

**DRAFT (OCTOBER 2005)**

# **Food Law**

**Practice Guidance (England)**

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Please sign and date to confirm replacement of relevant pages with amendments issued by the Food Standards Agency.

# **PREFACE**

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

Food Authorities should, however, be aware that law that applies to food is not necessarily made under the Food Safety Act. Law that applies to food is also made under the Animal Health Act 1981, the European Communities Act 1972, the Consumer Protection Act 1987, the Trade Descriptions Act 1968. Moreover, account must be taken of directly applicable EC Regulations.

Food Authority officers authorised under Section 5(6) of the Food Safety Act 1990 to carry out duties under that Act and Regulations made under it are not simultaneously authorised to deal with food law under other legislation. Separate and specific authorisation under that other legislation is also required, for example, as interpreted in the Food Hygiene (England) Regulations 2005<sup>1</sup> and the Official Feed and Food Controls (England) Regulations 2005<sup>2</sup>.

This guidance updates all previous guidance issued with the Code of Practice, which had previously been made solely under the Food Safety Act 1990.

Material in the previous guidance has been reviewed and updated to take account of the Food Hygiene (England) Regulations 2005, the Official Feed and Food Controls (England) Regulations 2005 and relevant EU Regulations.

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

Attention is drawn to the guidance on the scope and conduct of official checks on establishments subject to approval under Regulation 853/2004<sup>3</sup>.

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

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

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

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

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<sup>1</sup> SI 2005 No. 2059

<sup>2</sup> SI 2005 No. 2626

<sup>3</sup> Regulation (EC) No. 853/2004 laying down specific hygiene rules for food of animal origin

# **SECTION 1: ADMINISTRATION**

## **CHAPTER 1.1: INTER-AUTHORITY MATTERS**

### **1.1.1: Introduction**

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

### **1.1.2: Service to Consumers**

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

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

## **CHAPTER 1.2: QUALIFICATIONS AND EXPERIENCE**

### **1.2.1: Introduction**

This Chapter deals with the qualifications and experience of authorised officers of Food Authorities.

### **1.2.2: Pooling Expertise**

Food Authorities should consider identifying a pool of authorised officers within their local or regional liaison group, whose experience and qualifications encompass the range of product-specific establishments subject to approval under Regulation 853/2004 and food business establishments which undertake specialist or complex high-risk activities.

Food Authorities that lack officers with suitable qualifications and experience to inspect such activities may then seek assistance from such officers.

## **CHAPTER 1.3: CONFLICTS OF INTEREST**

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



## **CHAPTER 1.4: FOOD BUSINESS ESTABLISHMENT RECORDS**

### **1.4.1: Introduction**

This Chapter contains information about the Data Protection Act 1998 and the Freedom of Information Act 2000 as they relate to food business records.

### **1.4.2: Data Protection / Freedom of Information**

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

Food Authorities must uphold the principles of the Data Protection Act 1998 and the Freedom of Information Act 2000 (both of which implement the relevant EC Directives) in relation to any data and information they hold.

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

## **CHAPTER 1.5: REGISTRATION OF FOOD BUSINESS ESTABLISHMENTS**

All relevant information on the registration of food business establishments is contained in the Code of Practice.

## **CHAPTER 1.6: CROWN AND POLICE PREMISES**

### **1.6.1: Introduction**

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

### **1.6.2: Scope of Application of Food Law (Food Hygiene (England) Regulations 2005)**

The scope of the Food Hygiene (England) Regulations 2005 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 inspections in the same way as they do in any other food business.

As there are no specific exemptions for certain members of the Royal Family or certain Royal residences as afforded by the Food Safety Act 1990 (see Paragraph 1.6.3 below), Food Authorities should use discretion when exercising their powers in respect of Crown premises. In practice, Food Authorities should adopt the same approach to the enforcement of the Food Hygiene (England) Regulations 2005 in respect of Crown premises as they do in respect of the Food Safety Act 1990.

### **1.6.3: Scope of Application of Food Law (Food Safety Act 1990)**

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

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

### **1.6.4: Conduct and Frequency of Inspections**

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 inspection programme in accordance with the Code of Practice.

