 premises
- give prior notification before a proposed visit
- report safety issues found on inspection, which concern UK military ships and aircraft to single Service Environmental Health leads and the relevant Home Authority or Primary Authority
- must bear in mind the ultimate purpose of military ships and aircraft, and that galley design may have been constrained for operational reasons
- should give military policy, procedures and practices due consideration
- should take account of the relevant parts of 'JSP 456 Defence Catering Manual Vol. 3'

	Primary Authority	Environmental Health Lead
Royal Navy	Portsmouth City Council	SO2 Environmental Health Policy
	<b>雷</b> : (02392) 834253	<b>2</b> : (02392) 625554
RAF	Wycombe District Council	Command Environmental Health
	<b>雷</b> : (01494) 421710	Officer
		<b>2</b> : (01494 494334)
Army	Rushmoor Borough Council	SO1 Environmental Health Policy
	<b>2</b> : (01252) 398398	<b>2</b> : (01276) 412931

## 4.7.8 Food safety inspections of ships

## 4.7.8.1 Preparation

As with inland premises, ships or other vessels comprise a wide number of different types with a consequent wide variety of food operations on board. Some vessels serve members of the public (e.g. Ferries and Cruise Ships) whereas others operate with a permanent or semi-permanent crew on board and the food operation is purely for their own consumption. Vessels engaged on international voyages require a Ship Sanitation Certificate under the International Health Regulations 2005, issued by the World Health Organization. Inspection for these certificates includes inspection of the food operations against a set of technical standards that are intended to apply globally (The WHO Technical Handbook), but the primary purpose of these is protection against diseases and conditions of public health concern. It is thus possible that vessels may be inspected for dual purposes.

Before commencing an inspection for food safety purposes, authorised officers should ascertain whether it is appropriate to inspect the vessel based upon the suggested criteria in paragraph 4.7.8.7.

For clarity, the inspections referred to in this guidance are for food safety purposes rather than ship sanitation purposes. However, where there is a potential crossover between the two, reference is made to accord with best practice under both types of inspection.

The officer should ensure:

- the ship's Master (or appropriate officer in control) is aware of the purpose of the inspection
- they determine the scope of the food business activities taking place on the vessel

Initial discussions with the ship's Master or representative should include consideration of any documentation that is available and identification of all food and drink related activities undertaken on the vessel.

Where arrangements are in place, the relevant Port Health Authority should ensure that shipping operators are aware of their responsibilities in relation to providing information to the Food Authorities.

## 4.7.8.2 Decision to inspect and frequency of inspection

The decision to inspect vessels for food safety purposes should be based upon the following criteria:

- whether the food operation serves members of the public (whether paying or not)
- whether the vessel has its home port in the United Kingdom

If the answer to both questions is yes, the vessel should be inspected in a manner commensurate with inland food premises. The frequency of inspection should be based on the intervention ratings set out in Chapter 4 of the Code. The ship food safety inspection should be recorded on the Port Health Authority management information system and form part of a LAEMS return.

If the answer to either one of these questions is no, it will be the decision of each individual Port Health Authority as to whether they deem a food safety inspection appropriate at any particular time based upon the criteria in 4.7.8.7. Inspections may be recorded via LAEMS in this scenario.

If the answer to both of these questions is no, it will not normally be appropriate to carry out food safety inspections. Inspections can and should still be carried out as per the three scenarios set out in Annex 2 of the World Health Organization (WHO) <a href="Technical Handbook">Technical Handbook</a>. This will be an inspection for Ship Sanitation purposes and should not be recorded under LAEMS.

It is quite possible that inspections for both food safety and ship sanitation purposes could take place concurrently. In this scenario, the authorised officer must be clear upon where separate requirements begin and end and must clearly differentiate to the master of the vessel the differing findings from each inspection.

Account should also be taken of any available data-sharing facility with reference to historical evidence of non-compliance. Interventions necessary for food safety purposes should then be carried out accordingly and the outcome transmitted without delay to other UK Port Health Authorities via any appropriate method.

Inspection of the vessel:

When there is evidence or suspicion of non-compliance, officers may need to carry out an inspection of the relevant parts of the vessel.

Items for consideration include:

- specifications and sourcing of food and water
- transport to the vessel, loading and subsequent storage
- the type of vessel, the facilities, including equipment, for food preparation/production/storage and the storage, distribution and quality of water used in the food areas or available for drinking purposes

- adequacy of procedures based on the HACCP (hazard analysis critical control point) principles, which will depend on the type of vessel
- food temperature requirements in Annex II of Regulation (EC) No 852/2004
- their food handling activities, the food handlers' knowledge of food hygiene/own health status
- food and water sampling
- arrangements for international catering waste disposal
- pest control procedures
- any known adverse reports or cases/outbreaks of gastric illness, etc

Visits to other vessels, such as training yachts, based at specific ports should be decided on a basis of number of vessels, local conditions and knowledge gained through previous inspections.

## 4.7.8.3 Action on conclusion of the inspection

Following completion of the inspection, the officer should:

- discuss the findings with the ship's Master or delegated representative
- give an indication of the expected timescale of any corrective actions found to be necessary
- prepare an inspection certificate to be given to the ship's Master before leaving the vessel. Documents should be forwarded if this is not possible prior to the ship's departure, the ship's owner should also receive a copy
- send a copy of the inspection certificate to the MCA and the Port Health
  Authority at the next intended port of call, if in UK and, if designated, the
  relevant home Port Health Authority where any serious short comings are
  found. This should be prior to the next possible visit to the vessel

## 4.7.8.4 Liaison with the Maritime and Coastguard Agency (MCA)

Contact should be maintained with the MCA in accordance with the Memorandum of Understanding (MoU) between the Association of Port Health Authorities (APHA), and the MCA dealing with non-military vessels. Exchanges of copies of relevant inspection reports relating to food safety on ships should be undertaken between Food Authorities/Port Health Authorities and the MCA, in accordance with the MoU.

Should there be difficulties with serious shortcomings relating to the existence of a health risk condition (as defined by Regulation 7(2) and Regulation 8(4) of the Food Hygiene (Wales) Regulations 2006 i.e. there is a risk/imminent risk of injury to health) concerning food and water safety whilst a vessel is in port, consideration should be given to liaising with the MCA for the instigation of action to detain the vessel in accordance with procedures in the MoU. Such deficiencies should also be reported to the Food Authority of the state of registration of the vessel.

Vessels such as Passenger Ferries which operate from or are based in UK Ports and are a registered food business in Wales, will fall under the requirements of the Food Hygiene Rating (Wales) Act 2013 and related regulations.

In order to do this, vessels would need to be registered with the relevant Port Health Authority/Food Authority as a food business and given an intervention rating in accordance with Chapter 4 of the Food Law Code of Practice.

## 4.7.8.5 Other issues – ships

If appointed, the Home Authority 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 Food Authorities. For military ships see paragraph 4.7.7 in this guide.

Recipient Food 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 Food 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

#### 4.7.8.6 Other risk criteria

It might also be appropriate to take into consideration the following criteria when determining whether to inspect a vessel for food safety purposes:

- type and size of vessel, for example general cargo/passenger vessel, passenger ferries, cruise vessels
- port of registration
- age/condition/history of vessel
- crew and passenger numbers/profile/'turnover'
- vessels trading pattern/schedule/previous port(s) of call
- confidence in food and water safety management systems
- available documentation
- recent significant reports of food related problems on the vessel
- certificates from previous inspections level of compliance (these could include inspection certificates issued by Food Authorities outside the UK

## 4.7.8.7 Application of the International Health Regulations 2005 (IHR)

Nothing in the Code of Practice overrides or compromises the duties of Port Health Authorities to inspect and ensure compliance by vessels with their duties under the International Health Regulations 2005, their related technical standards and the Public Health (Ships) Regulations 1979.

## 4.7.9 Aircraft inspections

## 4.7.9.1 Preparation

Authorised officers should initially satisfy themselves that any information provided by the airline regarding its food and water suppliers and supplies is satisfactory. It is the responsibility of the airline to provide to the authorised officer any evidence of reputable food suppliers.

The decision to board an aircraft should be based largely on:

- any information provided by the airline
- confirmation of the authenticity of the information
- the receipt of any food or food hygiene related complaints from passengers or crew

If such information is satisfactory, there might be no need to board an aircraft, particularly if the information shows that specific types of aircraft and food safety practices meet requirements.

It is, however, essential to verify on-board conditions and practices at regular intervals by inspection. At least annual checks should be made on the information provided by the airline concerning food hygiene issues, either by:

- the Primary Authority
- an authorised officer of the relevant enforcing Food Authority in the absence of the above

Such checks should confirm, for example, that no changes have taken place to inflight caterers, source of water supply, etc. Such checks should also verify that the in-flight caterer's HACCP plan is being implemented on board and that systems are in place after food and drink has left the flight catering establishment to establish if risks of contamination (includes microbiological, physical, chemical and allergenic contamination) are controlled up to the point of service to the passenger.

Where arrangements are in place, Home Authorities should ensure that airlines are aware of their responsibilities in relation to providing information. Primary Authorities should provide relevant information to other Food Authorities, when requested to do so and, where this relates to general airline policy and procedures, be afforded appropriate confidentiality.

## 4.7.9.2 Information to be obtained to assist inspection procedures

If there is no Primary Authority arrangement, liaison with an airline it is essential to gain an understanding of how they operate food safety controls on board their aircraft, and to allow authorised officers to verify food safety systems.

The large number of airlines and, in some cases, the size of their fleets, requires the following information to be obtained and made available prior to deciding whether to undertake an inspection:

- named contact and contact details for an airline to deal with enquiries (this
  might be a food safety advisor employed by the airline)
- number of aircraft, their type and registration numbers, where appropriate
- routes flown long haul, short haul and countries of destination
- airline food safety policy/procedure documents or manual
- type of catering menus and the service of high-risk foods
- food handler (cabin staff) knowledge up-to-date guidance notes/explanatory sheets and/or training commensurate with the food handling activity covering personal hygiene; handling of food; cross contamination issues arising from other duties; pest awareness; food temperature control (as required by Annex II of Regulation (EC) No 852/2004), if appropriate, and monitoring; own health status and exclusion from work policy
- training records, standard of training, including retraining, when appropriate
- flight caterers, and/or nominated companies assembling and/or transporting
  meals to the aircraft, used by each airline. In-flight menus should assist in the
  assessment of whether high-risk foods are handled and/or prepared on board.
  The onus is on the airline to provide evidence that the food originates from a
  reputable source
- specifications in place with the caterer for the supply of food to aircraft and the accepted temperature for delivery, including for high-risk foods
- details of food and water safety arrangements when supplied to an aircraft in a foreign location
- potable water supply source, use of bowsers, cleaning/disinfection of storage tanks – frequency/effectiveness. To be checked prior to or after the inspection
- flights or routes with return catering including multiple sector catering, and from which airports
- pest control contract and monitoring
- cleaning contractor, with details of contracts, for example cleaning schedules, and monitoring of the effectiveness of the cleaning regime
- reports of analysis/examination of food and potable water on aircraft by the airline, which should relate to the Food Authority's own sampling regime
- whether the airline undertakes self-audits and whether any reports are available

The above information should assist an officer to assess the need to actually board a particular aircraft to carry out an inspection. In practice, taking account of Section 4.5 of the code, and with the appropriate information obtained from the airline company and/or the relevant Primary Authority, this might result in a visit to particular types of aircraft, providing high-risk meals once every eighteen months to two years, unless there are compelling reasons to undertake such visits in an intervening period.

## 4.7.9.3 Inspection of the aircraft

Cabin crew do occasionally prepare food on board an aircraft and should therefore be made aware in their training of possible cross contamination issues related to their other duties on board, such as handling sick bags and cleaning lavatories in flight. Inspections should normally be undertaken before passenger's board the aircraft, ideally after the aircraft has been cleaned, when food is on board, and when airline staff are able to provide assistance and information. Professional judgement should be applied, and inspections might be undertaken at other times as necessary. Should there be any uncertainty as to the information provided by cabin staff, the relevant head office (or Primary Authority) should be contacted for clarification.

## 4.7.9.4 Items for consideration in relation to food safety on aircraft

Following a documentary check, the following matters should be considered/confirmed, as listed in Section 4.7.9.2 when appropriate:

- flight caterers confirmation of the information obtained, regarding source of meals, etc
- transport and loading of aircraft, including the means of temperature control of the food in the delivery vehicle
- food storage facilities on the aircraft, including the provision of insulated containers and/or ice-packs and the maximum stated time period until serving and/or re-heating, taking account of the type of aircraft, for example long or short haul, and the food served
- whether food is prepared on the aircraft and the facilities available for such operations, for example personal hygiene; avoidance of cross-contamination; provision of disposable gloves for certain duties and disinfectant wipes
- return flight meals taking account of the shelf-life of the food
- temperature control (as required by Chapter IV of Annex II of Regulation (EC) 852/2004) and monitoring during flights
- reheating/cooking
- pest control
- water supply source and potability of water/cleanliness of tanks
- procedures for cleaning food handling areas, trolleys/carts
- food and water sampling

#### 4.7.9.5 Other issues – Aircraft

Airlines should be encouraged to adopt, where necessary, approved codes of practice, for example, the International Travel Catering Association (ITCA)/International Flight Services Association (IFSA) World Food Safety Guidelines, and to develop in-house supplier audits, 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 <u>Guidelines</u>.

Aircraft meals are mainly, but not exclusively, prepared prior to departure, some of which might be for return flights. 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 for an authorised officer 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 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, for example assessment of galley cleanliness, increased water sampling for analysis/examination, etc.

Delays to aircrafts 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 '<u>Airline Catering Guidance</u> for Inspectors'

#### 4.7.9.6 Action on conclusion of the inspection

Following inspection, a report should be sent:

- to the airline
- to the relevant Primary Authority (where such an arrangement exists)

Where aircraft from a particular airline are checked and found to be in contravention of the applicable law, full details should be provided to allow adequate follow up, for example:

- the type of aircraft
- flight number
- insufficient knowledge of food hygiene issues amongst the cabin crew

## Chapter 5 Incidents, alerts and food crime

#### 5.1 Introduction

This Chapter deals with:

- food incidents, hazards and alerts
- how Food Authorities are expected to respond and liaise, as appropriate, with other Food Authorities, government departments, delegated bodies, FBOs, the FSA, other relevant agencies (which might include Primary, Originating and Neighbouring Authorities, Medical Specialists, Food Examiners, Public Analysts and Microbiologists) and countries outside the UK
- the role of the National Food Crime Unit (NFCU) and addressing food criminality

## 5.2 Managing Food incidents and alerts

## 5.2.1 Food incidents contacts

<u>Guidance</u> is available to Food Authorities on incident reporting. Food incidents, where appropriate, should be reported using:

- online or via Incident Report Form
- by emailing an Incident Report Form to wales.foodincidents@food.gov.uk
- Tel: 029 2067 8961 (or 07789 926 573 out of hours)

# 5.2.2 Action by the Food Authority - responses to pre-incident contact by FSA

Potential food safety incidents may require the FSA to carry out scoping and assessment by contacting Food Authorities. At this stage of the process, these issues are not classed as food safety incidents: instead, they are *potential* food safety incidents. This contact should establish if a business is in receipt of any affected product(s).

Food Authorities should, where possible provide a response within two hours, so that potential food safety issues can be acted on promptly. If a response is not received within this time, the FSA will contact the food business, copying in the relevant Food Authority on the email message.

#### 5.2.3 Food Incident notifications to the FSA

Food Authorities must notify the FSA's Consumer Protection Team as soon as they become aware of a:

- serious localised food hazard
- non-localised food hazard
- withdrawal or recall of food by a FBO due to non-compliance with the food safety requirements of Article 19 of Regulation (EC) 178/2002
- suspected cases of food fraud/food crime
- significant 'non-hazardous' food incidents

 non-localised/serious localised outbreak of foodborne illness in conjunction with notifying the PHW Communicable Disease Surveillance Centre (PHW CDSC)

On receipt of a notification of a serious localised hazard, the FSA may request for additional information to enable and inform a scientific risk assessment for development of risk management advice or for the publication of a timely FSA alert notification. The Food Authority should where possible, respond to the FSA within two hours of this request.

For FSA requests for information in relation to an outbreak investigation that may require a site visit to be arranged, the Food Authority should respond to the FSA without undue delay, where possible within 48 hours of the request. If Food Authorities are unable to meet these timelines, then they should indicate the estimated time necessary to provide an informed response to the request.

## 5.2.4 Information received locally that may indicate a wider problem

Food Authorities are responsible for investigating and dealing with food that fails to comply with food safety requirements in their areas. Food 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 respectively
- as a result of complaints from members of the public, either directly or through a third party, for example, the police, citizens advice etc.
- through notifications from a manufacturing company, trade association, wholesaler, retailer, importer or caterer
- information from enforcement agencies in other countries; and/or
- 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 Wales – Centre of Infectious Disease, surveillance and Control (PHW – CIDSC)

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.

## 5.2.5 Action by the Food Authority - Root Cause Analysis (RCA)

Where a Food Authority becomes aware that a FBO has withdrawn or recalled food from the market in accordance with Article 19 of Regulation (EC) 178/2002, due to non-compliance with the food safety requirements of that Regulation, the Food Authority should:

- request the FBO to undertake a root cause analysis to determine the reason(s) that the withdrawal or recall occurred
- identify corrective actions which will mitigate reoccurrence

 where permitted, forward the results of the food business's assessment to the FSA for further analysis, to enable long-term preventative actions to be identified and best practice to be applied across the food industry

The root cause analysis performed should identify the initiating cause, in a causal chain, which leads to the withdrawal or recall; and also, the stage at which intervention could reasonably be implemented to mitigate risk and prevent future recurrence.

A root cause analysis reporting form and e learning course for food business operators are available on the <u>FSA website</u>.

In the event that information gathered suggests the presence of dishonesty, consideration should be given to signposting the outcome of the Root Cause Analysis to the National Food Crime Unit (NFCU) at the earliest opportunity. This will enable an early assessment to be made of lines of enquiry which may be required to secure and preserve evidence.

### 5.3 National Food Crime Unit

#### 5.3.1 Role of the NFCU

The NFCU applies developed law enforcement methodology based on the principles of Pursue, Protect, Prepare and Prevent (4P elements). Teams are dedicated to each of those areas appropriately.

The Unit has the remit to investigate serious fraud and related criminality within the food supply chain. This may involve persons operating in a planned and co-ordinated manner, and typically where the volume of material gathered in such an investigation, or the geographical spread of it, and financial loss or gain, or other harm is such that an investigation will demand the commitment of resources for significant lengths of time.

The Unit will aim to lead, support or co-ordinate activity at tactical and strategic levels around all 4P elements. That will be achieved through the development and assessment of intelligence, developed partnership arrangements and increasing capacity and capability to identify the signs of food crime at all levels.

More details on the NFCU are available on the FSA website.

## 5.3.2 Reporting suspicions of food crime to the Unit

Suspicions or information about food fraud or food crime are required to be shared with the NFCU by:

- emailing foodcrime@food.gov.uk
- contacting the Unit on 0207 276 8787
- using the online form for the reporting of intelligence

Food Authorities and regulatory partners should provide food fraud or food crime information. Ideally this will be on a graded and assessed Intelligence Report (sometimes referred to as a 3x5x2). If a 3x5x2 cannot be completed, such

information should still be shared with NFCU by the most appropriate means and by the means of communication listed above.

Where necessary the NFCU can upskill the staff in Food Authorities in identifying and recording intelligence.

## 5.4 Liaison with other countries outside the UK

# 5.4.1 The European Commission's Rapid Alert System for Food and Feed

The Rapid Alert System for Food and Feed (RASFF) is a network managed by the European Commission to facilitate communications between members of the network in responding rapidly to serious direct or indirect risks to human health relating to food and feed.

This section of the guidance is under review and will be updated, as necessary.

## 5.4.2 Notification of food hazards or incidents regarding imported food

This section of the guidance is under review and will be updated, as necessary.

#### 5.4.3 Trans-border matters

This section of the guidance is under review and will be updated, as necessary.

## 5.4.4 Communications with other countries outside the UK

All communications with other countries outside the UK regarding incidents will be via the FSA.

Food Authorities with Port Health and/or BCPs must notify the FSA's Consumer Protection Team if they identify an incident relating to an imported product(s) at the point of entry.

Inland Food Authorities must notify the FSA's Consumer Protection Team if they identify an incident relating to an imported product(s) in their area, that has been released by Port Health and/or BCPs.

Imports with non-compliance issues that has been released inland by Port Health and/or BCPs should continue to be managed via the business handling the goods and the associated importers as part of usual enforcement activities, to achieve compliance. However, Food Authorities should notify the FSA's Consumer Protection Team where there is persistent non-compliance, widespread non-compliance or non-compliance presenting a safety risk.

Subsequent communications to enquiries from countries outside the UK should be sent via the relevant FSA dedicated mailboxes.

- for imports by email at imported.food@food.gov.uk
- for exports by email at thirdcountryexports@food.gov.uk
- for incidents by email at wales.foodincidents@food.gov.uk

Further guidance on Food Authority responses as part of enquiries from other countries outside the UK is under review and will be updated, as necessary.