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

Mobile field kitchens should not normally be subject to inspection by the Food Authority.

#### **1.6.5: Enforcement (Food Hygiene (England) Regulations 2005)**

Unlike the Food Safety Act 1990, the Food Hygiene (England) Regulations 2005 do not exempt the Crown if it contravenes the Regulations. This means that the Crown can be prosecuted if it contravenes the Act etc. However, as mentioned in Paragraph 1.6.3 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 (England) Regulations 2005 in respect of Crown premises as they do in respect of the Food Safety Act 1990.

#### **1.6.6: Enforcement (Food Safety Act 1990)**

##### **1.6.6.1: Liability**

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

A 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 may be the responsibility of the Crown itself.

Any application 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.

### **1.6.6.2: 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 may still be prosecuted in the same way as any other person. Failure to comply with the provisions of food law could 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.

### **1.6.6.3: Statutory Notices**

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

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

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

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 may impose an emergency prohibition order, it may not impose a prohibition order, since a prohibition order can only be made when there has been a conviction under relevant food law.

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

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

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

## **CHAPTER 1.7: FOOD INCIDENTS AND HAZARDS**

### **1.7.1: Introduction**

This Chapter deals with food incidents and hazards that are identified by Food Authorities.

### **1.7.2: Information Received Locally Which 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;
- As a result of complaints from members of the public, either directly or through a third party, for example, the police, citizens' advice bureaux, etc;
- Through notifications from a manufacturing company, trade association, wholesaler, retailer, importer or caterer;
- Information from enforcement agencies in other countries;
- As a result of a notification from a GP of one or more cases of communicable diseases, including foodborne illness, or from the consultant in communicable disease control (CCDC), or the Health Protection Agency (HPA) Communicable Disease Surveillance Centre (CDSC).

The illustrations above are not intended to be comprehensive.

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

### **1.7.3: Guidance on Food Complaints**

#### **1.7.3.1: Notification of Food Complaints**

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

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

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

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

#### **1.7.3.2: 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 Home Authority Principle.

#### **1.7.3.3: 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 should be analysed, it should be sent to the Public Analyst. If it should be microbiologically examined, it should be sent to a Food Examiner. If any other investigation is necessary, the food should be sent to a suitably qualified expert who is able to give evidence in the event of a prosecution.

The subject of a complaint or other interested party may 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 that it does not compromise the proper storage, analysis, examination or evidential value of the sample.

## **SECTION 2: COMMUNICATION**

### **CHAPTER 2.1: FOOD ALERTS**

All relevant information on food alerts is contained in the Code of Practice.



## **CHAPTER 2.2: AGENCY COMMUNICATIONS AND GUIDANCE**

All relevant information on Agency communications and guidance is contained in the Code of Practice.

## **CHAPTER 2.3: INFORMATION TO BE SUPPLIED TO THE AGENCY**

All relevant material on information to be supplied to the Agency is contained in the Code of Practice.

## **CHAPTER 2.4: LIAISON WITH OTHER MEMBER STATES**

### **2.4.1: Introduction**

This Chapter deals with the administration of and the approach to the European liaison arrangements that are operated by the Agency. Detailed provisions on administrative assistance and co-operation with other Member States are set out in Articles 34 to 38 of Regulation 882/2004.

### **2.4.2: The Role of the Agency**

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

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

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

The Agency will deal directly with matters falling under categories A and B (see Chapter 2.4 of the Code of Practice).

### **2.4.3: The Role of Food Authorities**

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

- “Home Authority” means the food law enforcement authority in the Member State which has geographical responsibility for the area in which the responsible decision-making base of the food enterprise is located (e.g. this may be the factory, the head office or address on the product label);
- “Enforcing Authority” means the food law enforcement authority in a Member State which is investigating infringements or queries relating to food products received from other Member States;
- “Originating Authority” means the food law enforcement authority in a Member State in whose area a decentralised enterprise produces or packages goods or services. The Originating Authority has special responsibility for ensuring that goods and services produced within its area

conform to legal requirements. The functions of the Home Authority and Originating Authority may be combined in some areas.

#### **2.4.4: Enquiries from Member States**

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

#### **2.4.5: Documentation**

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

#### **2.4.6: Disclosure of Information**

Article 7 of Regulation 882/2004 sets out the general requirements in respect of transparency and confidentiality. Detailed provisions on administrative assistance and co-operation with other Member States are set out in Articles 34 to 38 of Regulation 882/2004. Article 34 stipulates that Articles 35 – 40 of that Regulation, which deal with administrative assistance and co-operation between Member States “shall not prejudice national rules applicable to the release of documents which are the object of, or are related to, court proceedings, or rules aimed at the protection of natural or legal persons’ commercial interests”.

Food Authorities should therefore ensure that any release of information is compatible with national legislation including that relating to Data Protection and Freedom of Information (see also Chapter 1.4).

#### **2.4.7: Use of Information in Criminal Proceedings**

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

EU Member States are parties to The European Convention on Mutual Assistance in Criminal Matters<sup>4</sup>. 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 Judicial Co-operation Unit of the Home Office. The Central Authority liaises with the judicial authorities in Scotland.

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<sup>4</sup> Council Act of 29 May 2000 establishing, in accordance with Article 34 of the Treaty on European Union, the Convention on Mutual Assistance in Criminal Matters between the Member States of the European Union [Official Journal C197, 12 .07.2000.

All requests via the Central Authority must be notified to the Agency so that they can fulfil their role as the UK single liaison body.

The UK Central Authority address is:

Home Office  
UK Central Authority  
5<sup>th</sup> Floor, Fry Building,  
Marsham Street,  
London  
SW1P 4DF.

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

Food Authorities are not “designated prosecuting authorities” for the purposes of the 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 Home Authority (or equivalent) in the Member State concerned to use the information in the proceedings.

#### **2.4.8: Non-compliance with Legislation**

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

## 2.4.9: Form – Notification of Incident to the Food Standards Agency



### Notification of Incident to the Food Standards Agency Exchange of Information: Routine Food Matters

**Please complete all parts of this form in capital letters or type**

**Directed to  
(Member State)**

**Info Only\***

☐

**EA Ref:**

**Action Requested\***

☐

**Agency  
Ref:**

\* (please tick as appropriate)

**Name and Address of Enforcing Authority:**

**Contact Officer:**

**Tel:**

**E-mail:**

**Fax:**

**Full product description (to include product name or brand name, identification codes):**

**Nature of complaint/request:**

**Date of Notification:**

**Photo: Yes** ☐ **No** ☐

**Name and Address of Manufacturer, Packer, Retailer, Wholesaler (where appropriate):**

**Details of Investigation by EA:** Please include details of who has been contacted i.e. importer; any appropriate UK Home Authority and include details of measures or actions taken and outcome of enquiry.

**Action to be requested of the Agency:** Please specify comprehensively the nature of the information requested.

**Is the information intended to be used for prosecution?**

**Yes:** ☐      **No:** ☐      **Maybe:** ☐      (Please tick as appropriate)

**If “maybe” please be aware of time delays due to the need to reconfirm information for prosecution purposes. In relation to offences under UK Food legislation please detail any time bars.**

**Signed..... Date sent: .....**

**Please return this form when completed to Hygiene Technical Support Branch,  
Room 415C, Aviation House, 125 Kingsway, London WC2B 6NH.**

## **SECTION 3: GENERAL ENFORCEMENT**

### **CHAPTER 3.1: APPROACH TO ENFORCEMENT**

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

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

<http://police.homeoffice.gov.uk/operational-policing/powers-pace-codes/pace-codes.html>



## **CHAPTER 3.2: HYGIENE IMPROVEMENT NOTICES / IMPROVEMENT NOTICES**

### **3.2.1: Introduction**

This Chapter deals with the use of hygiene improvement notices under Regulation 6 of the Food Hygiene (England) Regulations 2005, and the use of improvement notices under Section 10 of the Food Safety Act 1990 in connection with food standards issues.

### **3.2.2: The Enforcement Approach**

The primary objective of enforcement action should always be to achieve compliance in the most effective way possible.