## 5.4.5 Disclosure of information to countries outside the UK

If circumstances arise where this is required then confidentiality, data protection and human rights issues may need to be considered. In such circumstances, the Food Authority must take account of the contents of its own publication scheme under the Freedom of Information Act. They must apply the law and general principles set out in relevant legislation and case law to the specific facts with which they are dealing. This is best done at a local level, and local administrators must consult their own legal department. See the Practice Guidance for further information regarding disclosure of information to countries outside the UK.

Food Authorities must therefore ensure that any release of information is compatible with national legislation including that relating to Freedom of Information, and Data Protection.

## 5.4.6 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.

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 gathering of evidence from a foreign jurisdiction to be used within the criminal justice system of England, Wales and Northern Ireland can be secured through a Mutual Legal Assistance agreement between the Member State and the UK. This arrangement already exists for securing such evidence from outside the UK. Further information can be obtained from the UK Central Authority.

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 Directorate** 

Home Office 2<sup>nd</sup> Floor, Peel Building, 2 Marsham Street, London SW1P 4DF

Tel: 0207 035 4040

Email: UKCA-ILOR@homeoffice.gov.uk

Food Authorities must 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 <u>Section 3 of the Criminal Justice</u> (<u>International Co-operation</u>) Act 1990. Food 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 Food 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 Food Authority in the Member State concerned to use the information in the proceedings.



## **Chapter 6** Enforcement

#### 6.1 Introduction

This Chapter deals with how Food Authorities use the powers available to them to ensure non-compliances are rectified in an effective and timely manner.

## 6.2 Powers to carry out official controls

## 6.2.1 The Food Hygiene (Wales) Regulations 2006

Regulation 14 of these Regulations permits an authorised officer to enter premises to undertake official controls.

The same Regulation permits:

- inspection of records, including those held electronically
- seizure and detention of records, including those held electronically
- an authorised officer to obtain a warrant for entry

Further powers relating to the detention, inspection and seizure of food, the prohibition of certain activities and the procurement of samples are also contained in these Regulations.

## 6.2.2 The Official Feed and Food Controls (Wales) Regulations 2009

Regulation 18 of these Regulations contains further powers of entry which are applicable to the official control of food. These powers are separate and in addition to those given above and mainly concern the monitoring of official control bodies and must be read in conjunction with Regulation 17(1).

Regulation 31 permits authorised officers of Food Authorities to use the powers set out in Articles 46, 65 to 69, 71 and 72 of Regulation (EU) 2017/625 to take the following action in relation to imported food:

- official detention
- destruction
- re-dispatch
- special treatment

Measures taken by Food Authorities under Article 69(4) of Regulation (EU) 2017/625 are to be taken at the expense of the operator responsible for the consignment.

See section 6.15 of the Practice Guidance for further details on the use of these powers.

Regulation 39 of the Official Feed and Food Controls (Wales) Regulations 2009 may also be used by authorised officers to enter a premises for the purpose of ascertaining whether there has been any contravention of the import provisions of these Regulations in relation to food.

# 6.2.3 The Trade in Animals and Related Products (Wales) Regulations 2011

Regulation 33 of these Regulations provides powers of entry to authorised officers for the purpose of enforcing the provisions of the Regulations, including requirements on the importation of products of animal origin.

## 6.2.4 The Food Safety Act 1990

Section 32 of this Act permits an authorised officer to enter premises to undertake official controls.

The same Act permits:

- inspection of records, including those held electronically
- · seizure and detention of records, including those held electronically
- an authorised officer to obtain a warrant for entry

Further powers relating to the detention and seizure of food, the prohibition of certain activities and the procurement of samples are also contained in this Act.

## 6.3 Food complaints

## 6.3.1 General requirements

As a rule, anybody who may be prosecuted because of a complaint must be notified that the complaint has been made as soon as practicable.

The Food Authority must ensure:

- they notify anybody who has an interest, as soon as preliminary investigations indicate that a complaint may be well founded, and that other potential defendants are notified as they emerge
- where notification is provided other than in writing, confirmation in writing is provided as soon as practicable, which must include the date and nature of the complaint

In exceptional circumstances, where notification might impede an investigation, the notification must take place once it would no longer prejudice further investigation(s).

#### 6.3.2 Involvement of other Food Authorities

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

#### 6.3.3 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 must be sent to the Public Analyst. If it requires microbiological examination, it must 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 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 Food Authority should try to comply with any reasonable request provided it does not compromise the proper storage, analysis, examination or evidential value of the sample.

## 6.4 Dealing with non-compliance

## 6.4.1 The enforcement approach

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

Food Authorities should ensure that enforcement action taken by their authorised officers is reasonable, proportionate, risk-based and consistent with good practice.

Authorised Officer should take account of the full range of enforcement options including, for example:

- Educating and providing advice to FBOs
- Informal action
- Sampling
- Detention and Seizure
- Hygiene Improvement Notices / Improvement Notices
- Remedial Action Notices
- Fixed Penalty Notices
- Hygiene Emergency Prohibition Notices / Emergency Prohibition Notices
- Prosecution

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.

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

- the level of risks to consumer safety resulting from the non-compliance
- sensitivities around an issue, which could lead to:
  - loss of consumer confidence
  - economic loss to industry

- the potential for non-compliant foods being distributed widely with large numbers of consumers affected
- previous history of compliance
- an assessment of the FBOs willingness to undertake the work identified by the officer
- collaboration with the Primary Authority or Home Authority, if applicable

#### 6.4.2 Enforcement information

To ensure consistent interpretation and application of food law, Food Authorities must 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 and Practice Guidance
- EU Guidance documents
- UK Guides to Good Practice, where appropriate
- guidance/relevant correspondence issued by, jointly with, or on behalf of the FSA and / or WLGA
- FSA food alerts for example Food Alerts for Action
- relevant industry codes of practice
- appropriate technical literature

## 6.4.3 FSA's prosecution outcomes database

The FSA has created a central repository of information about successful prosecutions brought by Food Authorities and the FSA. The database includes food standards, food safety and food hygiene related prosecution cases. Food Authorities will be able to utilise this information to support their own enforcement activities. This can be found on Smarter Comms.

To help the FSA maintain the database, Food Authorities should report successful prosecutions 28 days after a conviction has been obtained unless the defendant has submitted an appeal. Cases should be reported using the <a href="Prosecution Outcomes spreadsheet">Prosecution Outcomes spreadsheet</a> which can be found on Smarter Comms.

Completed spreadsheets should be sent to the Relationship Management Team at <a href="mailto:prosecutionsuccess@food.gov.uk">prosecutionsuccess@food.gov.uk</a>.

The FSA will also record whether a defendant has been added to the <u>Prohibited</u> <u>Persons Register</u>, which can also be found on Smarter Comms.

## 6.5 Investigating offences

# 6.5.1 Powers of Entry, Inspection and Seizure and the Human Rights Act 1998

The right to privacy and respect for personal property are key principles of the European Convention on Human Rights, which the Human Rights Act 1998 gives further effect to.

Powers of entry, inspection and seizure must be fully and clearly justified before use because they may significantly interfere with the occupier's privacy. Authorised officers must consider if the necessary objectives can be met by less intrusive means.

Section 32(4) of the Food Safety Act 1990 and Regulation 14(5) of the Food Hygiene (Wales) Regulations 2006 permit an authorised officer to take with them such other persons as they consider necessary. This would include, for example, any officer assisting the authorised officer, or suitably qualified or skilled person, or an expert in a particular field whose presence is needed to help accurately identify the material sought or to advise where certain evidence is most likely to be found and how it must be dealt with. These provisions do not confer on the accompanying person any of the powers of an authorised officer, but they do give that person the right to be on the premises during the authorised officer's inspection without the occupier's permission.

Section 32(6) of the Food Safety Act 1990 and Regulation 14(7) of the Food Hygiene (Wales) Regulations 2006 provide that an authorised officer may 'seize and detain any records which he has reason to believe may be required as evidence in proceedings'.

In all cases authorised officers must:

- exercise their powers courteously and with respect for persons and property
- in circumstances where a warrant has been obtained and is appropriate, only use reasonable force when this is considered necessary and proportionate to the circumstances

## 6.5.2 Powers in relation to vehicles

Authorised officers have powers which could be used to stop a vehicle.

Where legislation provides powers of entry to a premises (which includes vehicles) and an offence for obstructing an authorised officer, then the failing to stop a vehicle when requested could be considered an obstruction. Examples of legislation this would apply to include:

- Trade in Animals and Related Products (Wales) Regulations 2011
- Official Feed and Food Controls (Wales) Regulations 2009

Food Authorities should ensure that where authorised officers use this power, they:

- follow a health and safety risk assessment that has been provided by the Food Authority
- have received appropriate training to stop vehicles and are issued with required personal protective equipment (for example, high visibility jackets)

## 6.5.3 Police and Criminal Evidence Act (PACE) Code B Notices

There is no obligation on authorised officers to issue routinely a PACE Code B Notice when undertaking their statutory duties in a food establishment to verify compliance with food law.

A PACE Code B Notice, which sets out the powers of authorised officers and rights of occupiers, must be used in those circumstances where authorised officers are carrying out a directed search. A directed search can be defined as looking for something predetermined as relevant to a suspected or alleged offence.

It may be appropriate as part of an ongoing investigation for example in response to a complaint where evidence of suspected offences may already exist. Ultimately a decision to serve a PACE Code B Notice will depend on the individual circumstance of the matter under investigation. Authorised officers should seek further guidance from their Food Authorities' own legal counsel if further clarification is needed.

PACE Codes of Practice including PACE Code of Practice B can be found on the Home Office website.

# 6.5.4 Consumer Rights Act 2015 and the Protection of Freedoms Act 2012 Notices

Notices under these Acts are required to be issued where Food Authorities enter and inspect businesses in relation to areas other than food, such as fair trading, product safety and weights and measures. These requirements do not apply to food law.

## 6.6 Food hygiene and food standards notices

#### 6.6.1 Introduction

This section deals with the use of:

- Hygiene Improvement Notices
- Improvement Notices Compliance Notices
- Fixed Monetary Penalty Notices
- Warning Notices
- Enforcement Notices
- Prohibition Notices (served under Wine Regulations 2011)
- Non-compliance Penalty Notices
- Enforcement Cost Recovery Notices

## 6.6.2 Issuing Notices and carrying out enforcement in a proportionate manner

Notices must be used in line with the Food 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.

When issuing a notice, Food Authorities must ensure that:

- relevant procedures have been followed
- evidence of the non-compliance is obtained
- continuity of evidence is maintained

Due to the variety of notices available, authorised officers must ensure they are using the correct notice for the correct non-compliance, and that they follow the requirements of each notice as set out in legislation before issuing the notice.

#### 6.6.3 When to use a notice

This section applies to those notices listed in section 6.6.1.

Notices may only be used for the provisions set out in the legislation, and may be appropriate in any of the following circumstances or a combination thereof where:

- formal action is proportionate to the risk to public health
- there is a record of non-compliance with breaches of the food legislation
- the authorised officer has reason to believe that an informal approach will not be successful

#### 6.6.4 When not to use a notice

This section applies to those notices listed in section 6.6.1.

Notices may not be appropriate in the following circumstances where:

- the contravention may be a continuing one and a notice would only secure an improvement at one point in time, for example, personal cleanliness of staff
- Where breaches exist in respect of food safety, which poses a potential
  and imminent risk of injury to health and it is considered that swift
  enforcement action is needed e.g. in transient situations it is considered
  that swift enforcement action is needed, for example, a one-day festival or
  sporting event (a Hygiene Emergency Prohibition Notice may be more
  appropriate to achieve an immediate effect)
- there is a breach of good practice but no failure to comply with an appropriate regulation
- the legislation does not provide for a notice in that particular situation

Food Authorities should ensure they deal with breaches of legislation by using the powers and notices in the relevant enforcement legislation. For example, for breaches of the Food Hygiene (Wales) Regulations 2006 a Hygiene Improvement Notice under Regulation 6 should be served. However, where the legislation concerned is made under the Food Safety Act 1990, such as the Fish Labelling (Wales) Regulations 2013 an Improvement Notice should be served under section 10 of the Food Safety Act 1990.

## 6.6.5 Drafting of notices

It must be clear from the notice 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 must be clear and easy to understand.

An authorised 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
- action required of the FBO can rectify all the failures cited on the notice
- time frames for compliance are all the same

Failure to comply with one or more items of such a notice, would be a failure to comply with the whole notice and constitute a single offence.

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 notices requiring structural work to be carried out, ideally before a notice is issued the authorised 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 and reach agreement with them on what must 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.

# 6.6.6 It is the FBO's responsibility to ensure that any requirements and permissions are fulfilled in respect of any building works e.g. planning permission, building control approval etc. Works of equivalent effect

Where notices provide that a FBO can carry out measures which are equivalent to those set out in the notice (for example, Improvement Notices), it is recommended that alternative measures are discussed with the authorised 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 Food Authority should respond in writing to any request from a FBO to vary the work, and any agreed alternative measures should be confirmed in writing.

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

Where notices do not state that works of equivalent effect may be taken, Food Authorities should still take into consideration any alternative measures suggested by the FBO to remedy the contravention.

## 6.6.7 Time limits

A notice must clearly state the time limit by which the measures required by the notice must be completed or the penalty paid. The time limit that must be given in the

notice varies depending on the type of notice being served, for example notices may require:

- a minimum time period, for example a hygiene improvement notice under the Food Hygiene (Wales) Regulations 2006 requires a minimum of 14 day period to be given
- the time to be no less than the time for appeal, for example compliance notices under The Quality Schemes (Agricultural Products and Foodstuffs)
   Regulations 2018 require the time limit to not expire within the 28 day appeal period
- no minimum period of time, for example improvement notices under the Food Information (Wales) Regulations 2014, which if reasonable, allows for the immediate rectification of the non-compliance

As an appeal can be lodged against the time limit, they 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 authorised 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
- nature of the problem
- availability of solutions

#### 6.6.8 Extension of time limits

Although notices are to be complied with by the stipulated time limit, Food Authorities should give due regard to any genuine difficulties that may occur in achieving compliance by that deadline.

There are no specific provisions 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 be received by the Food 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 must then be withdrawn, and a new notice issued reflecting the new time limit by which compliance must be achieved.

However, the authorised officer should never issue such a notice automatically. When deliberating a request for an extension of the time limit, the authorised 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 FBO
- any temporary action which the FBO proposes to take to rectify the noncompliance
- demonstrable evidence of steps taken to address the requirements contained in the notice

However, the following notices do include provisions for authorised officers to serve further notices varying the original notice:

- Warning Notices, Enforcement Notices and Prohibition Notices under the Wine Regulations 2011
- Compliance Notices, Non-Compliance Penalty Notices and Enforcement Costs Recovery Notices under the Quality Schemes (Agricultural Products and Foodstuffs) Regulations 2018

#### 6.6.9 Service of notices

All notices issued by Food Authorities must be served on the person they relate to and should be served by the authorised officer that observed the breach.

## 6.6.9.1 Methods of serving a notice

Notices must be served according to the requirements of the specific legislation, for example, Hygiene Improvement Notices must be served in accordance with Regulation 6 of the Food Hygiene (Wales) Regulations 2006, while Improvement Notices made under Section 10 of the Food Safety Act 1990, must be served or in accordance with Section 50 of the Act.

Generally, notices can be served either:

- by delivering it to that person
- in the case of an incorporated company or body, by delivering it to their secretary or clerk at their registered or principal office, or by sending it in a prepaid letter addressed to them at that office
- in the case of any other person, by leaving it, or sending it in a prepaid letter addressed to them, at their usual or last known residence

It is important to identify the person (FBO) where possible. However, under some legislation (i.e. Section 50 of the Food Safety Act 1990 and Regulation 28 of the Food Hygiene (Wales) Regulations 2006), if it is not practicable after reasonable inquiry to identify the person to serve the notice on, the notice may be addressed to the 'owner' or 'occupier' and left at the named premises.

The authorised officer serving a notice 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 FBO.

A notice can be served on a person outside of the Food Authority area provided there is contravention inside the Food Authority area.

Notices must be signed by the authorised officer that observed the non-compliance and should also be served on the FBO by that authorised officer. However, it may be served by a different authorised officer who is competent to explain the purpose of the notice, any steps to be taken and be able to deal with obstruction.

The document can be faxed and/or emailed 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, and proof of posting should be kept.

#### 6.6.10 **Appeals**

The Regulations that provide for notices include appeal mechanisms, so that a person who is aggrieved by the service of a notice can appeal it.

Due to this, all notices must make it clear to the recipient that there is a right of appeal and details of how that appeal can be made including the name and address of the relevant local court or body the appeal can be made to.

The recipient should also be asked to notify the Food Authority if an appeal is lodged.

Although all notices can be appealed, the mechanisms for appeals differ, and authorised officers must be aware of the appeal mechanisms for the notices being served. An overview of these mechanisms can be found in Table 1 below.

The procedure on an appeal to a magistrates' court will be governed by the Magistrates' Courts Act 1980.

Under the Quality Schemes (Agricultural Products and Foodstuffs) Regulations 2018 appeals are heard by the First-tier Tribunal (General Regulatory Chamber) and these will be governed by the Tribunal Procedure (First-tier Tribunal) (General Regulatory Chamber) Rules 2009.

Further information on appeals to the First-Tier Tribunal.

Table 1 – Appeals

Type of notice	Legislation	Appeal heard by	Time to appeal	Notice suspended until appeal heard?
Hygiene Improvement Notice	Food Hygiene (Wales) Regulations 2006	Magistrates Court	1 Month or time specified in notice, whichever is shorter	Yes
Improvement Notices	Made under Food Safety Act 1990	Magistrates Court	1 Month or time specified in notice, whichever is shorter	Yes
Improvement Notices made under specific legislation	Spirit Drinks Regulations 2008 Scotch Whisky Regulations 2009	Magistrates Court	28 days	No, unless Court directs otherwise
Compliance Notices	Quality Schemes (Agricultural Products and Foodstuffs) Regulations 2018	First-tier Tribunal (General Regulatory Chamber)	28 days	No, unless Tribunal directs otherwise

Type of notice	Legislation	Appeal heard by	Time to appeal	Notice suspended until appeal heard?
Non-compliance	Quality Schemes	First-tier Tribunal	28 days	Yes
Penalty Notice	(Agricultural Products and	(General Regulatory		
	Foodstuffs) Regulations	Chamber)		
	2018			
Enforcement	Quality Schemes	First-tier Tribunal	28 days	Yes
Cost Recovery	(Agricultural Products and	(General Regulatory		
Notice	Foodstuffs) Regulations	Chamber)		
	2018			
Warning Notices	Wine Regulations 2011	Person nominated by the	28 days	No, unless person nominated decides
		FSA		otherwise
Enforcement	Wine Regulations 2011	Person nominated by the	28 days	No, unless person nominated decides
Notices		FSA		otherwise
Prohibition	Wine Regulations 2011	Person nominated by the	28 days	No, unless person nominated decides
Notices		FSA		otherwise

### 6.6.11 Other discussions with the Food Authority

Although a FBO has a right of appeal against the notices listed in 6.6.1, the Food Authority should be prepared to discuss the:

- notice and its requirements informally with the FBO if they wish to do so
- requirements of any letter or other enforcement action

If a FBO indicates that the requirements of a notice are inconsistent with the interpretation or practice of other Food Authorities, the Food Authority should have regard to these views. If a Primary Authority partnership exists, the Food Authority must comply with the enforcement notification requirements.

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

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

#### 6.6.12 Compensation

Generally, there is no provision for compensation in relation to the notices listed in 6.6.1 issued by Food Authorities. If a notice is served in error and as a result a food business suffers financial loss, for example due to being unable to sell the food that is of a perishable nature, they may pursue compensation through a civil negligence claim against the Food Authority.

## 6.6.13 Compliance

The authorised officer who served the notice should:

- liaise with the FBO and monitor the work being undertaken
- encourage the FBO to notify the authorised officer when the work has been completed
- check the work as soon as practicable after notification has been received that is has been completed or as soon as possible after expiry of the notice
- confirm in writing to the FBO that the works have been satisfactorily completed

Another authorised officer should monitor the work if the authorised officer who served the notice is unable to do so.

#### 6.6.14 Enforcement

Non-compliance with notices may lead to criminal proceedings being brought by Food Authorities.

Non-compliance with the following notices are criminal offences:

- Hygiene Improvement Notices
- Improvement Notices
- Enforcement Notices
- Prohibition Notices

Non-compliance with the following notices, are not criminal offences, but means a Food Authority may take criminal proceedings for the matter specified in the notice:

- Non compliance Penalty Notice
- Warning Notice

However, before commencing criminal proceedings for these offences the Food Authority must ensure it complies with its own enforcement policy and the Code for Crown Prosecutors.

The Quality Schemes (Agricultural Products and Foodstuffs) Regulations 2018 do not provide any criminal offences for non-compliance with a Compliance Notice served under it. However, if the notice is not complied with then a Non-Compliance Penalty Notice may be served imposing a penalty of up to £40,000 on the person that has failed to comply with the Compliance Notice. If this penalty is unpaid it can be recovered as a civil debt or on order of the court.

Regulations may also provide criminal sanctions for breaches where a notice could be used. For example, regulation 10 of the Food Information (Wales) Regulations 2014 provides criminal offences in relation to certain allergen labelling/information requirements. Authorised officers will have the choice of taking a criminal prosecution in relation to the contravention or serving a notice, or both.

Decisions on whether to issue a notice, take a criminal prosecution or doing both, should take into account:

- the public health risk
- the evidence available
- the circumstances of the contravention
- what they believe is the most effective enforcement strategy

#### 6.6.15 Publication of notices

The Spirits Drinks Regulations 2008 and Scotch Whisky Regulations 2009 provide that where an Improvement Notice is issued under these Regulations, the Food Authority must publicise the fact that it has been issued.

The Food Authority must publicise the notice in any manner they see fit, but this should not be done until either the time for appealing the notice has passed or an appeal against the notice has been heard. The Food Authority must also not publicise the notice if it considers it would be inappropriate to do so. If a Food Authority decides against publicising a notice, they should keep records of why that decision was taken.

#### 6.6.16 Template notices

The Food Safety (Improvement and Prohibition - Prescribed Forms) Regulations 1991 provide a prescribed Improvement Notice to be used when issuing Improvement Notices under Section 10 of the Food Safety Act 1990.

Other template notices can be found on Smarter Comms.

### 6.6.17 Other guidance

Further guidance on the drafting and use of Hygiene Improvement Notices has been issued by WLGA and can be found on the Knowledge Hub.

The Food Authority may want to discuss enforcement issues on a regional level or via the Knowledge Hub with other Food Authorities to see if there is other established practice that should be considered. An opinion may be sought from the National Food Hygiene Focus Group or the Food Standards and Information Focus Group with cases submitted via the Regional Liaison Groups. Prohibition procedures.

#### 6.7 Remedial Action Notices

This section deals with the use of Remedial Action Notices (RANs) in relation to any food business establishment under Regulation 9 of the Food Hygiene (Wales) Regulations 2006.

Authorised officers must seek to remedy non-compliance in establishments by a graduated approach to enforcement. When necessary, the Hygiene Improvement Notice provisions in Regulation 6 must be considered. Authorised officers must consider these options before commencing any other enforcement action. However, Remedial Action Notices as provided for by Regulation 9 of these Regulations can be used, when appropriate.

If an authorised officer considers it necessary to serve a RAN owing to the conditions or practices found the authorised officer must also consider whether food at the establishment should be detained for the purposes of examination or seized. Further information relating to the seizing and detaining of food can be found below.

#### 6.7.1 When to use a Remedial Action Notice

Regulation 9 of the Food Hygiene (Wales) Regulations 2006 provides for authorised officers to serve a Remedial Action Notice where it appears to them that the requirements of the "Hygiene Regulations", as defined by Regulation 2 of the 2006 Regulations, are being breached or an inspection under the "Hygiene Regulations" is being hampered. More specifically, this provision provides, through the service of a Remedial Action Notice:

- for the prohibition of the use of any equipment or any part of the establishment,
- the imposition of conditions upon, or prohibiting, any process and
- allows for the rate of an operation to be reduced or, stopped completely.

Circumstances which may lead to the issue of a Remedial Action Notice in respect of an establishment include:

• the failure of any equipment or part of an establishment to comply with the requirements of the "Hygiene Regulations" as defined by Regulation 2 of the Food Hygiene (Wales) Regulations 2006;

- the need to impose conditions upon or the prohibition of the carrying on of any process breaching the requirements of the Regulations or hampering adequate health inspection in accordance with the Regulations; and,
- where the rate of operation of the business is detrimental to its ability to comply with the Regulations.

Such action must be proportionate to the risk to public health and where immediate action is required to ensure food safety. A Remedial Action Notice can be used if a continuing offence requires urgent action owing to a risk to food safety.

#### 6.7.2 When not to use a Remedial Action Notice

Remedial Action Notices may not be appropriate in the following circumstances where:

- In the case of maintenance/structural problems that can be rectified as a nonurgent matter where informal action or a Hygiene Improvement Notice would be more appropriate
- The operation of an entire establishment needs to be prohibited and the most appropriate course of action is the service of a Hygiene Emergency Prohibition Notice
- Suspension of an approval on an establishment approved under Regulation (EC) No 853/2004 is required

# 6.7.3 Drafting of Remedial Action Notices

A remedial action notice must be served as soon as practicable and state why it is being served i.e. the requirements of the Hygiene Regulations are not being met and/or that an inspection under the Hygiene Regulations is being hampered.

It must be clear and easy to understand from the notice:

- the grounds for serving the notice
- the measures (or equivalent measures) the recipient is required to take and
- the actions required to remedy the situation.

If the RAN is served under Regulation 9 (1)(a) i.e. when requirements of the Hygiene Regulations are being breached, the notice must also specify the breach

#### 6.7.4 Withdrawal of a Remedial Action Notice

As soon as the authorised officer who served the Remedial Action Notice is satisfied that the action specified in a Remedial Action Notice has been taken, the notice must be withdrawn by means of a further notice in writing.

#### 6.7.5 Appeals

Regulation 20 (1) (c) of the Food Hygiene (Wales) Regulations 2006 allows any person who is aggrieved by an authorised officer's decision to serve a RAN can appeal to the Magistrates Court. The time limit for such an appeal is 1 month from when the authorised officer served the notice. The notice remains in force until the

appeal decision is determined. The court may cancel or affirm the notice. If affirmed it, may do so either in its original form or with modifications.

#### 6.7.6 Template Forms

The following templates can be found on Smarter Comms:

Remedial Action Notices

Notice of Withdrawal of a Remedial Action Notice

#### 6.7.7 Prohibition procedures

#### 6.7.8 Introduction

This section deals with the use of:

- Hygiene Prohibition Orders and Hygiene Emergency Prohibition Procedures, under Regulations 7 and 8 of the Food Hygiene (Wales) Regulations 2006
- Prohibition Orders and Emergency Prohibition Procedures under Sections 11 and 12 of the Food Safety Act 1990

## 6.7.8.1 Hygiene prohibition procedures and prohibition procedures

Hygiene Prohibition Orders<sup>50</sup> (HPOs) and Prohibition Orders<sup>51</sup> (PO) are made by a Magistrates' Court following the conviction of a FBO for an offence either under the Food Hygiene (Wales) Regulations 2006 for an HPO or the Food Safety Act 1990 for a PO, to prohibit the use of:

- a process or treatment for the purposes of the business
- the premises or equipment for the purposes of the food business or any similar food business
- the premises or equipment for the purposes of any food business

The authorised officer may bring to the attention of the Court Regulation 7 of the Food Hygiene (Wales) Regulations 2006 or Section 11 of the Act so that a HPO/PO 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.

The Court may also make an order prohibiting a FBO from managing any food business, or a particular type of food business provided the FBO has been convicted of an offence and the Court thinks it appropriate in the circumstances of the case.

The sentencing guidelines covering food safety and hygiene offences includes considering this prohibition as part of the sentencing process. Further information can be found on the <u>Sentencing Council website</u>.

<sup>&</sup>lt;sup>50</sup> Regulation 7 of the Food Hygiene (Wales) Regulations 2006

<sup>&</sup>lt;sup>51</sup> Section 11 of the Food Safety Act 1990

# 6.7.8.2 Hygiene Emergency Prohibition Procedures and Emergency Prohibition Procedures

Unless the use of voluntary procedures are more appropriate in the circumstances, an authorised officer may serve a Hygiene Emergency Prohibition<sup>52</sup> Notice (HEPN) or Emergency Prohibition<sup>53</sup> Notice (EPN) on the FBO, if the health risk condition is fulfilled in respect of a food business and there is an imminent risk of injury to health.

If the appropriate evidence is found, a HEPN/EPN may be served on the FBO, followed by an application to a Magistrates' Court for a Hygiene Emergency Prohibition Order (HEPO)/Emergency Prohibition Order (EPO).

The effect of the notice is to immediately close the premises, or prevent the use of equipment, a process or a treatment.

The authorised officer must apply to a Magistrates' Court for a HEPO/EPO within three days of a HEPN/EPN being served, the day of service of the notice being Day 1.

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.

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.

The application is made by the Food Authority and hence it bears the burden of proof. 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.

Once made, a HEPO/EPO supersedes a HEPN/EPN.

# 6.7.9 'Health Risk Condition' / '(Imminent) Risk of Injury to Health'

Prohibition procedures and emergency prohibition procedures under the Food Hygiene (Wales) Regulations 2006 and Food Safety Act 1990 can only be used if the 'health risk condition' is fulfilled.

In respect of prohibition procedures there must be a risk of injury to health, while in respect of emergency prohibition procedures there must be an imminent risk of injury to health.

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

<sup>&</sup>lt;sup>52</sup> Regulation 8 of the Food Hygiene (Wales) Regulations 2006

<sup>&</sup>lt;sup>53</sup> Section 12 of the Food Safety Act 1990

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.

## 6.7.9.1 'Health Risk Condition' – Food hygiene

In relation to food hygiene, the health risk condition under the Food Hygiene (Wales) Regulations 2006 may exist if, for example:

- conditions in premises, or a defective process or treatment, carry a high risk of causing food borne infection
- the premises was in 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, resulted in the actual contamination of food or a significant risk of food contamination

Note: these examples are not prescriptive and are for illustrative purposes only.

Foods containing potentially harmful levels of pathogenic micro-organisms represent an imminent risk and should be seized or detained under Regulation 23 of the Food Hygiene (Wales) Regulations 2006 by using the powers in Section 9 of the Food Safety Act 1990. (see also Regulation 9 of the Food Hygiene (Wales) Regulations 2006 in this regard).

However, the process or treatment which exposed the food to this microbiological contamination should be dealt with under Regulation 9 of the Food Hygiene (Wales) Regulations 2006.

## 6.7.9.2 '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 following are examples of circumstances that could involve an imminent risk of injury to health and in which an authorised officer may therefore consider the use of prohibition powers. These examples are in no way prescriptive or exhaustive and are for illustrative purposes only.

- A process or treatment that introduces a teratogenic chemical (one that damages a developing foetus in the womb) into food, which might cause injury to the developing foetus, but the damage will not be apparent until the baby is born
- A process or treatment that introduces a genotoxic chemical (one that damages genes or chromosomes) into food, the effects of which might not manifest themselves until an affected child, as yet unborn, of a mother who has consumed the food, develops a malignant tumour 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.

# 6.7.10 Criteria for action - hygiene prohibition procedures/prohibition procedures

The following paragraphs provide examples of circumstances that may show that the health risk condition exists as defined by Regulation 7(2) of the Food Hygiene (Wales) Regulations 2006 or Section 11(2) of the Food Safety Act 1990, 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. Prohibition Orders can only be made by the courts.

# 6.7.10.1 Health risk conditions where prohibition on use 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

# 6.7.10.2 Health risk conditions where the prohibition on use 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 readyto-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

# 6.7.10.3 Health risk conditions where prohibition on use 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

# 6.7.11 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>54</sup>.

An authorised officer exercising a right of entry under Regulation 14 of the Food Hygiene (Wales) Regulations 2006 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.

## 6.7.12 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.

### 6.7.13 Prohibition of a person

When a 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.

<sup>&</sup>lt;sup>54</sup> The Institute of Food Science and Technology maintains a list of experts in particular fields.

## 6.7.13.1 Notification of a prohibition order against a person

A Prohibition Order<sup>55</sup> issued by a Court can only be fully effective if other Food Authorities are notified, as the individual concerned may try to start a business in another area.

The Food Authority must notify the FSA as soon as practicable after an order is made against a person prohibiting them from running a food business, provided the order is not the subject of an appeal, and the period allowed for appeal has expired, supplying the following information:

- case number
- court details
- date of Prohibition Order
- date(s) of offence
- nature of offence(s)
- regulation/section number under which offence was made
- penalties
- name of prohibited person
- name of the business
- food business establishment address including post code
- business type/main activity (for example catering, retail etc.)
- details of assumed names

Where there is an appeal and the order is confirmed, the information must be supplied at that point.

Food Authorities should report this information in the <u>spreadsheet</u> found on Smarter Comms.

Completed spreadsheets should be sent to the Relationship Management Team at <a href="mailto:prosecutionsuccess@food.gov.uk">prosecutionsuccess@food.gov.uk</a>.

### 6.7.14 Court proceedings

### 6.7.14.1 Evidence required

The authorised officer must collect sufficient admissible 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

<sup>&</sup>lt;sup>55</sup> Regulation 7(4) of the Food Hygiene (Wales) Regulations 2006 or Section 11(4) of the Food Safety Act 1990

the end of a visit to an establishment must be accurate and factual, so that they may rely on it in Court.

## 6.7.14.2 Application to the Court

Some Food Authorities have authorised officers under Section 223 of the Local Government Act 1972 to represent the Food Authority in proceedings before the Magistrates' Court as prosecutors.

Where such an arrangement does not exist, the Food Authority should try to agree procedures. The Food 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 the 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 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.

### 6.7.14.3 Action to be taken prior to the hearing

The authorised officer must organise monitoring of the premises between the service of the notice and the Court hearing. The authorised officer who served the notice need not necessarily carry out the monitoring but must fully brief the relevant colleague of the risks and evidence gathered, that gave rise to the service of the notice.

The premises must be re-inspected shortly before the hearing (preferably the day before or on the day of the hearing itself) by the authorised officer who served the notice.

If this is not possible, an authorised officer with relevant experience must carry out the re-inspection. This must 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 Hygiene (Wales) Regulations 2006 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.

## 6.7.14.4 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

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 concerning the defendant's bad character are met

## 6.8 Service of prohibition notices and orders

## 6.8.1 Methods of serving the notice or order

Every effort should be made to serve Prohibition Notices and Orders made under the Food Hygiene (Wales) Regulations 2006 and the Food Safety Act 1990 by delivering them by hand to the FBO, or to each of the operators/proprietors in the case of a partnership etc.

These notices and orders need not necessarily be served by the authorised officer who initiated the action. They must, however, be served by an authorised officer who is competent to explain the purpose of the order or notices, the necessary steps to be taken by the FBO and be able to deal with obstruction.

If a notice or order 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, for example the manager.

The authorised officer must ensure that the FBO is aware of the matters that constitute an imminent risk. Although this is included in the model HEPN 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.

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 must 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 and/or emailed to the operator/proprietor for information in advance of its formal service, but a hard copy must follow for it to be properly served.

Officers should record the time of service, even when the postal service is used.

Immediately once the document has been legally served by one of the methods mentioned in Regulation 28 of the Food Hygiene (Wales) Regulations 2006 or Section 50 of the Food Safety Act 1990, the prohibition on the use of the premises, 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.

## 6.8.2 Affixing the notice or order on the premises

Regulations 7 and 8 of the Food Hygiene (Wales) Regulations 2006 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 must be affixed in a conspicuous position on the premises by the Food 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, must take this action. A witness need only accompany the authorised officer if required by the Food 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 authorised officer must 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 Food Authority should arrange for periodic checks to be made on the document to establish that it is still there.

#### 6.8.3 Unauthorised removal or defacement of notices or orders

Neither the Food Hygiene (Wales) Regulations 2006 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 could be considered as obstruction under Regulation 15 of the Food Hygiene (Wales) Regulations 2006, 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.

# 6.9 Breach of a prohibition notice or order

Where a notice or order is breached, the following offences may apply:

- a person who knowingly contravenes a HPO or a Prohibition Order is guilty of an offence under Regulation 7(5) of the Food Hygiene (Wales) Regulations 2006 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 Hygiene (Wales) Regulations 2006 or Section 12(5) or (6) of the Food Safety Act 1990, respectively

Where a notice is breached, there are potentially several offences including the breach of the:

- regulations and
- notice requiring the non-compliance to be addressed

Both are offences and should, having regard to the Food Authorities enforcement policy, 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 must use their professional judgement and consider all relevant circumstances in their decision.

The Food 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. Food Authorities must refer to their enforcement policy when deciding what action to take regarding the breach of regulations and or notices.

# 6.10 Lifting a notice or order

## 6.10.1 Lifting prohibition notices and orders

The FBO must apply in writing to the Food 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 and determine as soon as 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 authorised 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 Food 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 Hygiene (Wales) Regulations 2006, 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 three 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 Hygiene (Wales) Regulations 2006, or Section 11(7) (b) or Section 12(9) (b) of the Food Safety Act 1990 as appropriate for the Food Authority to issue a notification of continuing risk to health as quickly as possible, and in any event within three days. The Food Authority must give reasons why it is not satisfied that the health risk condition has been removed.

If an authorised officer conducts a further 'inspection/audit before the Court hearing and they are satisfied that the health risk condition no longer exists, the authorised officer may still wish to continue with the application to request the HEPO/EPO. The reason for this is, that the hearing to request the HEPO/EPO may lessen the possibility of a claim for compensation by the FBO.

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 Hygiene (Wales) Regulations 2006 or the Food Safety Act 1990 as appropriate.

The Food Authority should ensure that the Court is informed in this situation.

## 6.10.2 Lifting of prohibition orders against persons

Hygiene Prohibition Orders or Prohibition Orders<sup>56</sup> against persons imposed by a Court can only cease to have effect if, on an application by the FBO or food business proprietor, the Court gives such a direction. No application will be entertained within six months of the date of the order being made.

The Food Authority must notify the FSA at the earliest opportunity after they learn that a Hygiene Prohibition Order or Prohibition Order against a person ceases to have effect.

#### 6.10.3 Appeals – refusal to lift prohibition order

Regulation 20(1)(b) of the Food Hygiene (Wales) Regulations 2006 and Section 37(1)(b) of the Food Safety Act 1990 allow anybody who is aggrieved by a Food Authorities decision to refuse to issue a certificate saying there is no longer a risk, to health to appeal by way of a complaint to the Magistrates' Court. The time limit for

<sup>&</sup>lt;sup>56</sup> Regulation 7(6)(b) and 7(8) of the Food Hygiene (Wales) Regulations 2006 or Section 11(6)(b) and 11(8) of the Food Safety Act 1990

such an appeal is one month from the date when the Food 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.

## 6.11 Compensation

Regulation 8(10) of the Food Hygiene (Wales) Regulations 2006 and Section 12(10) of the Food Safety Act 1990 provide for the Food Authority to compensate the FBO in respect of 'any loss' which is directly attributable to the wrongful service of the notice. Any disputed question as to the right to or the amount of any compensation payable is to be determined by arbitration.

The Food Authority can assess the amount of compensation due considering 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 spoilt food
- loss of goodwill
- loss of wages
- how much of the damage to trade is reparable?
- 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

#### 6.12 Detention and seizure

#### 6.12.1 Introduction

This section concerns the use of the detention/inspection and seizure powers under Regulation 27 of the Food Hygiene (Wales) Regulations 2006 and Section 9 of the Food Safety Act 1990.

### 6.12.2 Food which fails to comply with food safety requirements

If food does not satisfy food safety requirements for reasons other than hygiene, 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 and require it not to be removed or removed to some place as specified in the Notice.

Section 8 of the Act provides that food which is unsafe within the meaning of Article 14 of Regulation (EC) No 178/2002, fails to comply with food safety requirements.

Food Authorities must use the forms set out in the Detention of Food (Prescribed Forms) Regulations 1990 when using powers under Section 9 of the Act.

### 6.12.2.1 Food hygiene

When food has not been produced, processed or distributed in compliance with the 'Hygiene Regulations'<sup>57</sup> an authorised officer may use Regulation 27 (see also Regulation 23 in this regard) of the Food Hygiene (Wales) Regulations 2006 to seize the food under Section 9 of the Food Safety Act 1990.

Following the certification required by Regulation 27 the food must be treated for the purposes of Section 9 of the Food Safety Act 1990 as failing to comply with food safety requirements.

A model certificate for this purpose can be found on Smarter Comms.

#### 6.12.2.2 Food standards

The following legislation gives specific powers of seizure and detention to Food Authorities carrying out food standards controls.

- Contaminants in Food (Wales) Regulations 2013
- Eggs & Chicks Regulations (Wales) 2010
- Food Irradiation (Wales) Regulations 2009
- Genetically Modified Food (Wales) Regulations 2004
- Tryptophan in Food (Wales) Regulations 2005
- Scotch Whisky Regulations 2009
- Spirit Drinks Regulations 2008
- The Food Additives, Flavourings, Enzymes and Extraction Solvents (Wales) Regulations 2013
- The Novel Foods (Wales) Regulations 2017

#### 6.12.2.3 Presumption it is food

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 authorised 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 a FBO wished to argue for a contrary intention, then it is for the FBO to prove this.

#### 6.12.3 Dealing with batches, lots or consignments of food

Article 14(6) of Regulation (EC) No 178/2002 stipulates that where, 'any food which is unsafe is part of a batch, lot, or consignment of food of the same class or description, it shall be presumed that all the food in that batch, lot or consignment is also unsafe, unless following a detailed assessment there is no evidence that the rest of the batch, lot or consignment is unsafe'.

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<sup>&</sup>lt;sup>57</sup> Regulation 27 of the Food Hygiene (Wales) Regulations 2006

If a quantity of food of different types or batches is being detained, the authorised officer must issue a separate Detention of Food Notice in respect of each type or batch.

When considering whether to seize or detain/inspect a batch, lot or consignment, the authorised officer must take account of the:

- evidence available
- nature of the contamination
- nature and condition of any container holding the food
- risk to health
- quantity of food involved in relation to any sampling which has been undertaken

The authorised officer must 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.

### 6.12.3.1 Taking action without inspecting

The provisions of Section 9 of the Food Safety Act 1990 also apply to food that has not been inspected.

This could apply when the authorised 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, for example another Food Authority, PHW, the CCDC, or the FSA, 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.