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.

Conversely, the service of a hygiene improvement notice or improvement notice does not preclude parallel action such as prosecution for matters that are subject of the notice. Such a course of action may be particularly appropriate where conditions are serious or deteriorating.

### **3.2.3: Service of Notices**

The Food Hygiene (England) Regulations 2005 require a hygiene improvement notice to be served on a food business operator. The Food Safety Act 1990 requires an improvement notice to be served on the proprietor of a food business.

Hygiene improvement notices or improvement notices should normally be served either by delivery to the food business operator / food business proprietor in person, or at their usual or last known residence by a postal or courier service that includes proof of posting or despatch and, ideally, proof of delivery.

It is not always possible to identify the food business proprietor, and Section 50(2) of the Act therefore allows an improvement notice to be addressed to the “owner” or “occupier” and left at the premises if the proprietor cannot be identified. Similarly, Regulation 28(2) of the Food Hygiene (England) Regulations 2005 allows a hygiene improvement notice to be addressed to the “food business operator” and left at the premises.

The officer serving a hygiene improvement notice or improvement 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 food business operator / food business proprietor.

### **3.2.4: Drafting of Notices**

It should be clear from the hygiene improvement notice or improvement notice exactly what the recipient is required to do, and why; it should therefore be clearly drafted and easily understood.

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

The alternative of serving 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.

The officer should normally discuss the detail of any structural work to be carried out with the food business operator / food business proprietor, or with a person acting on the operator's / proprietor's behalf who is in a position to authorise the work, before a notice is issued. However, the issue of a notice should not be unduly delayed if agreement cannot be reached or a responsible person cannot be contacted.

### **3.2.5: Time Limits**

A hygiene improvement notice or improvement notice should clearly state the time limit by which the measures required by the notice must be completed. Both the Food Hygiene (England) Regulations 2005 and the Food Safety Act 1990 specify a minimum period of 14 days.

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

The time limit should normally be discussed and agreed with the food business operator / food business proprietor or with a person acting on the operator's / proprietor's behalf who is in a position to agree a time limit, before a notice is issued. The officer may, however, set a time limit without such agreement if agreement cannot be reached or a responsible person cannot be contacted.

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

- The risk to public health;
- The nature of the problem;
- The availability of solutions.

### **3.2.6: Extension of Time Limits**

Although hygiene improvement notices and improvement notices should be complied with in the shortest practicable time, due regard should be given to any genuine difficulties that may occur.

There is no specific provision in the regulations to extend the time limit for compliance with a notice, but it may be unreasonable not to allow an extension if the proprietor has a genuine reason for needing more time.

The food business operator / food business proprietor should be advised when the notice is served that any request for an extension of time should be made in writing before the notice expires.

If the officer considers that the request is reasonable, they should make a note of the reasons for their decision on the relevant establishment file. The existing notice should then be withdrawn and a new notice issued reflecting the new time limit by which compliance must be achieved. The operator / proprietor should be advised of the decision in writing and any new time limit confirmed.

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

- The risk to public health associated with the fault if an extension was granted;
- The reason for the request;
- The remedy involved;
- The past record of co-operation of the food business operator / proprietor;
- Any temporary action which the operator / proprietor proposes to take to remedy the defect.

### **3.2.7: Works of Equivalent Effect**

Notices should make it clear that Regulation 6 of the Food Hygiene (England) Regulations 2005 and Section 10 of the Food Safety Act 1990, as appropriate, allow a food business operator / food business proprietor to carry out measures of at least equivalent effect to those specified in a hygiene improvement notice / improvement notice and recommend that alternative measures are discussed with the officer who served the notice before starting work to avoid unnecessary expenditure or inappropriate work.

The Food Authority should respond in writing to any request from an operator / proprietor to vary the work, and any agreed alternative measures should be confirmed in writing.

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

Food Authorities should ensure that they have procedures to consider such matters, so that it is clear to the operator / proprietor that there is a proper review.

### **3.2.8: Compliance**

The officer who served the hygiene improvement notice or improvement notice should liaise with the food business and monitor the work being undertaken and encourage the food business operator / food business proprietor to notify the officer when the work has been completed. Another authorised officer should monitor the work if the officer who served the notice is unable to do so.