#### 6.12.4 Detention of food

Unless the circumstances require immediate action, a decision to detain food must only normally be taken if it has been discussed with the owner or person in charge of the food and, if appropriate, with the manufacturer.

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.

#### 6.12.4.1 Location of detention

Where the authorised officer has served a Detention of Food Notice, professional judgement must be used to determine whether the food should be detained where it is or moved elsewhere.

If the authorised officer has any doubts about the security or physical care of the food, the Detention of Food Notice must specify a place to which the food is to be moved.

If food is to be removed to another Food Authority's area the authorised officer must notify that Food Authority and make any necessary arrangements for the food to be checked while it is being detained.

In all cases, but especially with highly perishable food, the authorised officer must act expeditiously at every stage and provide full information to those required to carry out analysis or examination of samples of the food.

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.

If food is to be detained where it is found, the authorised officer must be satisfied that adequate arrangements can be made to ensure its security and prevent tampering. The authorised officer must organise periodic monitoring of the food throughout the period of detention.

Before making such arrangements, regard must be had to the nature of the food, the quantity, any health hazard that it represents, and the ownership of the establishment where it is located. The authorised officer must avoid leaving it in the charge of, or in an establishment owned by, any person who may be prosecuted for an offence under food law.

The decision to detain a whole batch, lot, or consignment needs careful consideration before a notice is served.

#### 6.12.4.2 Detention of food notice

A Detention of Food Notice must be signed by the authorised officer who takes the decision to detain the food under Regulation 9(5) of The Food Hygiene (Wales) Regulations 2006. Food Authorities must use the Detention of Food Notice set out in the Detention of Food (Prescribed Forms) Regulations 1990.

#### 6.12.4.3 Withdrawal of detention of food notice

The authorised officer must act as quickly as possible when evidence or information indicates that detained food can be released, and in any case within 21 days of the detention, a Withdrawal of Detention of Food Notice must be served.

The decision to issue a Withdrawal of Detention of Food Notice must be taken either by the authorised officer who originally issued the notice or initiated the action, or by another authorised officer with the relevant experience and competence. A Withdrawal of Detention of Food Notice must be served as soon as possible to prevent deterioration of the food and to minimise the Food Authority's exposure to compensation under Section 9(7) of the Food Safety Act 1990. The notice need not be served by the authorised officer who made the decision but can be served by any authorised officer.

Food Authorities must use the Withdrawal of Detention Notice set out in the Detention of Food (Prescribed Forms) Regulations 1990.

#### 6.12.5 Seizure of food

## 6.12.5.1 Arrangements for treatment or processing

When considering whether to seize food, authorised officers must consider whether the food in question can be treated or processed before consumption and if so, whether the food, after treatment or processing, would satisfy food safety requirements. It must be noted that mixing of food to reduce high levels of contaminants is not permitted by Article 3 of Regulation (EC) No 1881/2006.

Arrangements for the treatment or processing of food in these circumstances must be agreed by the authorised officer, and the owner or the person in control of the food and the subject of a signed, written undertaking.

Any arrangement that involves food being moved to the area of another Food Authority for treatment or processing must be accepted by the receiving Food Authority before the agreement is concluded.

Arrangements must be made for that Food Authority to take steps to ensure the processing or treatment is carried out, including the service of a Detention of Food Notice, if appropriate.

If the receiving Food Authority is unable to accept responsibility for ensuring that the food is properly processed or treated, the arrangement must not proceed, unless there is no other way of rectifying the problem with the food product.

#### 6.12.5.2 Seizure of food - Process

Unless the preceding paragraphs of this Section apply, or the use of Voluntary Procedures is more appropriate, food must be seized if an authorised officer has evidence that it does not satisfy food safety requirements.

If evidence indicates that food that has already been detained must be seized, the authorised officer must serve a Food Condemnation Notification, warning of the intention to take the food before a Justice of the Peace and apply for its condemnation.

Food that has been seized must be dealt with by a Justice of the Peace as soon as practicable, normally within two days, but if necessary, longer to ensure that parties can attend and be represented should they choose to do so. Highly perishable food must be dealt with by a Justice of the Peace at the earliest opportunity.

The person in charge of the food or the owner must be given the opportunity of being present and represented should they choose to do so when the food is dealt with by

the Justice of the Peace, although action must not be delayed if the owner cannot be traced or contacted. The Food Safety Act 1990 requires that anyone who may be liable to prosecution is entitled to attend the hearing, and good service of notice of the hearing must be documented and retained to show the Court that was the case.

The authorised officer must ensure continuity of evidence whether or not there may be a subsequent prosecution and must make every attempt not to leave the food unsecured once it has been seized, as the authorised 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 authorised officer is confident that it will not be moved, used for human consumption, or the evidence destroyed.

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.

## 6.12.5.3 Food condemnation warning

A food condemnation notification giving details of the time and place of the appearance before a Justice of the Peace must 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 authorised officer delivering the notification does not need to hold the same qualifications as the authorised 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.

#### 6.12.5.4 Notices of seizure

When food is seized, written notification of the seizure must be issued as soon as practicable. This notification must include details of the type and quantity of the food seized, including any distinguishing marks, codes, dates etc.

A Food Condemnation Notification must be given to the person in charge of the food when the authorised officer intends to have the food dealt with by a Justice of the Peace. The notification must, where possible also be given to the owner of the food if different from the person in charge.

Food Authorities must use the Food Condemnation Warning Notice set out in the Detention of Food (Prescribed Forms) Regulations 1990.

## 6.12.6 Destruction or disposal of food

The Food Authority is responsible for ensuring the destruction or appropriate disposal of food that has been condemned under Section 9(6) of the Food Safety Act 1990 or voluntarily surrendered.

Food Authorities must ensure arrangements are made for the food to be supervised until it can be dealt with in the appropriate manner. If possible and if there is likely to be some delay before destruction or disposal, the food must be disfigured, to prevent any possibility of it being returned to the food chain.

In the case of destruction, the Food Authority must ensure the total destruction of the food by incineration or some other appropriate method, having regard to the requirements of relevant waste disposal legislation. If total destruction is not possible, Food Authorities must ensure such a degree of disfigurement that the food could never re-enter the food chain, for example by flattening tin cans for disposal in a suitably licensed landfill site.

A copy of the waste transfer note must be obtained and kept on file for any food that has been disposed of by a licensed waste disposal contractor under these arrangements.

# 6.13 Voluntary procedures

## 6.13.1 General requirements

Voluntary procedures may be used as an alternative to formal action and can be suggested by either an authorised officer or a FBO.

Where voluntary procedures are used, Food Authorities should ensure:

- they are used in line with the Food Authorities enforcement policy
- they consider the risks of the business not complying with the voluntary agreement, as there is no legal sanction against a FBO for not adhering to it, although formal enforcement action for these non-compliance(s) may remain available
- the circumstances would have permitted the authorised officer to take formal enforcement action if the voluntary arrangement was not agreed to
- the FBO agrees that there is a non-compliance
- the voluntary agreement is put in writing and signed by both the authorised officer and FBO. If the FBO is not present, any manager agreeing to the voluntary arrangements has the authority of the FBO to agree to such action
- the document clearly indicates that it is a voluntary agreement, so that a FBO is not misled into believing it is a formal notice
- the voluntary agreement sets out the non-compliance, including legislative references
- the voluntary agreement clearly states what the FBO is agreeing to (i.e. prohibiting use of a premises)
- the voluntary agreement makes clear there is no formal appeal nor right to compensation

## 6.13.2 Voluntary prohibitions

Voluntary prohibitions are an undertaking by the FBO not to use the premises, equipment, process or treatment set out in the voluntary agreement, as appropriate, to remove a health risk condition.

They can be used when a FBO agrees that a health risk condition exists (i.e. there is an imminent risk of injury to health) and the authorised officer would have been able to use a Hygiene Emergency Prohibition Notice or Emergency Prohibition Notice, if the voluntary prohibition was not agreed to.

The authorised officer should consider whether there is a risk of the establishment continuing to use the premises, equipment, process or treatment, without the authorised officer's knowledge and/or agreement. If this were to cause a food incident, the Food Authority could be criticised for not having used statutory powers.

Where a voluntary prohibition is agreed to by the FBO, the written documentation should include an undertaking by the FBO not to re-open without the authorised officer's prior approval.

The authorised officer must ensure that frequent checks are made on the establishment to ensure that they are adhering to this voluntary prohibition.

#### 6.13.3 Voluntary surrender/destruction

Voluntary surrender/destruction can be used to remove food that is not suitable for human consumption from the food chain.

They can be used when the owner of the food agrees the food is not suitable for human consumption.

A receipt must be issued for food that is voluntarily surrendered to the Food Authority for destruction. The receipt must:

- indicate that the food has been voluntarily surrendered to the Food Authority for destruction (with reasons)
- be signed and counter-signed by the authorised officer and the person surrendering the food
- include space for recording the time, place and method of destruction of the food, these details must be recorded on the office copy by the authorised officer in due course
- be retained by the Food Authority

If the Food Authority does not secure, as part of the voluntary surrender, an agreement by the owner to pay the reasonable expenses of destruction or disposal, then it would have to bear the expenses itself.

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 a Justice of the Peace had condemned food may 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.

## 6.14 Enforcement in establishments subject to approval

#### 6.14.1 Introduction

In addition to the enforcement powers detailed above, authorised officers have other powers available to them under the Official Feed and Food Controls (Wales) Regulations 2009, in respect of establishments subject to approval under Regulation (EC) No 853/2004.

Powers to withdraw or suspend the approval or conditional approval of an establishment subject to approval under Regulation (EC) 853/2004, are provided by Article 138(2)(j) of Regulation (EU) 2017/625.

Food Authorities should bear in mind that the immediate effect of the suspension or withdrawal of an establishment's approval is such that the establishment cannot be used for any activities which would render it subject to approval under Regulation (EC) No 853/2004, or to place products of animal origin on the UK market.

On the discovery of non-compliance in establishments subject to approval under Regulation (EC) No 853/2004, the Food Authority must, before considering suspension or withdrawal, explore other enforcement options to control the food hazards presented by the establishment.

Non-compliance must not necessarily be considered sufficient to justify the immediate suspension or withdrawal of an establishment's approval or conditional approval, and a reasonable opportunity to achieve compliance must be allowed where this is appropriate.

Food Authorities must only initiate procedures to suspend an establishment's approval or conditional approval if:

- non-compliances have been established<sup>58</sup>
- other enforcement options have been considered
- in line with the Food Authorities enforcement policy

Suspension of approval must be lifted in writing by the Food Authority, once the non-compliances have been permanently resolved.

Food Authorities may request that any guarantee regarding future production made by a FBO in accordance with this Article is made in writing, although Food Authorities should be aware that they cannot insist on this as no requirement exists in law to provide such guarantees in writing.

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<sup>&</sup>lt;sup>58</sup> Article 138(1) of Regulation (EU) 2017/625

## 6.14.2 Withdrawal of approval or conditional approval

Food Authorities must only initiate procedures to withdraw an establishment's approval or conditional approval if:

- non-compliances have been established<sup>59</sup>
- other enforcement options have been considered
- in line with the Food Authorities enforcement policy

An establishment's approval or conditional approval must only be withdrawn in circumstances where the FBO is unable to satisfy the Food Authority to the extent that the Food Authority has a reasonable expectation that the identified deficiencies will be rectified, and an acceptable standard will be maintained in the future. The provisional decision to revoke the approval must be communicated in writing to the FBO.

# 6.14.3 Notifications of suspension or withdrawal of approval or conditional approval

Under Article 138(3) of Regulation (EU) 2017/625, the Food Authority must notify the FBO in writing of its decision to suspend or withdraw an establishment's approval or conditional approval.

This notification must:

- give the reasons for the suspension or withdrawal
- give the matters necessary to satisfy the requirements of the Regulation
- make it clear that activities requiring approval cannot be undertaken
- inform the FBO of their right of appeal, against the decision, including information on the time limit<sup>60</sup>, and provide the address of the Magistrates' Court where such an appeal can be made

Copies of notifications must be retained on the Food Authority's files. The Food Authority must also notify the FSA when an establishment's approval or conditional approval has been suspended or withdrawn (see Chapter 2 of the Practice Guidance).

# 6.14.4 Appeals against suspension or withdrawal of approval or conditional approval

Food Authorities should bear in mind that the FBO has the right to appeal to a relevant Court against the decision to withdraw or suspend an approval or conditional approval. Rights of appeal are subject to Regulation 12 of the Official Feed and Food Controls (Wales) Regulations 2009 (as amended). From the date on which the notice of the decision is served on the relevant person the establishment

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<sup>&</sup>lt;sup>59</sup> Article 138(1) of Regulation (EU) 2017/625

<sup>60</sup> Regulations 12(2) of The Official Feed and Food Controls (Wales) Regulations 2009

cannot continue operating whilst the appeal is being determined, irrespective of whether it is a suspension or withdrawal.

#### 6.14.4.1 Detention Notices

Powers to issue Detention Notices in respect of establishments subject to approval under Regulation (EC) No 853/2004 are provided by regulation 9 of the Food Hygiene (Wales) Regulations 2006.

Regulation 9 of the Hygiene Regulations makes provision for the detention of any food, including the taking of samples for the purposes of examination, by the service of a Detention Notice.

Circumstances which could lead to the issue of a Detention Notice include where there are indications or suspicions that food at an establishment is unsafe and therefore examination is necessary, including the taking of samples.

If the authorised officer is satisfied that the food no longer needs to be detained, the relevant notice must be withdrawn by means of a further notice in writing.

#### 6.14.5 Template forms

The following templates can be found on Smarter Comms:

- Remedial Action Notice
- Detention Notice
- Notice of Withdrawal of a Detention Notice

Enforcement regarding food imported outside the UK where an authorised officer has detained a food consignment pending any results of examination, they must notify in writing the person/importer responsible for it, serving a notice under Regulation 32 of the Official Feed and Food Controls (Wales) Regulations 2009. The notice must specify that the food must not be removed from the place stated, until the authorised officer has properly considered the results of the examination.

Article 65 of Regulation (EU) 2017/625 and Regulation 31 of the Official Feed and Food Controls (Wales) Regulations 2009 do not specify a time limit for examination and investigation of consignments. However, such examinations, and/or detention periods, must be expedited as quickly as practicable to avoid unreasonable disruption to the trade.

Where samples are submitted for analysis or examination, and the consignment is detained pending the results, Food Authorities must inform the analyst or examiner of that fact and ensure that the consignment is stored appropriately and securely. The importer or the importer's agent must be informed of the analysis/examination results as soon as possible and should be given a copy of the certificate of analysis/examination.

Arrangements must be in place to ensure that detained food is stored appropriately, particularly to avoid contamination of other goods.

# 6.14.5.1 Food consignments which are injurious to human or animal health or are unsafe

Article 67 of Regulation (EU) 2017/625 requires that where official controls indicate that a consignment is injurious to human health or is unsafe, it must be isolated or quarantined pending any further decision.

The Food Authority must retain the consignment under official detention pending its destruction, or it being subject to special treatment in accordance with Article 71(1) and 71(2) of Regulation (EU) 2017/625.

Food which is to be destroyed or disposed of must be dealt with to ensure that there is no possibility of it re-entering the food chain. Copies of waste disposal notes must be kept on file.

### 6.14.5.2 Food consignments not complying with food law

If it appears to an authorised officer upon inspection or examination of food, that a batch, lot or consignment fails to comply with food law, Regulation 32 of the Official Feed and Food Controls (Wales) Regulations 2009 allows, after having heard from the importer, for the authorised officer to serve a notice requiring:

- destruction of the relevant batch, lot or consignment in accordance with Article
   67(a) of Regulation (EU) 2017/625
- the food be subjected to special treatment in accordance with Article 71(1) and (2) of Regulation (EU) 2017/625
- re-dispatch of the food outside the UK in accordance with Article 72 (1) and (2) of Regulation (EU) 2017/625
- another use of the food for purposes other than those for which they were originally intended

In practice, the options specified in the notice must be drawn up after appropriate consultation with the person importing the food or their representative.

Any decision on the approval of alternative usage of rejected goods should be informed by any relevant guidance issued by the FSA on the appropriateness of alternative use or re-exportation.

#### 6.14.5.3 Special treatments

Special treatment can consist of:

- treatment or processing to bring food into line with the requirements of:
   UK law
  - the non-UK country to where it is to be re-dispatched
- processing in any other suitable manner for purposes other than human or animal consumption

Where special treatment is permitted, liaison must take place with any other relevant enforcement authority or organisation to ensure the necessary processing has been carried out. This process can also be used where a non-conforming product is being imported specifically for the purpose of undergoing treatment to comply with <a href="UK law">UK law</a>.

Special treatment can include decontamination, where appropriate, but not dilution.

#### 6.14.5.4 Re-dispatch of consignments

A consignment must only be re-dispatched outside the UK where the:

- destination has been agreed with the FBO responsible for the consignment
- FBO has informed the Food Authority for the non-UK country of destination why it has been rejected for import into the UK
- Food Authority of the non-UK country of destination (if not the non-UK country of origin) has notified the relevant UK Food Authority of its willingness to accept the consignment

The consignment must be officially detained pending re-dispatch.

Article 69 of Regulation (EU) 2017/625 requires that re-dispatch takes place within 60 days of the Food Authority notifying the operator of the destination of the consignment. However, this period can be extended to obtain results from a second expert opinion, as long as there is no adverse effect to human health. Otherwise the consignment shall be destroyed.

Where a product is to be re-dispatched, notifications identifying the product and its final destination must be given to the FSA, who will then inform HMRC, the Commission and Member States.

# 6.14.5.5 Appeals against notices served under Regulation 32 of the Official Feed and Food Controls (Wales) Regulations 2009

The importer must be given the Food Authority's decision by way of a notice in writing. The decision must relate to the most effective way of dealing with the product and must not be used as a punitive measure.

There is a right of appeal against the Food Authority's decision provided by Regulation 33 of the Official Feed and Food Controls (Wales) Regulations 2009. Appeals against the notice must be made within one month of the notice being issued.

### 6.14.5.6 Other provisions

Imported food failing food safety requirements can also be subjected to Food Safety Act 1990 provisions to ensure appropriate action is taken. Such provisions include detention and seizure powers, applied in accordance with the Code and the Practice Guidance.

In deciding on the action to take authorised officers must have regard to:

- the Official Feed and Food Controls (Wales) Regulations 2009
- the Contaminants in Food (Wales) Regulations 2013
- any relevant Emergency Control Regulations, which might provide for specific detention powers and notice provisions in relation to certain foods.

# 6.14.6 Enforcement powers for imported Products of Animal Origin (POAO)

Where illegal imports of POAO are found inland in an area/premises outside Customs control, the local Food Authorities for that area have responsibility for the enforcement action.

Where an authorised officer wishes to detain any POAO found inland in order to investigate further to establish its safety or compliance, voluntary co-operation might be sought in the first instance.

In situations where this is not possible, enforcement provisions are provided under Regulation 34 of the Trade in Animals and Related Products (Wales) Regulations 2011.

#### 6.14.7 Further Guidance

Further <u>guidance on the enforcement provisions</u> relating to imported food is available on Smarter Comms.

#### 6.15 Crown establishments

#### 6.15.1 Introduction

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.

## 6.15.2 Powers of entry and interventions

### 6.15.2.1 Food Safety Act 1990

The powers of entry under Section 32 of the Food Safety Act 1990 may be used in respect of food standards issues, in relation to police premises and most Crown premises (subject to exemptions for certain members of the Royal Family and certain Royal residences) to investigate complaints and to carry out interventions in the same way as they do in any other food business. Authorised officers therefore have the power to enter police premises and most Crown premises.

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.

Additionally, a national security certificate may have been issued by a Secretary of State certifying that powers of entry under the Food Safety Act 1990 cannot be exercised. If an authorised officer seeks entry to Crown premises and is informed that such a certificate has been issued, the authorised officer is entitled to see the certificate or a copy of it.

### 6.15.2.2 Food Hygiene (Wales) Regulations 2006

The scope of the Food Hygiene (Wales) Regulations 2006 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.

The powers of entry under Regulation 14 of the Food Hygiene (Wales) Regulations 2006 may be used in relation to Crown premises, as the Regulations do not contain the specific exemptions for certain members of the Royal Family or certain Royal residences afforded by the Food Safety Act 1990.

Food 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 Hygiene (Wales) Regulations 2006 in respect of Crown premises as they do in respect of the Food Safety Act 1990.

#### 6.15.2.3 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 Food Authority's planned intervention programme in accordance with the Code of Practice.

Permanent kitchens serving military training camps should receive 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 Food Authority.

### 6.15.3 Categories of Crown premises

For the purposes of obtaining entry, Crown premises fall broadly into three categories, although premises may move from one category to another between inspections.

**Group 1** - includes premises situated on Crown land where there are normally no security implications, for example restaurants in museums or Royal Parks. These premises must be treated like any other food business.

Group 1 premises must normally be visited without prior arrangement.

**Group 2** - includes premises with controlled entry but normally minimal security implications. Most government and police premises fall within this category. They are similar to many private businesses with security systems.

First visits to Group 2 premises must be by prior arrangement. Future visits may be unannounced, but arrangements for subsequent visits must be agreed at the first inspection and confirmed in writing.

**Group 3** - includes premises where unannounced entry is not possible because of security implications and/or for the personal safety of the authorised officer, for example HM Forces, defence and national security establishments, prisons and remand centres, and parts of police premises that accommodate prisoners.

Group 3 premises must always be visited by prior arrangement with the appropriate contact at the establishment concerned, for example the defence establishment security officer, the commanding officer or nominated representative of an HM

Forces establishment, the Governor of a prison service establishment, or the officer in charge of police premises. This will enable the authorised officer to obtain entry without undue delay. The contact may be reminded of the power of entry if an authorised officer considers that the suggested appointment is too far in advance.

Authorised officers who have not been security cleared will be subject to visitor control procedures and escorted at all times. Authorised officers must carry an identity card that incorporates their photograph.

Authorised officers must bear in mind that there may be times when it will not be possible for an inspection to take place or continue in Group 3 premises. Any such reasonable restriction must not be regarded as obstruction.

The authorised officer's name, date of birth, card or pass number (if any) and the registration number of the authorised officer's motor vehicle must be given in advance of a visit to Group 3 premises, if required.

If the Food Authority is in doubt as to how to classify particular premises to which this section applies, they must be treated as Group 3 premises and reviewed at a later stage, if necessary.

An incident such as a food poisoning outbreak may require an authorised officer to visit premises at short notice even though prior notice would normally be required. A telephone notification that the authorised officer is on the way is essential in Group 3 premises and may save time in gaining entry to Group 2 premises. It is not normally necessary in such circumstances to give more than the briefest notice of such a visit.

Authorised officers must be aware of matters of confidentiality when visiting those parts of premises that accommodate prisoners. Such matters may be discussed when the visit is arranged.

Inspections must be confined to areas used by the food business or where records relating to it are held, unless the visit is connected with the investigation of an outbreak of foodborne illness and it is necessary, as part of the investigation, to inspect other areas.

Military activities must not be impeded or interrupted by a visit.

Authorised officers must conform to the security requirements of the establishment concerned, including baggage inspections and identity checks.

## 6.15.3.1 Photographs

Before taking any photographs, making sketches or taking measurements on Group 3 premises, 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.

#### 6.15.4 Enforcement

#### 6.15.4.1 Food Safety Act 1990

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 Food 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.

#### 6.15.4.2 The Food Hygiene (Wales) Regulations 2006

Unlike the Food Safety Act 1990, the Food Hygiene (Wales) Regulations 2006 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, Food 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 Hygiene (Wales) Regulations 2006 in respect of Crown premises as they do in respect of the Food Safety Act 1990.

#### 6.15.4.3 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.

Food 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.

#### 6.15.4.4 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 FBO 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, for example the Governor of a prison, or the Commanding Officer of a military establishment.

Food 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 FBO 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 Food 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.

#### 6.15.4.5 Liaison with the Primary Authority/the FSA

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

## **Chapter 7** Subject specific guidance

### 7.1 Matters relating to live bivalve molluscs

#### 7.1.1 Introduction

This Section provides specific guidance to Food Authorities on the official controls and enforcement of the aspects of Regulations (EC) No 852/2004, 853/2004, 2073/2005, Regulation (EU) 2017/625, 2019/624 and 2019/627 relating to Live Bivalve Molluscs (LBMs). These provisions relating to LBMs also include live echinoderms, tunicates and marine gastropods, with the exception of the provisions on purification. The classification requirements do not apply to marine gastropods which are not filter feeders.

Under Regulation (EU) 2017/625 the Food Authority must classify production and relaying areas from which it authorises the harvesting of LBMs. Production and relaying areas may be one of three classification categories according to the level of faecal contamination in shellfish flesh (using *E.coli* as the indicator organism). Classified areas are routinely monitored for microbiological quality, marine biotoxins, phytoplankton and chemical contamination.

#### 7.1.2 The Local Market Exemption (Small Quantities)

Regulation (EC) 853/2004 does not apply to the direct supply of small quantities of primary products 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 so 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 – Cerastoderma edule	25.0 tonnes
Oysters – Ostrea edulis and Crassostrea gigas	5.0 tonnes
King Scallops – Pecten maximus	5.0 tonnes
Queen Scallops – Aequipecten opercularis	10.0 tonnes
Mussels – Mytilus spp.	20.0 tonnes
Other Live Bivalve Molluscs	10.0 tonnes
Marine Gastropods	20.0 tonnes

Although exempt from the detailed requirements of Regulation (EC) No 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 Regulation (EC) No 178/2002. The general traceability requirements for Products of animal origin (POAO) in Regulation (EU) No 931/2011 also apply.

In order for harvesters of small quantities to meet the food safety requirements of Regulation (EC) No 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 Food Authorities may consider it reasonable to presume, unless there is an indication to the contrary, that individuals gathering small amounts of LBMs totalling less than 5kg in a day are gathering for private domestic use. These levels are for 'whole' LBMs and include the weight of the shell. This should not however detract Food 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

Scallops ('pectinidae') and non-filter feeding gastropods may be harvested from outside classified production areas, providing they meet the requirements of Annex III, Section VII, and Chapter IX of Regulation (EC) No 853/2004. FBOs are required to ensure that product placed on the market meets the food safety requirements and should have a system of 'own checks' in place to verify this. Food Authorities can carry out verification checks of FBOs compliance in accordance with Article 11 of Regulation (EU) 2019/624.

#### 7.1.4 Permitted treatment methods

LBMs which are to undergo a permitted treatment method or other processing, for example freezing, are subject to the requirements of Regulation (EC) No 853/2004 that relate to LBMs up to the point where processing begins in an approved establishment. After that point they are considered to be fishery products (see section on fishery products).

The permitted treatment methods for bivalve molluscs from Class B or Class C areas are set out in Annex III, Section VII, Chapter II (5) of Regulation (EC) No 853/2004 and, if appropriate Annex III, Chapter IX of Regulation (EC) No 853/2004.

#### 7.1.5 Shellfish liaison arrangements

The Food 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 mentioned in 7.1.1.

It is essential for the effective enforcement of the Regulations that adjoining Food Authorities, including Port Health Authorities, maintain effective liaison arrangements.

Each local shellfish liaison group should include representatives of other relevant local and national organisations, including the Food Standards Agency, the Centre for Environment, Fisheries and Aquaculture Science, Natural Resources Wales, Dŵr Cymru (Welsh Water), Welsh Government Marine and Fisheries Division, Public Health Wales Laboratories and other Official Control 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 classified production and 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 issuing of Closure Notices covering waters from more than one Food 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 Requirements for classified live bivalve mollusc (LBM) production and relaying areas

The FSA analyses official control microbiological monitoring results for all classified shellfish production areas to ensure compliance with the classification requirements in Regulation (EU) 2019/627:

- Class A (80% of results less than or equal to 230 E.coli /100g, no results exceeding 700 E.coli /100g) - LBM can be harvested for direct human consumption
- Class B (90% of samples must be less than or equal to 4,600 *E.coli* /100g, all results must be below 46,000) LBM can go for human consumption after:
  - purification in an approved purification establishment
  - relaying for at least one month in an approved class A relaying area
  - after heat treatment or sterilisation meeting the requirements of UK Law in an approved establishment
- Class C (≤ 46,000 *E.coli* /100g) LBM can go for human consumption only after:

- relaying for at least two months in an approved class B relaying area followed by treatment in an approved purification centre
- relaying for at least 2 months in an approved class A relaying area; or
- after heat treatment or sterilisation meeting the requirements of the UK
   Law in an approved establishment

In all cases, the health standards in Annex III of Regulation (EC) No 853/2004 and the microbiological criteria in Regulation (EC) No 2073/2005 must be met.

For prohibited areas, LBMs must not be harvested from areas that have not been classified or have been closed.

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 production areas are compliant. Classifications are also reviewed in-year as part of a rolling compliance system and amendments to classifications carried out when necessary.

Further information on the classification protocol can be found on the <u>FSA website</u>.

A list of classified LBM production and relaying areas is published on the <u>FSA</u> website.

Any changes to or new shellfish classifications that occur during the year are notified through the interim update process and a letter is issued to relevant stakeholders, including Food Authorities. These changes may include upgrades, downgrades, new classifications, re-classification, dormancy, declassifications and prohibitions. Food Authorities should forward the interim update letter concerning the classification status of production areas to 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 changes. The main classification list on the FSA website is updated accordingly.

#### 7.1.7 Monitoring of registration documents

Food Authorities must carry out regular examinations of the use and completion of registration documents to verify traceability. Examination of the documents should be carried out as part of the inspection of dispatch, purification centres or processing establishments (see Chapter 7 of the Code of Practice). However, checks can be made at any part of the traceability chain.

Regulation (EC) No 853/2004 requires food businesses placing LBMs on the market to complete a registration document (unless issued with a permanent transport authorisation) to identify each batch harvested from classified production and relaying areas. 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 by the FBO at the dispatch centre, purification centre, relaying area, or processing establishment when

the batch is received. Operators and gatherers/harvesters are required to retain registration documents for at least 12 months<sup>61</sup>.

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 (for example ICES coordinates, OS grid references etc.).

Food Authorities must be aware of the commercial advantages of abusing the registration document procedure, for example by suggesting that LBMs have been taken from waters with a superior microbiological quality.

One method 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. However, 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 for example 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. Food 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 and Cefas websites respectively.

It is not possible for Food Authorities to monitor every landing in their area, or to detect abuse in the use of registration documents by concentrating resources on sampling only. Food 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 (for example pectinidae). This can be achieved through effective and periodic liaison with other statutory inspectorates for example Welsh Government Marine and Fisheries Division. They may provide other vital information to help verify the information contained in registration documents and the activities of harvesters for example the seasonality of the harvesting, minimum landing sizes, checks on whether shellfish were harvested under the appropriate permits.

Food Authorities responsible for establishments receiving batches of LBMs should ensure that establishments are only accepting shellfish with the appropriate registration documents. Food Authorities receiving shellfish from outside their Food Authority area, should contact the issuing Food Authority when inspecting registration documents. In order to ensure efficiency in this verification process, Food

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<sup>&</sup>lt;sup>61</sup> Regulation (EC) 853/2004 Annex III, Chapter 1 (6).

Authorities are advised to keep a log of all registration documents that have been issued by them for 12 months, including details of the harvesters to whom they have been issued and the production areas for which the harvester requires the registration documents.

In addition to local liaison, Food 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 Food Authority stamps in conjunction with unique reference numbers on documents to help ensure registration documents are not easily falsified. In some circumstances it may be prudent 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.

Food Authorities must be aware that registration documents may 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'. Food Authorities might wish to consider amending their forms to reflect this activity.

#### 7.1.8 Sampling of Live Bivalve Molluscs by FBOs

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 (EC) No 2073/2005
- The health standards referred to in Annex III, Section VII, Chapter V of Regulation (EC) No 853/2004
- limits for chemical contaminants in Regulation (EC) No 1881/2006

The legislation does not prescribe a frequency for FBOs to undertake these tests, but they must be in line with the businesses' food safety management system for example HACCP and reflect the nature and size of the business<sup>62</sup>.

In determining what level of sampling and testing is appropriate, the Food Authority must have regard to HACCP principles and any advice issued by the FSA or WLGA or contained in voluntary guidelines produced by relevant trade associations or Seafish.

## 7.1.9 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

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<sup>&</sup>lt;sup>62</sup> Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs

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 using a method for which the lab has been accredited can give the FBO more confidence in the test results. FBOs must be able to demonstrate to the Food 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 Food Authorities should consider whether the laboratory is accredited for the relevant method(s) and participates in proficiency testing as part of a recognised external quality assurance scheme. Alternative methods may be used if they are validated against the reference method in accordance with the criteria in EN/ISO 16140.

#### 7.1.10 Microbiological testing of live bivalve molluscs

The current recognised method for microbiological testing of LBMs 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 EU Regulation (EC) No 2073/2005 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 LBMs.

#### 7.1.11 Marine biotoxins

The regulatory limits and recognised methods for the detection of marine biotoxins are included in the table below.

Toxin Group and Regulatory Limit (Reg. 853/2004)	Reference Method (Annex V of Reg. 2019/627)	Method of Analysis in Wales
ASP - 20 mg of domoic acid/kg shellfish flesh	HPLC/UV	HPLC/UV – all species
PSP - 800 µg of saxitoxin eq/kg shellfish flesh	HPLC	HPLC/FLD - all species
Lipophilic toxins (LT)  160 µg okadaic acid eq/kg  3.75mg yessotoxin eq/kg  160 µg azaspiracids eq/kg	LCMS/MS	LCMS/MS – oysters, cockles, hard/razor clams, mussels and scallops

Official control Biotoxin and Phytoplankton results are reported by the laboratory directly to the relevant Food Authorities and the FSA which are published on a weekly basis on the <u>FSA website</u>.

## 7.1.12 Official controls testing - sampling of Live Bivalve Molluscs by Food Authorities

Food Authorities are required to verify food safety management plans at dispatch, purification and processing establishments. Part of this verification process may include the taking of samples to be analysed at an accredited official control laboratory. Any results that show breaches of the food safety requirements should be investigated by the FBO in the first instance and corrective action taken which could include follow-up sampling, withdrawals/recalls. The Food Authority should follow up any investigation to verify that corrective actions have been taken.

Where necessary, Food Authorities should communicate non-compliant test results to neighbouring Food Authorities, the FBO and the FSA at <a href="mailto:lasupportwales@food.gov.uk">lasupportwales@food.gov.uk</a>

The purpose of sampling by Food Authorities must be the verification of the FBO's compliance with the appropriate requirements at all stages of production, processing and distribution. Results that are inconsistent with the FBO's own records must be followed up by further investigations and tests by the FBO.

#### 7.1.13 Standards for purification centres

Regulation (EC) No 853/2004 outlines the structural and hygiene requirements for purification centres. 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 Seafish. These documents contain recommendations designed to help shellfish processors achieve high quality standards, as well as to comply with the requirements of the 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 Seafish website.

Food Authorities may 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. <u>A further guide</u> to assist Food Authority inspections of purification establishments is available.

## 7.1.14 Live Bivalve Molluscs and other shellfish which fail to satisfy requirements

In accordance with Regulation 27 of the Food Hygiene (Wales) Regulations 2006, any LBM or other shellfish that have not been produced, processed or distributed in accordance with the Regulations should be treated under the purposes of Section 9 of the Food Safety Act 1990. If food safety requirements have not been met then the authorised officer may give notice to the person in charge of the food, that until the notice is withdrawn, the food is not to be used for human consumption or removed

except being removed to a specified place. The authorised officer can also seize the food and remove it, to be dealt with by a Justice of the Peace<sup>63</sup>.

## 7.1.15 Transfer of seed Live Bivalve Molluscs to classified production areas

Seed LBMs might be transferred from areas that are not classified as production areas for 'growing on' within a production area of any class. Such LBMs must be genuine 'seed shellfish' (shellfish too small to be marketed). In fisheries regulated for conservation purposes under the Seafish (Conservation) Act 1967, transfers may only be carried out on approval of the holder of the Regulating Order for that fishery and in discussion with the Fish Health Inspectorate regarding biosecurity.

Transfers of 'seed shellfish' 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 LBMs 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 Food Authority if any such movements are contemplated.

# 7.1.16 Closure Notices (temporarily closing Live Bivalve Mollusc harvesting areas)

See also Chapter 7 of the Code of Practice. When *E.coli* LBM results are recorded above trigger levels, an Action State for all classifications will be instigated. An Action State is where immediate action is required by the Food Authority to deliver a responsive public health control system. The Food Authority should implement short term control measures to protect public health, through initiation of their Local Action Plan (LAP). Examples of high result scenarios and short-term control measures are detailed in the Local Action Group (LAG) guidance on the FSA website, for example, issuing a Temporary Closure Notice (TCN) or a temporary classification downgrade which would ensure additional product treatment prior to LBMs being sold for human consumption. Procedures are set out in the classification protocol and in LAG guidance on the FSA website.

A TCN should also be considered where, a classified production area has been subject to sudden or accidental pollution, including unconsented and emergency sewage discharges, which is likely to have an adverse impact on LBMs in a classified production area. In the event of a regulatory breach of marine biotoxins, results equal to or above the regulatory limits the Food Authority must implement short term control measures to protect public health by closing the production area and issuing a TCN, as well as initiating their LAP. Procedures are set out in the LAG guidance on the FSA website.

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<sup>&</sup>lt;sup>63</sup> Section 9 of the Food Safety Act 1990

A link to the model Closure Notice can be found at 7.1.19 below. This should be copied to the FSA at <a href="mailto:lasupportwales@food.gov.uk">lasupportwales@food.gov.uk</a>. Any person who contravenes or fails to comply with the closure would be committing an offence in breach of the terms of Regulation 17(1) of the Food Hygiene (Wales) Regulations 2006 and is committing an offence.

### 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 food safety reasons. It is also illegal for food businesses to place on the market scallops and non - filter feeding gastropods harvested from outside classified areas unless they meet food safety requirements for microbiological, marine biotoxins or chemical contamination.

Food Authorities should monitor harvesting areas within their remit, including areas affected by TCNs to ensure illegal harvesting does not occur. Where authorities become aware of these instances, they need to consider appropriate surveillance and follow up enforcement. Food Authorities are encouraged to establish close working relationships with other organisations who might be able to assist in combating the practice for example 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 to the FSA's National Food Crime Unit, which can be contacted using this link.

Food Authorities can contact the <u>FSA's National Food Crime team</u> for further advice on surveillance and enforcement.

#### 7.1.18 Shellfish identification marks

As part of the monitoring of the use of shellfish identification marks, Food 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. Food Authorities must co-operate with other Food Authorities in any random check through the production and distribution chain.

Note: retailers are to retain the label/identification tags attached to the packaging of LBMs that are not in individual consumer-size packages for at least 60 days<sup>64</sup> after splitting up the contents 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 Food Authority must carry out an investigation to establish where the procedures have not been properly observed. In such cases they must also

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<sup>&</sup>lt;sup>64</sup> Regulation (EC) 853/2004 Annex III, Section VII, Chapter 7(3)

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 Template forms and additional guidance notes

The following template forms and guidance notes can be found on Smarter Comms:

- Live Bivalve Molluscs/Live Shellfish Registration Document
- Model notice of temporary closure of classified production area(s) (live bivalve molluscs/shellfish)
   Q&A live bivalve molluscs

### 7.2 Matters relating to fishery products

#### 7.2.1 Introduction

This section provides specific guidance to Food Authorities on the application and enforcement of the fishery products aspects of Regulations (EC) No 852/2004, 853/2004 and Regulation (EU) 2017/625 and 2019/627.

#### 7.2.2 Food Authority

The FSA is the UK Central Food Authority with lead responsibility for these regulations. Food Authorities are responsible for enforcement of the regulations at their local level, and therefore approve fishery products establishments, register certain markets and fishing vessels, and otherwise enforce the regulations.

### 7.2.3 Scope of approval

The provisions of Regulation (EC) No 853/2004 do not apply to retail unless expressly indicated. A retail establishment which supplies fishery products to the final consumer therefore does not need to be approved. Approval would however be required where operations are carried out to supply fishery products to other establishments unless that supply is to other retail establishments only and is a marginal, localised and restricted activity.

Factory and freezer vessels, auctions and wholesale markets are required to have approval and must be inspected at regular intervals to check for compliance with food safety, hygiene, temperature controls and structural requirements and subject to Regulation (EC) No 853/2004, Annex III, Section VIII, Chapters I and II.

#### 7.2.4 Direct supply of small quantities 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 these purposes, a small amount is considered a total amount of not more than 25 tonnes of fishery products (not including live bivalve molluscs) in a calendar year. While the Regulations do not apply to this allowance, the supplier must still ensure that these products meet the food safety requirements set down for placing fishery products on the market.

#### 7.2.5 Conditions during and after landing

UK law requires periodic inspection and checks on the fitness for human consumption of fishery products 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 inspections to be carried out at the time of landing. An organoleptic examination of the fishery products normally satisfies this requirement.

A Food Authority can authorise the transfer of fishery products from the landing (exquay) 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 Food Authority.

Deferring checks to an approved establishment must, however, be subject to liaison and agreement with the receiving Food 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 raises doubt as to the freshness of the product, the Food 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 UK marketing standards regulations by other statutory bodies. Authorised officers must, where necessary, liaise with other statutory inspectors, for example the Defra Sea Fisheries Inspectorate, or Marine Scotland Directorate to ensure that any enforcement action taken is appropriate.

#### 7.2.6 Information on standards to be applied

Guidance on the requirements of EU Regulations relating to the Seafish industry can be obtained from Seafish. Food Authorities can use the guidance as a reference in establishing a consistent approach to the requirements of the Regulations. However, Food Authorities should exercise caution and avoid using, in support of formal enforcement action, those parts of the Seafish guidance that are directed towards the achievement of good industry practice and high-quality standards.

#### 7.2.7 Checklists and additional guidance notes

The following Checklists and additional guidance notes can be found on Smarter Comms:

- Fishing Vessel Check List
- Freezer Vessel Check List
- Factory Vessel Check List
- Q&A Fishery Products

Although the content of these documents is regarded as the minimum required, Food Authorities may adapt them as necessary to meet local requirements.

### 7.3 Matters relating to meat

#### 7.3.1 Meat - Guidance

A <u>Food Safety Management Diary for meat producers</u> has been produced for voluntary use.

For guidance on Halal food requirements see Smarter Communications.