The work should be checked as soon as practicable after notification has been received that it has been completed and the officer should confirm in writing that the works have been satisfactorily completed.

### **3.2.9: Appeals**

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

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

The food business operator / food business proprietor should also be asked to notify the officer if an appeal is lodged.

### **3.2.10: Other Discussion with the Food Authority**

Although a food business operator / food business proprietor has a right of appeal against a hygiene improvement notice or improvement notice, the Food Authority should be prepared to discuss a notice and its requirements informally with the proprietor if they wish to do so.

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

If an operator / proprietor 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 the views of the "home authority" as defined in the LACORS Home Authority Principle.

Food Authorities should have internal arrangements to consider such requests for further discussion and consider how they make these arrangements known to operators / proprietors.

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

### **3.2.11: Other Guidance**

[Further guidance on the use and preparation of hygiene improvement notices and improvement notices has been issued by LACORS].

## **CHAPTER 3.3: PROHIBITION PROCEDURES**

### **3.3.1: Introduction**

This Chapter deals first with the use of hygiene prohibition procedures and remedial action notice / detention notice procedures under Regulations 7, 8 and 9 respectively of the Food Hygiene (England) Regulations 2005 and the associated voluntary closure procedures. It then deals with the prohibition procedures of Section 11 and Section 12 of the Food Safety Act 1990, the associated voluntary closure procedures and the prohibition of persons under Section 11 of the Act, in connection with food standards issues.

### **3.3.2: The Food Hygiene (England) Regulations 2005**

#### **3.3.2.1: Regulation 7 (Hygiene Prohibition) Procedures**

A Magistrates Court may make a hygiene prohibition order under Regulation 7 of the Food Hygiene (England) Regulations 2005 to:

- Prohibit a particular process or treatment;
- Prohibit the premises or equipment from being used for the purposes of the food business or any similar food business;
- Prohibit the premises and/or equipment from being used for the purposes of any food business;

The Food Authority must first successfully prosecute the food business operator for a breach of the Food Hygiene (England) Regulations 2005.

The Court will make an order if it considers that the premises, equipment, treatment and/or process fulfils the health risk condition as per Regulation 7(2).

The Court may also make an order prohibiting a food business operator from managing any food business, or a particular type of food business.

#### **3.3.2.2: Regulation 8 (Hygiene Emergency Prohibition) Procedures**

An authorised officer may serve an hygiene emergency prohibition notice under Regulation 8 of the Food Hygiene (England) Regulations 2005 if the health risk condition is fulfilled in respect of a food business and there is an imminent risk of injury to health. The effect of the notice is to immediately close the premises, or prevent the use of equipment, or the use of a process or treatment. Unlike Regulation 7, these powers cannot be used against a person.

The authorised officer must apply to a Magistrates Court for a hygiene emergency prohibition order within three days of a hygiene emergency prohibition notice being served, the day of service of the notice being Day 1.

### **3.3.2.3: Regulation 9 (Remedial Action Notices / Detention Notices)**

See paragraph 5.2.3 of the Code of Practice.

### **3.3.3: The Food Safety Act 1990**

#### **3.3.3.1: Section 11 (Prohibition) Procedures**

A Magistrates Court may make a prohibition order under Section 11 of the Act to:

- Close food premises;
- Prohibit premises from being used for particular kinds of food business;
- Prevent the use of a piece of equipment for any food business, or a particular food business;
- Prohibit a particular process;
- Prohibit the proprietor from managing any food business.

The Food Authority must first successfully prosecute the proprietor of the business for a breach of relevant food law.

The Court will make an order if it considers that the premises, equipment or process pose a risk of injury to health.

The Court may also make an order prohibiting a proprietor or manager from managing a food business.

#### **3.3.3.2: Section 12 (Emergency Prohibition) Procedures**

An authorised officer may serve an emergency prohibition notice under Section 12 of the Act if there is an imminent risk of injury to health in food premises. The effect of the notice is to immediately close the premises, or prevent the use of the equipment or process, although unlike Section 11, these powers cannot be used against a person.