#### 7.3.2 Meat - Approval of establishments

Details of FSA approved establishments, and <u>guidance on approval of</u> establishments, can be found on the FSA's website.

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, game handling establishments or wholesale meat markets.

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 hygiene enforcement in meat products, minced meat, meat preparations, mechanically separated meat plants, cold stores or edible coproducts 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 for example a retail butcher, dual Food Authority/FSA enforcement continues to apply.

#### 7.3.3.2 Stand-alone establishments

Food Authorities are responsible for enforcement in stand-alone establishments that produce meat products, minced meat, meat preparations and mechanically separated meat, and in establishments exempt from approval under Regulation (EC) No 853/2004.

#### **7.3.3.3** Cold stores

Cold stores supplying the final consumer (see definition in 8.3.4.1) exclusively or supplying other establishments (including caterers) on a 'marginal, localised and restricted' basis (see 8.3.4.2) are not subject to approval and must be registered under Regulation (EC) No 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 (EC) 853/2004 lays down requirements. There is no requirement for veterinary control of cold stores and Food Authorities are therefore responsible for approving cold stores and for enforcement in cold stores, except where they are colocated 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 <u>FSA Guidance for LAs</u> on the approval of establishments.

#### 7.3.3.4 Wild game

There are exemptions from the scope of Regulation (EC) No 853/2004 for the supply of wild game by primary producers or by hunters. Such supply can be in-fur or infeather but must only be supplies of small quantities directly to the final consumer or to retail outlets directly supplying the final consumer – see 8.3.4 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 (EC) No 853/2004 and Regulation (EC) No 852/2004. However, they are responsible for supplying safe food under Regulation (EC) No 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 (EC) No 852/2004 and are subject to enforcement by Food Authorities.

Establishments that process wild game and do not qualify under the Wild Game exemptions to supply in-fur/in-feather carcases 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 (EC) 852/2004 and specific provisions for the initial handling of large/small wild game in Regulation (EC) No 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 (EC) No 1069/2009.

#### 7.3.3.5 Edible co-products

Food 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 will be made available on the FSA website.

#### 7.3.4 Exemptions from approval

See the Approval of establishments - Guidance for local authority authorised officers

## 7.3.4.1 Retail establishments (Regulation (EC) No 853/2004, Article 1(4) (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 <u>and</u> 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 retail establishments

In respect of fresh or processed meat including meat products, the terms 'marginal', localised' and 'restricted' should be interpreted as:

- 'Marginal': Regulation (EC) No 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.

If either (i) or (ii) applies, the establishment is exempt from the requirements of Regulation (EC) No 853/2004. Provided, in relation to meat, the 'localised' criteria below is also met.

- '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 in the Scottish islands, local is interpreted as
  anywhere within Scotland.
- **'Restricted'** only applies to the supply of wild game. Supply is subject to the game having been examined by a trained person and carcases 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 (for example 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)

Regulation (EC) No 853/2004 Article 1(3) (e) exemption repeats the one at Regulation (EC) No 852/2004 Article 1(2) (c) allowing primary producers to supply small quantities of wild game carcases (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 these regulations.

Regulation (EC) No 853/2004 Article 1(3) (e) exemption applies only to individual hunters who prepare wild game meat from carcases 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 (EC) No 853/2004, not from Regulation No (EC) 852/2004.

For these exemptions, the UK is interpreting supply of 'small quantities' as self-defining because the demand for in-fur/in-feather carcases from local consumers and local retailers is limited. In the case of the hunter claiming a Regulation (EC) No 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 7.3.1.2).

The summary table at 7.4.4 below provides information on what elements of the various regulations apply to the hunting of wild game and its placing on the market.

Separate <u>guidance on the supply of wild game outside approved premises</u> can be found on the FSA website.

# 7.3.4.5 On-farm slaughter and cutting of small quantities of poultry and lagomorphs

Regulation (EC) No 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>65</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 (EC) No 852/2004) will be set out in national law. These national rules are set out in Schedule 5 of the Food Hygiene (Wales) Regulations 2006.

Which producers benefit from this exemption?

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

<sup>&</sup>lt;sup>65</sup> As amended by Article 3 of Regulation (EC) No 2076/2005 (Transitional and Implementing Measures)

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 (EC) No 852/2004 applies to producers who benefit from this exemption. This includes, among other things, the requirement to register the establishment with the local Food 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 Hygiene (Wales) Regulations 2006 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 Regulation (EU) No 1169/2011.

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 Food Authority on request.

## 7.3.5 Meat products, minced meat and meat preparations – Cutting of meat

Premises that cut meat exclusively for the manufacture of meat products, minced meat, meat preparations or mechanically separated meat require approval in respect of their manufacturing activities and need to comply with the relevant requirements of Annex III of Regulation (EC) No 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 Wales

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 (EC) No 852/2004 and Regulation (EC) No 853/2004. However, Regulation (EC) No 999/2001 applies wherever a Transmissible Spongiform Encephalopathies (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 TSE requirements (Regulation (EC) No 999/2001) and Animal By-Product requirements (Regulation (EC) No 1069/2009). Animal Welfare requirements under Regulation (EC) No 1099/2009 also apply. A more <u>detailed guide on home slaughter</u> is available on the FSA website.



## 7.3.7 The wild game sector - which regulations apply to which activities

ACTIVITY	Regulation (EC) 852/2004	Regulation (EC) No 853/2004	Regulation (EU) 2017/625 <sup>66</sup>
Shooting for own consumption	No Art 1.2a exemption	No Art 1.3a exemption	No
Supply direct to final consumer or to local retailers (directly supplying final consumer) of small quantities of:			
a) whole carcasses by primary producer (hunter or estate)	No Art 1.2c exemption National rules apply <sup>67</sup>	No Art 1.3c exemption	No
b) meat from carcasses (produced by hunter from own shooting)	Yes  Premises to be registered as food business <sup>68</sup> and to operate under Annex II	No Art 1.3e exemption National rules apply	No
Supply of whole carcasses to approved game handling establishments (AGHEs)	Yes	Parts relating to primary producer ('trained	Parts relating to primary producer's documentation and

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<sup>&</sup>lt;sup>66</sup> Regulation (EU) No 2017/625 and regulations made under it, such as Regulation (EU) 2019/627 and Regulation (EU) 2019/624

<sup>&</sup>lt;sup>67</sup> Food Safety Act 1990 (as amended by General Food Regulations 2004)

<sup>&</sup>lt;sup>68</sup> By the Food Authority (Local Authority)

either direct from shoot or from game larder operated by primary producer	Premises to be registered as food business <sup>20</sup> and to operate under Annex I	person <sup>69</sup> requirements and hygiene practices for example, initial handling, temperature controls and transport)	hygiene practices, including OV <sup>70</sup> examination of 'trained person <sup>23</sup> ' information
Supply of whole carcasses to approved game handling establishments (AGHEs)  not by the primary producer	Yes  Premises to be registered as food business <sup>20</sup> and to operate under Annex II (including any game larders and vehicles)	Parts relevant to documentation originally supplied by 'trained person <sup>23</sup> ', plus temperature controls, hygienic handling and transport	Parts relevant to supplier's hygiene practices, plus OV <sup>24</sup> to check supply of documentation from 'trained person <sup>23</sup> '
All other (non-retail) establishments preparing wild game meat for placing on the UK domestic or export market These are approved game handling establishments (AGHEs)	Yes	Yes Premises to be approved by FSA	Yes

<sup>&</sup>lt;sup>69</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 Food Authority (see Regulation (EC) No 853/2004, Annex III, Section IV, Chapter I)
<sup>70</sup> Official Veterinarian

#### 7.3.8 Less than thoroughly cooked (LTTC) burgers

In March 2017 a specific requirement for establishments supplying minced meat (MM) and/or meat preparations (MP) intended to be eaten less than thoroughly cooked (LTTC) to be approved by either the FSA or their Food Authority was introduced. Specific approval of this activity is an important step in delivering a high level of public protection. A <u>published list of establishments approved for this activity</u> can be viewed. The list assists FBOs at catering establishments to identify approved producers of MM/MP which are suitable for use in the production of burgers intended to be LTTC.

There is guidance for food businesses and authorised officers on 'Less than thoroughly cooked burgers' on the FSA website.

#### 7.3.9 Halal food issues

Guidance for food law enforcement officers on Halal food requirements can be found on Smarter Comms.

### 7.4 Matters relating to raw milk and dairy products

#### 7.4.1 Introduction

This section provides specific guidance to Food Authorities with regard to Raw Milk and Dairy Products and clarifies enforcement responsibilities between Food Authorities and the FSA.

#### 7.4.2 Enforcement

Food Authorities approve dairy establishments, and otherwise enforce the Regulations except in the cases listed below:

Requirements in Regulation 5(2)(b) of the Food Hygiene (Wales) Regulations 2006 relating to milk production holdings and the subsequent supervision and inspection of production holdings (apart from animal health checks - see below) are dealt with by the FSA Dairy Hygiene Inspectors (DHIs)<sup>71</sup>.

The DHIs are also responsible for controls under Schedule 6 of the Food Hygiene (Wales) Regulations 2006 on the sales restrictions of raw cows' drinking milk (RCDM), i.e.

- ensuring that raw cows' drinking milk is only supplied from farms direct to consumers, at registered farmers markets, or via distributors,
- ensuring compliance with the appropriate raw drinking milk (RDM) labelling requirements, and
- the management of the sampling programme to ensure adherence to standards for such milk

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

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<sup>&</sup>lt;sup>71</sup> With effect from April 2012

appropriate, including annual TB testing of cattle herds that produce raw drinking milk for direct human consumption.

FBOs whose operations are both as a milk production holding and a processing establishment are registered with the FSA as a production holding and either registered or approved by the Food Authority as a dairy establishment for processing activities.

## 7.4.3 FBOs selling raw drinking milk and cream intended for direct human consumption

Article 10(8) of Regulation (EC) No 853/2004 allows the UK to establish national rules on the sale of raw milk and cream intended for direct human consumption.

The FSA is responsible for the enforcement of Schedule 6 of the Food Hygiene (Wales) Regulations 2006 with respect to RCDM for direct consumption. DHIs verify compliance with those provisions and are the relevant enforcement authority for failure to comply with:

- micro parameters for RCDM,
- the limitations on sales routes for RCDM for direct consumption, and
- the health warning requirements for RCDM

Food Authorities are responsible for enforcing the sampling requirements of Schedule 6 of the Food Hygiene (Wales) Regulations 2006 in respect of sales of RDM intended for direct human consumption, *from species other than cows* – specifically paragraph 5 and for the health warning requirements for RDM of non-cow species.

There are no similar restrictions on sales routes of raw drinking milk from other species under this Schedule though the product is still required to comply with the food safety and traceability requirements set out in Articles 14 and 18 of Regulation (EC) No 178/2002.

Food Authorities are currently responsible for verifying compliance with hygiene requirements during bottling or packaging processes for RDM of all species for direct consumption. They are also the enforcement authority for general food labelling, including durability marking of RDM of all species.

All RDM for direct consumption is also required to comply with the food safety criteria under Regulation (EC) No 2073/2005 with respect to ready to eat foods, and the legal safety and traceability requirements for food.

If Food Authorities have concerns about the microbiological standard of RCDM 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 1990 if appropriate. Close collaboration should be maintained with the local DHI in these circumstances.

Food Authorities should also alert the FSA as soon as possible if they become aware of sales of RCDM other than from the farm, registered farmers markets, 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 Food Authorities liaise closely with the FSA and the regional APHA offices to maintain an up-to-date list of local FBOs selling RDM and raw milk products.

#### 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

FBOs are responsible for ensuring that the requirements of Regulation (EC) No 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. FBOs will need to keep evidence of such visits for example a receipt/invoice - and of any follow up action taken if problems occur – for checking by authorised officers. First commercial purchasers (or processors) of raw milk are also required to ensure, for example 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 Food Authorities by the FSA, APHA or private veterinary surgeons. Longer-term issues arising from records can also be referred to Food Authorities. Where Food 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 first commercial purchaser/processor, or with the producer direct, and advise them to take appropriate advice for example from their private veterinary surgeon. The Food Authority should also inform the FSA so that DHIs can take action as a result of the referral or complaint.

#### 7.4.6 Criteria and standards for raw milk

In the case of the standards laid down in Regulation (EC) No 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 first commercial purchaser. Authorised officers need to ensure that FBOs are carrying out the specified sampling programme. Authorised officers should check FBOs' 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 (EC) No 853/2004, as amended by Article 8 / Annex VII(2)(d) of Regulation (EC) No 2074/2005.

# 7.4.7 Temperature requirements for milk used for the manufacture of dairy products

Regulation (EC) No 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 for example cheeses and also instances over a weekend for example when establishments are unable to process milk within the specified period. Authorisation by the Food 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 (EC) No 853/2004, as amended by Article 8 / Annex VII (2) (d) of Regulation (EC) No 2074/2005.

### 7.4.9 Phosphatase testing

Regulation (EC) No1664/2006, which amended Regulation (EC) No 2074/2005, implemented new requirements for the alkaline phosphatase (ALP) testing method for heat-treated milk:

- All FBOs 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

The Practice Guidance provides information and advice for Food Authorities in Wales who have dairy herds and/or dairy establishments in their area, including those producing RCDM<sup>72</sup> and/or unpasteurised milk-based products. The guidance will be of

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<sup>&</sup>lt;sup>72</sup> In this context raw cows' milk also includes raw buffalo's milk.

assistance to those involved in follow up actions following notification from APHA of the loss<sup>73</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 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. APHA is responsible for carrying out surveillance testing of dairy cattle herds for bovine tuberculosis (and brucellosis where appropriate) on a disease risk basis.

#### 7.4.11.3 Legislative background

The details of the legislative background can be found in the following Milk Hygiene on the Dairy Farm Guide in Section 2 which summarises the provisions of Regulation (EC) 853/2004, Annex III, Section IX, Chapter 1 for raw milk and dairy products.

#### 7.4.11.4 Food 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 herd owner (FBO), FSA and relevant Environmental Health Officer (EHO). TB restrictions are imposed on the herd owner under the Tuberculosis (Wales) Order 2010 (as amended) and this effectively suspends (or withdraws) the OTF status of that herd until further notice.

On receipt of the notification, the FSA commences the process to ensure that milk from the herd is no longer used for raw milk-based products. The FSA liaises with the TB Advice team at APHA to establish the circumstances of the case and the OTF status of the herd. If the herd is no longer officially TB free, the FSA will remove the registration for RDM.

The Notice served by APHA on the FBO advises that the FSA is the Food Authority for the enforcement of Regulation (EC) No 853/2004 at 'registered' primary production holdings in Wales and Local Authorities act as the Food Authority at 'approved' dairy processing establishments, collection centres, re-wrapping and repackaging centres.

The Notice includes the following information:

1. Milk from reactors must not be used for human consumption. Milk from these animals must be withheld from the bulk tank. It is recommended that you do not

<sup>73</sup> For the purpose of the Practice 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').

- feed it to calves or other livestock, on your own holding. If fed, reactor milk may only be given to animals on the same farm, after suitable heat treatment.
- 2. Milk from animals (from a reactor herd) that do not show a positive reaction to the test for tuberculosis must be heat treated before being sold for human consumption. The FBO or person in charge at the primary production holding must contact their milk purchaser to ensure that all milk undergoes heat treatment.
- 3. FBOs with an additional registration in Wales and England to sell raw milk for direct human consumption must cease such sales. If raw milk is to be used by the FBO of the primary production holding as an ingredient to make cream, cheese, etc., the FBO must ensure that such milk is heat treated before use.
- 4. Milk from inconclusive reactors may still go for human consumption, provided it is heat treated before it is sold, as detailed in point 2 above.

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.

On receipt of notification Food Authorities should:

- 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.
- 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 DHIs and any other Food Authorities, including the Food Authority of the first purchaser who might need to become involved where appropriate.

Where the affected farm has heat treatment facilities installed, the Food Authority should confirm that all HACCP systems and procedures are in place and working effectively, including adequate heat treatment.

#### Notify the FSA Consumer Protection Team immediately if:

- milk from reactor animals is found to have entered the food chain after the loss of OTF status,
- milk from the non-reactor animals in a non-OTF 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

• Enforcement officers of Food Authorities will wish to consider the public health implications of products made prior to the herd losing its OTF status, via a risk assessment undertaken locally with the Consultant in Communicable Disease Control (CCDC), the regional APHA office and the DHIs. Advice should also be obtained where appropriate from Public Health Wales (PHW). 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.
- 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 Food Authority with the risk assessment.
- Regulation (EC) No 853/2004 does not prohibit the marketing of products manufactured before the removal of OTF status. If a voluntary solution cannot be agreed with the producer, Enforcement Officers might consider enforcement action if they suspect that the products concerned fail to comply with food safety requirements; as defined in Article 14 of Regulation (EC) No 178/2002. For any prosecution to succeed, officers will need to prove that an offence had occurred under Regulation 17(1) of the Food Hygiene (Wales) Regulations 2006. This makes it an offence for any person to contravene or fail to comply with any of the specified EU provisions including Article 14 of Regulation (EC) No 178/2002.

#### Action to take before OTF problems arise

- The FSA liaises with APHA to ensure that herds supplying RCDM and/or establishments or processors manufacturing unpasteurised dairy products are tuberculin tested annually. The FSA notifies APHA when they become aware of the sale of RCDM for human consumption. Food 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. Food Authorities should contact APHA who will be able to supply further information about these issues.
- Food Authorities might find it helpful to liaise with relevant Food Authority Animal Health and Welfare Trading Standards Inspectors as their responsibilities include checking farm records under animal health legislation.

## 7.4.11.5 CCDC notification to Enforcement Authority of person with confirmed bovine TB

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 Food Authority. If there is a risk that a herd and/or other farm stock might be infected, then the authorised officer should notify APHA so that checks can be made on the herds. It may also be appropriate to notify other relevant Food 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 Welsh Government Bovine TB guidance.

If further advice is needed on the action to be taken on stocks of raw milk based products following the loss of OTF status, Food Authorities should contact the FSA Consumer Protection Team: <a href="www.Wales.Foodincidents@food.gov.uk">Wales.Foodincidents@food.gov.uk</a>, who will work with the local investigation team.

If more information is required on Defra procedures concerning TB controls Food Authorities should contact the duty Veterinary Officer at local or regional Offices of APHA.

The following web sites may be useful:

- Animal Plant and Health Agency
- Welsh Government Bovine TB Guidance and Services

### 7.5 Matters relating to egg packing centres

#### 7.5.1 Introduction

This section provides specific guidance to Food Authorities for the enforcement of Annex III, Section X, Eggs and Egg Products, Chapters I and II respectively of Regulation (EC) No 853/2004.

In addition to the relevant requirements of Regulation (EC) No 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 (EC) No 853/2004, egg-packing centres will be subject to the appropriate provisions of Regulation (EC) No 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, Food 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 (EC) No 853/2004, may be classed as 'retail' as defined in Article 3(7) of Regulation (EC) No 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 authorised 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 authorised 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 (Wales) Regulations 2009 cover most aspects of egg production, marking, transport, grading, packing and onward marketing.

The 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 the EMI in order to be permitted to grade them as Class A eggs.

All registered establishment are allocated with a distinguishing number that 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 <u>egg quality and marketing regulations</u>. These regulations are the responsibility of Defra. Inspections under these regulations are carried out by EMIs. 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.

Both schemes incorporate 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 or 'Laid in Britain' eggs. The Lion scheme also has a 'best-before' date stamped on the shell as well as on the pack.

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 Food Authorities or the EMI inspections.

## 7.6 Matters relating to egg products and liquid egg

#### 7.6.1 Introduction

This Section provides specific guidance to Food Authorities on the enforcement of Section X, Eggs and Egg Products Chapter II of Regulation No 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 (EC) No 853/2004 apply to retail, as defined by Regulation (EC) No 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 (EC) No 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 (EC) No 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 Food Authority should specify whether the approval is for i) or ii) and if the establishment 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 Food 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 (EC) No 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 (EC) No 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. If the egg in question is liquid egg, then the label must also state the words 'non-pasteurised egg products - to be treated at place of destination' and indicate the date and hour of breaking.

#### 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.

Food 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 UK legislation on microbiological criteria.

Where a non-standard process is proposed, the onus is on the food business to show that adequate research has been carried out into its effectiveness. In establishments where heat processing takes place, Food 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 (EC) No 853/2004 lays down analytical specifications that the end product must not exceed. Although there are no prescribed methods for testing for lactic or butyric acids, methods do exist. Where such methods are used, 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 food businesses develop sampling plans, which 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 (EC) No 852/2004.

### 7.7 Food for specific groups

#### 7.7.1 Regulation (EU) No 609/2013

National legislation was introduced in July 2016 on 'The Food for Specific Groups (Information and Compositional Requirements) (Wales) Regulations 2016' (SI No. 639 (W.175)), which puts enforcement provisions in place to enable the Regulation on foods for specific groups (referred to as FSG Regulation) on Regulation (EU) No 609/2013 to be enforced in Wales.

This legislation replaced the rules on Foods intended for Particular Nutritional Uses (PARNUTS foods). The Regulation repeals framework Directive 2009/39/EC on PARNUTS foods and covers:

- infant and follow-on formula,
- processed cereal-based food and baby food,
- food for specific medical purposes, and
- total diet replacement for use in energy restricted diets for weight control.

#### The new regulation:

- sets general compositional and labelling rules
- transfers rules on gluten-free foods and very low gluten under Regulation (EU)
   No 1169/2011 on food information to consumers (FIC) in order to ensure clarity and consistency.
- Establishes that foods previously regulated under the PARNUTS framework, such as meal replacement products for weight control, will be treated as general foods and regulated under Regulation (EC) No 1924/2006 on nutrition and health claims.

The FSG Regulation lays down *general* requirements for the four food categories above. In terms of labelling, there are only general requirements established for not misleading the consumer or attributing to the food the property of preventing, treating or curing a human disease. There are additional requirements for infant formula and follow-on formula which require the labelling, presentation and advertising to be designed so as not to discourage breastfeeding and must not include pictures or text idealising the use of infant formula or follow-on formula.

The FSG Regulation established *specific* compositional and information rules through Delegated Regulations for each of the four categories of food. These rules have applied from 2019.

Under the new approach, food for other population groups will be regulated as regular foodstuffs under general food law. From 20 July 2016, young-child formulae and food intended for sportspeople are exclusively covered by horizontal rules of EU food law.

The Regulations implement the minimal requirements of the FSG Regulation and give enforcement officers the power to serve Improvement Notices for failure to comply with existing provisions for labelling, composition, and advertising of foods for specific groups (see the FSA letter ENF/E/16-04 for further guidance).

# 7.7.2 Legislative Requirements for infant formula, follow on formula and baby foods

Information on legislation in this area can be found on the **EU website**.

#### Infant formula and follow-on formula

Infant formula and follow-on formula are products designed to satisfy the specific nutritional requirements of healthy infants and young children. Infant formula is suitable from birth and is the only food which can be marketed as satisfying by itself the nutritional requirements of infants during the first months of life. Follow-on formulas are foods intended for older infants when appropriate complementary feeding is introduced and constituting the principal liquid element in a progressively diversified diet of such infants. These products are specifically covered by Commission Directive 2006/141/EC.

Under the new FSG Regulation, Delegated Regulation (EU) 2016/127 providing the detailed labelling and compositional rules for infant and follow-on formula will apply from 22 February 2020.

The legislation sets 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 legislation 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 legislation also requires all infant formula to be notified to the Department of Health prior to being placed on the market.

The legislation also encompasses the specific rules on the presence of *pesticides* residues in infant and follow-on formulae. 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>74</sup>.

In addition to the requirements relating to infant formulae and follow-on formulae, 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.

The new Delegated Regulation (EU) 2016/127:

- Updates the existing compositional requirements based on the latest scientific advice.
- Modifies the rules on labelling to ensure consistency with Regulation (EU) No 1169/2011 on the provision of food information to consumers.

<sup>&</sup>lt;sup>74</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 <u>the</u> gov.uk website

 Prohibits the use of nutrition and health claims on infant formula to protect breastfeeding.
 Strengthens the requirement to ensure infant formula and follow-on formula are clearly distinct from each other.

As a member state, the UK Government was fully involved and committed to the introduction of the new regime within the EU. The Delegated Regulation is enforced in Wales by the <u>Food for Specific Groups (Information and Compositional Requirements)</u> (Wales) (Amendment) Regulations 2020

Detailed guidance on the rules on infant formula and follow-on formula can be found at the following <u>link</u> (separate, but parallel legislation is implemented in Scotland, England and Northern Ireland).

### 7.7.3 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 <u>Commission Directive 2006/125/EC</u>. 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 <a href="Commission Directive 99/39/EC">Commission Directive 99/39/EC</a> 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 Wales are the Processed Cereal-based Foods and Baby Foods for Infants and Young Children (Wales) Regulations 2004 as amended by the Food for Particular Nutritional Uses (Miscellaneous Amendments) (Wales) Regulations 2007.

The new FSG Regulation requires the Commission to adopt, through delegated act, specific compositional and labelling rules for processed cereal-based foods and baby foods, which will replace Directive 2006/125/EC. Until the finalisation of the delegated act, the rules of Directive 2006/125/EC remain applicable.

# 7.7.4 Food for special medical purposes (FSMP)

Medical foods are classified as dietary foods for special medical purposes (FSMP) for which the compositional and labelling requirements are laid down and regulated by the following Regulations: <u>The Medical Food (Wales) Regulations 2000.</u>

Delegated Regulation (EU) 2016/128 providing the detailed labelling and compositional rules for FSMP came into force on 22 February 2019. This is enforced by the Food for Specific Groups (Information and Compositional Requirements) (Amendment) (Wales) Regulations 2019.

With regard to FSMP designed to meet the nutritional requirements of infants, Delegated Regulation (EU) 2016/128 applies from 22 February 2020 and this is enforced in Wales by the Food for Specific Groups (Information and Compositional Requirements) (Wales) (Amendment) Regulations 2020.

# 7.7.5 Foods for total diet replacement for weight control

Low and very low-calorie diet foods are specially formulated foods which replace the whole of the diet. Foods for total diet replacement for weight control are regulated in Great Britain by the Foods Intended for Use in <a href="Energy Restricted Diets for Weight Reduction Regulations 1997">Energy Restricted Diets for Weight Reduction Regulations 1997</a> (as amended) These Regulations implement <a href="Commission Directive 96/8/EC">Commission Directive 96/8/EC</a> on foods intended for use in energy-restricted diets for weight reduction. Since 20 July 2016, Directive 96/8/EC no longer applies to foods presented as a replacement for one or more meals of the daily diet. Rules that regulate meal replacement for weight control are transferred to Regulation (EC) No 1924/2006 on nutrition and health claims made on food.

Delegated Regulation (EU) 2017/1798 on total diet replacement for weight control was adopted in June 2017 and is set to apply in Europe from 27 October 2022. Until then, the rules of Directive 96/8/EC remain applicable to foods for total diet replacement.

### 7.7.6 Addition of substances to FSG for specific nutritional purposes

Nutritional substances belonging to the following categories: vitamins, minerals, amino acids, carnitine and taurine, nucleotides, choline and inositol, that may be used in the manufacture of foods for specific groups are laid down in the Annex to the <a href="#">FSG</a></a>Regulation (EU) No 609/2013. The category of food which each substance may be added to is specified in the Annex of the Regulations.

### 7.7.7 Notification procedures

When the following foods are placed on the market, the manufacturer or importer must notify the Welsh Government by completing a notification form and forwarding a model of the product label as required by the Food for Specific Groups (Information and Compositional Requirements) (Amendment) (Wales) Regulations 2019, the Food for Specific Groups (Information and Compositional Requirements) (Wales) (Amendment) Regulations 2020 and The Infant Formula and Follow-on Formula (Wales) Regulations 2007.

- New or updated formulations of Infant formula
- Dietary foods for special medical purposes (FSMP)

- From 22 February 2020 some follow-on formula products will also need to be notified i.e. if their composition differs from the requirements of Annex II of Regulation (EU) 2016/128
- From 22 February 2021 follow-on formula containing protein hydrolysates will need to be notified.

# 7.7.8 Foods for sports people

There is no specific legislation on foods intended to meet the expenditure of intense muscular effort, especially for sports people; general food law therefore applies. Products presented as 'food supplements' need to comply with <a href="Directive 2002/46/EC">Directive 2002/46/EC</a>. All products presented for sports people need to ensure that any nutrition or health claims made are compliant with the <a href="Nutrition & Health Claims Regulation No 1924/2006">No 1924/2006</a> and the EU Register of authorised claims.

# 7.7.9 Foodstuffs suitable for people intolerant to gluten

The rules on use of the statements 'gluten-free' and 'very low gluten' will be incorporated into Regulation (EU) No 1169/2011 on the provision of food information to consumers.

# 7.8 Temperature control provisions

### 7.8.1 Introduction

Temperature control requirements for food businesses in the UK are set out in Annex II, Chapter IX, Paragraphs (5) and (6) of Regulation (EC) No 852/2004. These requirements are given effect in Wales by Regulation 30 and Schedule 4 of the Food Hygiene (Wales) Regulations 2006. In respect of circumstances exempted from the requirements of Regulation 30 and 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) No 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 (EC) No 852/2004 would still apply, as appropriate.

Regulation 30 and Schedule 4 does not apply in respect of any FBO to which Regulation (EC) No 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 (EC) No 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 (EC) No 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 flatheaded 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, for example 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 FBO 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 Food 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

Thermometers and other temperature measuring devices used for inspection and/or enforcement purposes must be periodically tested and calibrated by a suitably

accredited tester (for example 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.

Food Authorities must also check devices for accuracy at regular intervals between each calibration (for example 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.

Food 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, for example 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:

- 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.
- 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 +/-0.5°C, or better when the sensor is measuring within the temperature range -20°C to +30°C
- the accuracy must not change by more than +/-0.3°C when the instrument is operated in temperatures of -20°C to +30°C
- the instrument display must be readable to at least 0.1°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 interconnecting 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 FBO 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 FBO 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 30 and Schedule 4 of the Food Hygiene (Wales) Regulations 2006

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 Hygiene (Wales) Regulations 2006, the officer must deal with the food under regulation 27 of the Regulations (see also regulation 23 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 within this range.

Authorised officers should enquire into the history of the food, in particular to ascertain whether it could previously have been exposed to such temperatures. 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. In considering the approach to take, enforcement officers should consider how likely it is that food may be being consistently placed on the market at these temperatures.



### 7.9 Bottled waters

#### 7.9.1 Introduction

This section provides guidance to Food Authorities on enforcement of The Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) 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 safety and 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.
- Commission Regulation (EU) No 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 Food Authorities for regulatory purposes.
- Directive 2013/51 EURATOM laying down requirements for the monitoring of radioactive substances in water intended for human consumption in so far as those requirements apply to bottled water.
- Commission Directive (EU) 2015/1787 amending Annexes II and III to Council Directive 98/83/EC on the quality of water intended for human consumption in so far as those requirements apply to bottled water.

### 7.9.3 Natural mineral waters (NMW)

Regulations require each natural mineral water source to be recognised by the Food Authority for the area in which the source is located.

Once recognition has been granted, the Food 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 in accordance with Schedule 3 and 4 of the Regulations.

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 <u>EU's</u> <u>website</u>.

The updated list of NMW recognised in the UK can also be found online in the <u>following</u> guidance.

# 7.9.4 Recognition of natural mineral waters

Applications for recognition of natural mineral waters in Wales are submitted in writing to the Food Authority. The Food Authority is required to assess all the information required by the Regulations.

Food Authorities must notify 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.gov.uk

Bottled Drinking Water Food Compositional Standards Food Chain Directorate 2nd Floor Seacole Building 2 Marsham Street London SW1P 4DF

Food 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 bottling plant must be in a closed pipeline which must be of materials suitable for water and so built as to prevent any chemical, physico-chemical or microbiological alteration of the water.

### 7.9.5 Recognition as natural mineral water from outside Wales

Water is recognised as natural mineral water where:

- (a) in the case of water extracted from the ground in Wales, recognition is granted by the relevant authority in accordance with Part 1 of Schedule 3;
- (b) in the case of water extracted from the ground in another part of the United Kingdom, it is recognised there pursuant to Directive 80/777 by a responsible authority of that part of the United Kingdom;
- (c) in the case of water extracted from the ground in an EEA State other than the United Kingdom, it is recognised there pursuant to Directive 80/777 by a responsible authority of that EEA State; and
- (d) in the case of water extracted from the ground in a country other than an EEA State (i) it is recognised by the Agency, in accordance with Part 2 of Schedule 3, or (ii) it has an equivalent recognition, given by a responsible authority of (aa) another part of the United Kingdom, or (bb) an EEA State other than the United Kingdom.

### 7.9.6 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.

Among them, the one and the same spring rule applies.

# 7.9.7 Spring and other bottled drinking water

The recognition process required for Natural Mineral Water does not apply for spring and bottled drinking water. The parameters to be measured and the maximum limits which need to be met for spring and bottled drinking water also differ from those in natural mineral water.

The latest amendment (2017) to the Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations updates monitoring obligations by relevant authorities in relation to radioactive substances for spring and bottled drinking water and establishes the criteria for sampling by the Food Authorities.

In relation to chemical and microbiological parameters, the minimum frequency for check monitoring and audit monitoring sampling as well as the parameters to be taken by each relevant authority for spring and bottled drinking have been removed by the latest amendment to the Regulations.

However, intervention by relevant authorities will continue to be required since official controls under Regulations (EC) No 178/2002 and Regulation (EU) 2017/625 are applicable. Furthermore, the sampling of water to ascertain that it remains compliant with the Regulations in terms of chemical and microbiological parameters will continue to be required.

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.

### 7.9.8 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.

Among them, the *one and the same spring rule* also applies for spring water.

Bottled drinking waters are subject to the general labelling requirements of the Food Information (Wales) Regulations 2014 and specifically cannot use any sign, whether emblematic or not, the use of which is liable to cause confusion of the water with a natural mineral water, or the description 'mineral water'.

# 7.10 Food waste and animal by-products

#### 7.10.1 Introduction

This section provides guidance to Food Authorities on the control of food waste and disposal of animal by-products.

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 Regulation (EC) 852/2004.

For the purposes of the Practice Guidance, 'food waste' includes food material that is not fit or not intended for human consumption, although please note 'food waste' is

often used to refer to food that is being redistributed and so in those cases remains 'on the market' in food law terms.

Many food businesses will be making efforts to reduce food waste and distribute surplus food to charities or redistributive groups. The FSA supports food surplus redistribution where it can be done safely. A guidance document with helpful advice for charities and businesses redistributing surplus food titled 'Best practice on food date labelling and storage advice' published in November 2017 by WRAP in collaboration with the FSA and Defra is available.

### 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:

- include the arrangements in ports and airports for the collection and disposal of imported food waste from ships and aircraft; and
- 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) No 1069/2009 Animal by-products (ABP) means entire bodies or parts of animals, products of animal origin or other products obtained from animals (includes eggs, milk and honey), which are not intended for human consumption including oocytes, embryos and semen<sup>75</sup>. 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.

Food material consisting of or containing products originating from animals becomes an ABP when the food business manager determines that the product is no longer to be used for human consumption. Once this decision is made it is irreversible. The material then becomes a low risk (category 3) ABP, and the origin and nature of this food material determines how it can be disposed of or used, and the records required to be kept.

Where appropriate, inspections, which may be carried out by an EHO or a TSO depending on the way that controls are arranged within the Food Authority, 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

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 $<sup>^{75}</sup>$  as defined in point (1) of Article 3 of Regulation (EC) No 1069/2009

processing and subsequent human consumption. Articles 12-14 of Regulation (EC) No 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 <u>Industry Guide to Edible co-products and Animal By-products</u>.

# 7.10.4 Animal feed – former foodstuffs and co-products

Former foodstuffs, which can also be described as surplus food, may, subject to animal by-product rules be supplied for animal feed where for commercial reasons the food is no longer intended for human consumption. This can include out of date, out of specification, surplus product or ingredients, or food in damaged packaging.

Co-products of food processing may also be supplied for animal feed for example fruit pulp from the production of fruit juice, brewers' grains from the production of beer.

Former foodstuffs and co-products may be supplied direct to a farm or sent for further processing.

FBOs supplying former foodstuffs or co-products are feed business operators. If they are aware that their products are destined for feed they must register as a feed business with their feed authority and ensure compliance with <a href="Regulation (EC) No 183/2005">Regulation (EC) No 183/2005</a> Feed Hygiene, <a href="Regulation (EC) No 178/2009">Regulation (EC) No 178/2009</a> Marketing and Use of Feed including labelling and <a href="Regulation (EC) No 178/2002">Regulation (EC) No 178/2002</a> on the general principles and requirements of food law including feed.

Where during inspection of a food premises it is identified that former foodstuffs or coproduct is supplied for animal feed, it should be established if the business is registered as a feed business with their local feed authority. If the FBO is not registered as a feed business or it cannot be established, the local feed authority must be informed. Animal feed – animal by-product controls

If former foodstuffs or co-products consist of, contain or is contaminated with products of animal origin, it becomes subject to Animal By-Products controls. These products generally cannot be used for feed for farmed animals. Further information on disposing food and former foodstuffs is available from <a href="APHA guidance">APHA guidance</a>. When a FBO makes the decision that food of animal origin or food that contain products of animal origin is no longer for human consumption then the former foodstuff becomes an animal by-product and this decision cannot be reversed.

# 7.10.5 Animal feed – catering waste

Catering waste is any waste food (including used cooking oil) that comes from restaurants, catering sites, commercial or household kitchens. Catering waste must never be sent for use as animal feed including for pet food. Due to the risk of cross contamination with products of animal origin for example milk, this includes vegetarian kitchens. Processed catering waste, known as 'swill', is also banned from feeding to animals. See the following article for supporting information.

# 7.10.6 Major investigations

Food 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, for example 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 Food Authority's ability to carry out its routine inspection and enforcement programme. If such circumstances arise, it is important that the Food Authority contacts the FSA as soon as practicable.

The FSA and the Food Authority will then be able to discuss options, including whether support might be available, or whether the Food Authority's inspection programme must be re-prioritised to ensure that inspections of higher-risk premises are maintained.

# 7.11 Distance selling/mail order

#### 7.11.1 Introduction

This section provides guidance to Food 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 the Practice Guidance, 'the distance selling of food' means the advertisement of food for sale directly to consumers where the subsequent sale or supply 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 Food 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 Food 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

# 7.11.3 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, even if the purchaser is based overseas.

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 the same legal requirements as food sold from a high street supermarket or advertised in a UK national newspaper.

#### Food Authorities:

- are 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
- must therefore have appropriate means of monitoring the distance selling of food by businesses for which they act as Primary Authority
- 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

# 7.11.4 Distance selling of food from outside the UK

The distance selling of food from outside the UK takes place when the advertisement of food for sale or the sale transaction itself takes place outside the jurisdiction of the UK.

#### 7.11.5 Other references

A <u>Guide to Good Hygiene Practice for the Mail Order Food Industry</u>, developed in accordance with Article 8 of Regulation (EC) No 852/2004, was published in 2007. There is also <u>FSA guidance on food sold online</u> (as well as guidance for food businesses and consumers).

Generic law regulating distance selling in the UK is set out in the Consumer Protection (Distance Selling) Regulations 2000, which implement Council Directive 97/7/EC in the UK.

The central UK Food Authority with responsibility for these Regulations is the Department for Business, Energy and Industrial Strategy (BEIS). Enforcement is the responsibility of the Competition and Markets Authority (CMA) and Trading Standards Departments.

# 7.12 Additional guidance notes to Food Authorities

Additional guidance on a variety of food law matters is available on Smarter Comms.

# Glossary

# **Animal By-Products (ABP)**

Defined in Article 3 of Regulation (EC) No 1069/2009 as 'entire bodies or parts of animals, products of animal origin or other products obtained from animals that are not intended for human consumption'.

# **Approved Game Handling Establishment (AGHE)**

An approved premise in accordance with the Regulation (EC) No 853/2004. Where a business is processing unlimited quantities of game meat from brought -in fur/in feather carcases and supplying it to retail and wholesale customers.

### Alkaline phosphatase (ALP)

In regard to phosphatase testing in milk AP; is an intrinsic enzyme secreted by ruminants in their milk. The enzyme is denatured during pasteurisation of the milk, hence is used to determine the efficacy of milk being heat treated.

#### Alternative interventions

Alternative interventions are interventions other than official controls conducted at low risk food businesses and includes alternative enforcement strategies.

# **Animal Plant Health Agency (APHA)**

APHA is an executive agency of Defra operating across Great Britain and is responsible for the protection of animal health and welfare.

APHAs feed enforcement activities are focused on the ban on feeding animal protein to ruminants, under Regulation (EC) No 999/2001 (known as the 'TSE Regulations'), controls relating to catering waste and swilling feed under Regulation (EC) No 1069/2009 (known as the 'ABP Regulations') and approval or registration of premises handling animal by-products.

### Approved establishment

An establishment that has been approved pursuant to Article 4 of Regulation (EC) No 853/2004 for handling, preparing and/or producing products of animal origin.

### **Audit**

Audit has the meaning as defined by Article 3(30) of Regulation (EU) 2017/625 to mean a systematic and independent examination to determine whether activities and related results of such activities comply with planned arrangements and whether these arrangements are applied effectively, by the FBO, and are suitable to achieve objectives. This includes planned partial or full audits:

- a 'full audit', is an examination of planned arrangements and whether they are implemented effectively and will consider all aspects of a FBO's operations
- a 'partial audit', is an audit that covers only certain aspects of a FBO's operation

#### Authorised officer

Means a person (whether or not an officer of the enforcement authority) who is authorised by the Food Authority, either generally or specifically, to act in relation to matters arising under the Hygiene Regulation.

### Awarding bodies

In relation to the Code, the awarding bodies are: The Chartered Institute of Environmental Health (CIEH); Chartered Trading Standards Institute (CTSI) and; The Institute of Food Science and Technology (IFST).

### **Border Control Post (BCP)**

Has the meaning defined in Article 3(38) of Regulation (EU) 2017/625 to mean a place, and the facilities belonging to it, designated for the performance of official controls on animals and goods listed in Article 47(1), on import into the UK.

### **Consultant in Communicable Disease Control (CCDC)**

A senior role within the health protection them to provide leadership, management and oversight of the health protection function, including the response to incidents and outbreaks.

# **Critical Control Point (CCP)**

Any step in a process in which hazards can be prevented, eliminated or reduced to acceptable levels. Example of critical control points include cooking, cooling, e-heating and holding.

### Centre for Environment, Fisheries and Aquaculture Science (Cefas)

Cefas is an executive agency of DEFRA that collects and manages and interprets data on aquatic environment, biodiversity and fisheries.

# **Central Food Authority**

Has the meaning as defined in part, by Article 3(3)(a) of Regulation (EU) 2017/625 to mean the appropriate authority competent for the organisation of official controls and other official activities and in the UK, is the FSA.

### **Chartered Institute of Environmental Health (CIEH)**

A membership and awarding body for the environmental health sector.

### **Chartered Trading Standards Institute (CTSI)**

CTSI represents trading standards professionals working in the UK and overseas - in local authorities, business and consumer sectors and central government. CTSI exists to:

- promote and protect the success of a modern vibrant economy
- safeguard the health, safety and wellbeing of citizens by enhancing the professionalism of its members

# **Confidence in Management (CIM)**

The confidence in management score is part 3 of the Hygiene/Standard Rating Intervention Rating Scheme. The Food Authority assesses the business's food safety management/control procedures using their judgement on the likelihood of satisfactory compliance being maintained in the future. Factors that influence the CA's judgement include: the previous record of compliance with the FBO; knowledge on food safety; attitude towards hygiene compliance and satisfactory food safety management procedures.

# Cleaning in Place (CIP)

A method of cleaning, applied to remove residues from complete items of plant equipment without dismantling or opening the equipment.

# **Common Health Entry Document (CHED)**

The Common Health Entry Document is used for food and feed of non-animal origin subject at their entry into the UK to any of the measures or conditions provided for in points (d), (e), or (f) of Article 47(1) of Regulation (EU) 2017/625.

# **Compliance notice**

A notice served by an authorised officer where they have reasonable grounds for believing that any person has not complied with, is not complying with, or is not likely to comply with any provision specified in the first column of Table 2 of Schedule 1, 2, 3 or 4 or regulation 13(2) of the Food Additives, Flavourings, Enzymes and Extraction Solvents (Wales) Regulations 2013.

### Compliant

Conforming with the requirements of the law.

### **Conditional approval**

Approval granted by a Food Authority pursuant to Article 148(4) of Regulation (EU) No 2017/625 if it appears to a Food Authority that an establishment meets all the infrastructure and equipment requirements. Conditional approval must not exceed a total of six months, with the exception of factory and freezer vessels, conditional approval must not exceed 12 months.

#### Consignment

Has the meaning as defined in Article 3(37) of Regulation (EU) 2017/625 to mean a number of animals or quantity of goods covered by the same official certificate, official attestation or any other document, conveyed by the same means of transport and coming from the same territory or non-UK country, and, except for goods subject to the rules referred to in point (g) of Article 1(2) of Regulation (EU) 2017/625, being of the same type, class or description.

# **Control verification procedures**

More commonly referred to as internal monitoring procedures, has the meaning as defined in Article 2(6) of Regulation (EU) 2017/625 to mean the arrangements put in place and actions performed by the Food Authorities for the purpose of ensuring that official controls and other official activities are consistent and effective.

#### Could

Is generally used to indicate those provisions which are for guidance only.

# **Continuing Professional Development (CPD)**

How members of a profession maintain, improve or broaden their knowledge and skills and develop the qualities required in their professional lives.

# Department for Environment, Food and Rural Affairs (Defra)

The Department of Food and Rural Affairs (Defra) is the UK government department responsible for the environment, food and farming industry.

#### **Detention Notice**

A notice served on a FBO or duly authorised representative where detention of any animal or food for the purpose of examination (including the taking of samples) is required as specified in in Regulation 9 of The Food Hygiene (Wales) Regulations 2006.

#### **Distance Communication**

Any means of communication which, without the simultaneous physical presence of the supplier and the consumer, may be used for the conclusion of a contract between those parties.

# **Documentary check**

Has the meaning as defined by Article 3(41) of Regulation (EU) 2017/625 to mean the examination of commercial documents and, where appropriate, official certificates, official attestations and other documents required under feed or food law to accompany the consignment.

### **Domestic premises**

A dwelling house or other building used principally, but not exclusively as a dwelling and its curtilage.

### **Earned Recognition**

FBOs who demonstrably maintain high standards of food safety by taking appropriate steps to comply with the law, may have these standards recognised by the Food Authority when determining the frequency of their official controls and therefore earn recognition.

# Escherichia coli O157 (E.coli O157)

A VTEC strain that can cause illness in humans. Symptoms can range from mild gastroenteritis, diarrhoea, and kidney damage.

# **European Economic Area (EEA)**

Consists of the EU member states and the three countries of the European Free Trade Association (EFTA). An agreement concerning the four fundamental pillars of the internal market, namely the free movement of goods, people, services and capital.

### **Environmental Health Officer (EHO)**

Authorised officers responsible for carrying out measures for protecting public health, including administrating and enforcing legislation related to environmental health.

# **Environmental Health Registration Board (EHRB)**

An awarding body in the UK which issues certificates of registration to those who have successfully completed an approved course of study in the subject of environmental health that includes and accredited course, work based learning and professional examinations.

# **Emergency Prohibition Order (EPO)**

Has the meaning as defined by Regulation 12(1) of the Food Safety Act 1990 to mean if an authorised officer is satisfied the health risk is fulfilled, he may, by notice, serve on the proprietor of the business impose the appropriate prohibition.

### **Enforcement Authority**

Has the meaning as defined by Regulation 2(1) of The Food Hygiene (Wales) Regulations.

### **Establishment**

Has meaning as defined in Article 2(c) of Regulation (EC) No 852/2004 to mean any unit of a food business

#### **Evidence**

Is the requirement of proof that is presented to convince the alleged facts of a case.

### Early Warning System (EWS)

An emerging risk detection tool to predict hazards for specific food and feed

### **Export**

The action of sending or transporting a commodity outside the UK.

### Feasibility study

A small-scale preliminary study, conducted as part of an FSA led Programme, in order to identify feasibility, time, cost, adverse events, predict an appropriate sample size, and help to develop the study design prior to larger scale "Pathfinder" activity/project.

# Food Hygiene Rating Scheme (FHRS)

A scheme that applies to Wales, England and Northern Ireland designed to give information to the public on what each food business had achieved on their last food hygiene inspection carried out by the its local authority, rated from 0 (urgent improvement needed) – 5 (Hygiene standards are very good).

# Food Authority

Has the same meaning as defined in Article 3(3) of Regulation (EU) 2017/625 to mean the Competent Authority responsible for the performance of official controls and of other official activities, in accordance with that Regulation and the rules referred to in Article 1(2).

#### **Food business**

Has the meaning as defined by Article 3(2) of Regulation (EC) No 178/2002 to mean any undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to any stage of production, processing and distribution of food.

# Food business operator (FBO)

Has the meaning as defined by Article 3(3) of Regulation (EC) No 178/2002 means the natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control.

#### **Food Examiner**

Any person who possesses the requisite qualifications to carry out examinations.

### **Food Hygiene**

The measures and conditions necessary to control hazards and to ensure fitness for human consumption of a foodstuff, taking into account its intended use as set out in Regulation (EC) No 852/2004.

# **Food Hygiene Intervention**

An intervention that ensures food meets the requirements of food hygiene law, including:

- microbiological quality
- absence of pathogenic micro-organisms
- safety for consumption

#### **Food Standards Intervention**

An intervention that ensures food meets the requirements of food standards law, including:

- proper presentation labelling and advertising so as not to confuse or mislead compliance with compositional standards
- the absence of non-permitted or excessive levels of additives, contaminants and residues

# **Food incident**

Any event where, based on the information available, there are concerns about actual or suspected threats to the safety, quality or integrity of food that could require intervention to protect consumers' interests.

#### Food alert

Communication from the FSA to a Food Authority concerning a food hazard or other food incident, where specific actions/responses are required to be undertaken by the Food Authority. A 'Food Alert Update' should be read accordingly.

#### Food hazard

A biological, chemical or physical agent in food capable of causing adverse effect to public health.

### Formal action

The taking of action against a FBO 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.

#### **Framework**

Framework Agreement on Local Authority Food Law Enforcement.

### Food Standards Agency (FSA)

The Central Food Authority in England, Wales and Northern Ireland.

#### Food Standards Scotland (FSS)

The Central Food Authority in Scotland.

### Food for Specific Groups (FSG)

The Food for Specific Groups (Information and Compositional Requirements) (Wales) Regulations 2016 establishes compositional and information requirements for the

following categories of food: infant formula and follow-on formula; processed cereal-based food and baby food; food for special medical purposes; total die replacement for weight control.

### **Full approval**

Full approval only given to an establishment if it appears from a new official control of the establishment, carried out within three months of granting conditional approval, that the establishment meets the other relevant requirements of feed or food law.

#### Hazard

A biological, chemical or physical agent in, or condition of, food or feed with the potential to cause an adverse health effect as specified in Regulation (EC) No 178/2002, Article 3(14).

# **Hazard Analysis Critical Control Points (HACCP)**

Hazard Analysis and Critical Control Point, HACCP is a systematic preventive approach to food and feed safety from biological, chemical, and physical hazards in production processes, that can cause the finished product to be unsafe, and designs measurement to reduce these risks to a safe level.

### **Home Authority**

Means 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 (HEPN)**

A notice served by the authorised officer where there is an imminent risk of injury to health which prohibits the use of a process, treatment, premises or equipment, as appropriate, as specified in Regulation 8 of the Food Hygiene (Wales) Regulations 2006.

### **Hygiene Improvement Notice (HIN)**

A notice served by the authorised officer on a FBO where they have failed to comply with specified food law as specified in Regulation 6 of the Food Hygiene (Wales) Regulations 2006.

### **Hygiene Prohibition Order (HPO)**

An order granted by the magistrate's court following the conviction of a FBO for an offence under specified feed law as specified in Regulation 7 of the Food Hygiene (Wales) Regulations 2006.

# **Identity check**

Has the meaning as defined by Article 3(42) of Regulation (EU) 2017/625 to mean a visual inspection to verify that the content and the labelling of a consignment, including the marks on animals, seals and means of transport, correspond to the information provided in the official certificates, official attestations and other documents accompanying it.

# Institute of Food Science and Technology (IFST)

A professional body concerned with all aspects of food science and technology.

### **Import**

The action of bringing in goods and/or services from another country outside of the UK.

# **Improvement Notice**

A notice served on a FBO by an authorised officer who has reasonable grounds for believing that the proprietor of a food business is failing to comply with any regulatory requirement, as specified in in Section 10 of the Food Safety Act 1990.

#### Inspection

To mean 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. This includes partial or full inspections:

- a 'full inspection', is a check on compliance with legal requirements and will consider all aspects of an FBOs operations
- a 'partial inspection', which is an inspection that covers only certain aspects of an FBOs operations

#### Intervention

Regulatory actions taken by a government in order to affect or interfere with decisions made by individuals, groups, or organizations regarding social and economic matters. Interventions include official controls and other interventions such as education, advice and coaching, information and intelligence gathering (including sampling where the analysis is not to be carried out by an Official Control Laboratory).

### Investigation

The action taken by the Food Authority to gather evidence where it believes an offence has been committed.

### Lead food officer (LFO)

The Authorised Lead Food Officer(s), appointed by the Food Authority in relation to food, who demonstrates the requirements, set out in the Competency Framework set out in Chapter 3 of the Practice Guidance.

#### Live bivalve molluscs

References to live bivalve molluscs also include live echinoderms, live tunicates and live marine gastropods, in line with Annex I, Section 2 of Regulation (EC) No 853/2004 laying down specific hygiene rules for food of animal origin), except for parts of the Code which deal with purification of live bivalve molluscs.

# **Local Authority Enforcement Monitoring System (LAEMS)**

A web-based system to allow LA to upload data generated from their local system(s) on which they record data on food law enforcement activities.

# **Local Action Group (LAG)**

A non-profit group, made up of representatives of the local community that deliver support to their respective rural areas especially the implementation of small-scale projects.

# Local Authority (LA)

Has the meaning as defined in Section 270 of the Local Government Act 1972 to mean a country council, a county borough council, or community council.

# Less than thoroughly cooked (LTTC)

Burgers not thoroughly cooked, they contain pink meat in the middle.

# Malicious tampering

For the purposes of the Code and Practice Guidance, means the deliberate contamination of food by terrorist activity, or with a view to blackmail or extortion.

# Maritime and Coastguard Agency (MCA)

The MCA is an executive agency of the Department of Transport working to prevent the loss of life on the coast and at sea. They also produce legislation and guidance on maritime matters and provide certification to seafarers.

#### May

On its own indicates an optional exercise of a power or function.

#### May not

Indicates a prohibition.

### Minced Meat (MM)

Meat that has been grounded or minced.

# 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 – motor vehicles which are constructed solely for the purpose of carrying no more than 8 passengers (including the driver) and their personal effects, tents, or moveable premises which are ordinarily kept outside Great Britain.

### Monitoring

To mean conducting a planned sequence of observations or measurements with a view to obtaining an overview of the state of compliance with food law.

### **Memorandum of Understanding (MoU)**

A written agreement on the exchange of information between two or more parties.

#### MP

Meat preparation.

#### Must

Is used to confirm an obligation.

### **National Enforcement Priorities (NEPs)**

The NEPs for animal feed and food hygiene at the level of earned assist Food Authorities and businesses in maintaining standards and safeguarding public health in England.

### **National Food Crime Unit (NFCU)**

The National Food Crime Unit provides a nationwide focus on enforcement against serious fraud and related criminality in food and feed supply chains.

### National Health Service (NHS)

A government funded medical and health care service in the UK.

### Non-compliance

A failure to comply with the one or more requirements of a food law.

#### Official attestation

Has the meaning as defined by Article 3(28) of Regulation (EU) 2017/625 to mean any label, mark or other form of attestation issued by the operators under the supervision, through dedicated official food controls, of the Food Authorities or by the Food Authorities themselves, and providing assurance concerning compliance with one or more requirements laid down in this Regulation or in the rules referred to in Article 1(2) Regulation (EU) 2017/625.

#### Official certificate

Has the meaning as defined by Article 3(27) of Regulation (EU) 2017/625 to mean a paper or electronic document signed by the certifying officer and providing assurance concerning compliance with one or more requirements laid down in the rules referred to in Article 1(2) of Regulation (EU) 2017/625.

#### Official controls

As defined by Article 2(1) of Regulation (EU) 2017/625 to mean activities performed by the Food Authorities, or by the delegated bodies or the natural persons to which certain official control tasks have been delegated in accordance with Regulation (EU) 2017/625 in order to verify compliance by the operators and that animals or goods meet the requirements laid down in the rules referred to in Article 1(2) of (EU) 2017/625, including for the issuance of an official certificate or official attestation.

# 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).

### Other official activities

As defined by Article 2(2) of Regulation (EU) 2017/625 to mean activities, other than official food controls, which are performed by the Food Authorities, or by the delegated bodies or the natural persons to which certain other official activities have been delegated in accordance with Regulation (EU) 2017/625. Including activities aimed at verifying the presence of animal diseases or pests of plants, preventing or containing the spread of such animal diseases or pests of plants, eradicating those animal diseases or pests of plants, granting authorisations or approvals, and issuing official certificates or official attestations.

### **Outbreak**

Usually/particularly a foodborne disease and or infectious intestinal disease.

### Official Veterinarian

Has the meaning as defined in Article 3(32) of Regulation (EU) 2017/625 to mean a Veterinarian appointed by a Competent Authority, either as staff or otherwise, and appropriately qualified to perform official food controls and other official activities in accordance with this Regulation and the relevant rules referred to in Article 1(2) of Regulation (EU) 2017/625.

### **Penalty**

The punishment imposed by a court on conviction for an offence under food legislation.

# Physical check

Has the meaning as defined in Article 3(43) of Regulation (EU) 2017/625 to mean check on animals or goods and, as appropriate, checks on packaging, the means of transport, labelling and temperature, the sampling for analysis, testing or diagnosis and any other check necessary to verify compliance with the rules referred to in Article 1(2) of (EU) 2017/625.

### **Port Health Authority**

Has the meaning as defined in Section 2 Public Health (Control of Diseases) Act 1984 to mean in relation to a port or part of a port any local authority whose district, or any part of whose district, forms part of, or abuts on, that port or part of a port, and any conservators, commissioners or other persons having authority in, over or within that port or part of a port.

# **Primary Authority**

Has the meaning set out in Section 25 Regulatory Enforcement and Sanctions Act 2008 to mean in relation to a regulated person, a qualifying regulator for the exercise of the partnership functions in relation to that person as nominated by the Secretary of State, or in relation to a regulated group, a qualifying regulator for the exercise of the partnership functions in relation to the members of the group as nominated by the Secretary of State.

# **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 (PO)**

An order served by the Court imposing appropriate prohibitions to a food business when convicted of an offence under any regulations to which the Food Safety Act 1990 apply, and where the Court is satisfied the health risk condition is fulfilled by that business.

### **Prohibited Person**

A FBO that has been convicted of an offence under the Food Hygiene (Wales) Regulations 2006 and has been issued a prohibition order.

### **Public Analyst**

Scientists that ensure the safety and correct description of food by testing for compliance with legislation as specified in in Section 27 Food Safety Act 1990 and Regulation 4 Food Safety (Sampling and Qualifications) (Wales) Regulations 2013.

### **Public Health Wales (PHW)**

National Public Health agency, which reports to the Cabinet Secretary for Health, Wellbeing and Sport in Welsh Parliament. Its role is to protect and improve health and well-being and reduce health inequalities in Wales.

# Royal Air Force (RAF)

The UK aerial warfare force.

# Raw cows' drinking milk (RCDM)

Cow's milk that has not been heat treated above 40°c (it is raw milk) and is intended for direct human consumption.

# Readily available

Any documents that are required to be readily available means that both consumers and businesses can quickly and easily obtain them, either in electronic or hardcopy format.

#### Records

Means information preserved in writing or the like.

### **Remedial Action Notice (RAN)**

A notice served by an authorised officer to a FBO by an authorised officer where any of the requirements of the 'Hygiene Regulations', as defined by Regulation 2 of the Food Hygiene (Wales) Regulations 2006, are being breached or an inspection under the Hygiene Regulations is being hampered.

# Registering authority

The Food Authority in whose area the FBO is located. In relation to a mobile establishment, the registering authority will be where it is ordinarily kept.

#### Risk

The chance or probability that a person will be harmed or experience an adverse health effect if exposed to a hazard.

### **Rural Payments Wales (RPW)**

Rural Payments Wales is the division within Welsh Parliament, which is responsible for administering all aspects of the Common Agricultural Policy schemes in Wales.

### 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.

# Sampling

To mean 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.

### Safe Catering

Safe Catering is a food safety management guide for Northern Ireland. It helps catering businesses and retailers with a catering function to comply with food hygiene regulations.

# Safer food better business (SFBB)

Food safety management procedures and food hygiene regulations for small businesses.

# Scottish Food Safety Officers Registration Board (SFSORB)

A committee of the Royal Environmental Health Institute of Scotland, who determine the pre-registration academic standard to be attained by persons applying for the award of the Higher Certificate in Food Premises Inspection, the Ordinary Certificate in Food Premises Inspection and the Higher Certificate in Food Standards Inspection qualifications.

# Shellfish environmental monitoring

The collection of shellfish and water official control samples from designated sampling points as part of the Shellfish Official Control Monitoring Programmes, in accordance with Article 57 and Chapter II of Title V of Commission Implementing Regulation (EU) 2019/627.

#### Should

Is used to confirm best practice.

### Signed

Means having a signature affixed either in writing or by electronic means.

### Simple caution

A simple caution (once known as a formal or police caution) is a formal warning that may be given by the police to persons aged 18 or over who admit to committing an offence ('offenders'). The simple caution scheme is designed to provide a means of dealing with low-level, mainly first-time, offending without a prosecution. A simple caution may only be given where specified criteria are met. Further detail is set out in Ministry of Justice guidance note: 'Simple Cautions for Adult Offenders'.

#### **Standards**

Rules or principles defined in food safety law that are used as the basis for judgment against.

#### Surveillance

To mean a careful observation of one or more feed businesses, or FBOs or their activities.

# **Tuberculosis (TB)**

An infectious disease usually caused by the Mycobacterium tuberculosis bacteria that mainly affects the lungs.

### **Non-UK Country**

A country outside the United Kingdom.

### United Kingdom Accreditation Service (UKAS)

United Kingdom Accreditation Service. UK's National Accreditation Body, responsible for determining, in the public interest, the technical competence and integrity of organisations.

# **United Kingdom Food Surveillance System (UKFSS)**

The National Database for Food sampling data in Local Authorities, Port Health Authorities & Public Analyst Laboratories.

#### Validation

Means confirmation that requirements have been complied with.

#### Verification

To mean the checking, by examination and the consideration of objective evidence, whether specified requirements have been fulfilled.

### Welsh Local Government Association (WLGA)

The WLGA are the national voice of local government, working with Food Authorities to support, promote and improve local government services.

### Writing

Has the meaning as defined by Schedule 1 of the Interpretation Act 1978 to mean typing, printing, lithography, photography and other modes of representing or reproducing words in a visible form, and expressions referring to writing are construed accordingly.