The authorised officer must apply to a Magistrates Court for an emergency prohibition order within three days of an emergency prohibition notice being served, the day of service of the notice being Day 1.

Although there is no legal requirement for the application to be heard within the three days, the Court should be asked to list the application for hearing at the earliest opportunity.

The proprietor must have at least one day's notice of the intention to make the application.

Once made, an emergency prohibition order supersedes an emergency prohibition notice.

### **3.3.4: “Health Risk Condition” / “(Imminent) Risk of Injury to Health”**

Regulations 7 and 8 of the Food Hygiene (England) Regulations 2005 can only be used if the “health risk condition” is fulfilled. In respect of Regulation 7, there must be a risk of injury to health and in respect of Regulation 8 there must be an imminent risk of injury to health. Section 11 of the Food Safety Act 1990 can only be used if the “health risk condition” is fulfilled and Section 12 can only be used if there is an “imminent risk” of injury to health.

In respect of Regulation 8 of the Food Hygiene (England) Regulations 2005 and Section 12 of the Food Safety Act 1990, the word “imminent” qualifies the word “risk”. There must always be an imminent risk of injury to health before a hygiene emergency prohibition notice or emergency prohibition notice can be served. It is the risk of injury that must be imminent. The injury itself may occur sometime in the future, but it is essential to show that it could occur for the action to succeed. Not everyone exposed to the risk of injury will actually suffer the injury. It is the exposure to the risk of injury that enables action to be taken.

### **3.3.5: Food Hygiene (England) Regulations 2005**

In relation to food hygiene, the health risk condition under the Food Hygiene (England) Regulations 2005 may exist if, for example, conditions in premises, or a defective process or treatment, carries a high risk of causing foodborne infection, e.g. cases of botulism associated with an ingredient of yoghurt.

Foods containing potentially harmful levels of pathogenic micro-organisms represent an imminent risk and should be seized or detained under Regulation 27 of the Food Hygiene (England) Regulations 2005 by using Section 9 of the Food Safety Act 1990 (See also Regulation 23 in this regard). However, the process or treatment which exposed the food to this microbiological contamination should be dealt with under Regulation 8 of the Food Hygiene (England) Regulations 2005.

### **3.3.6: Food Safety Act 1990**

In relation to food standards, the health risk condition under the Food Safety Act 1990 may exist if, for example:

- A process or treatment introduces a teratogenic chemical (one that injures a developing foetus in the womb) into food, but the damage will not be apparent until the baby is born;
- A process or treatment introduces a genotoxic chemical (one that damages genes or chromosomes) into food, the effects of which may not manifest themselves until abnormal offspring or a malignant tumour occur some time 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.



### **3.3.7: Criteria for Action**

#### **3.3.7.1: Hygiene Prohibition Procedures / Prohibition Procedures**

The criteria for action depend on the conditions in Regulation 7(2) of the Food Hygiene (England) Regulations 2005 and Section 11(2) of the Food Safety Act 1990 being met, i.e. that either the construction or condition of the premises, or any equipment or the use of any process or treatment involves a risk of injury to health.

An authorised officer should use professional judgement to decide whether premises, process, treatment or piece of equipment or its use involves a risk of injury to health.

The general criminal law principle is that the onus of proof rests with the party who asserts the affirmative issue that the court should make an order. The persuasive burden remains with the prosecution throughout (except where the defence raise insanity, a statutory objection to the proviso or where the statute transfers the onus). A similar rule applies in civil proceedings.

#### **3.3.7.2: Hygiene Emergency Prohibition Procedures / Emergency Prohibition Procedures**

In the case of Regulation 8(2) of the Food Hygiene (England) Regulations 2005 and Section 12(2) of the Food Safety Act 1990, the application is made by the Food Authority and hence it bears the onus of proof and the persuasive burden. The necessary evidential requirements are respectively set out in Regulation 7(3) and 7(4) and Regulation 8(1) and 8(4) of the Food Hygiene (England) Regulations 2005, and Section 11(3) and 11(4) and Section 12(1) and (4) of the Food Safety Act 1990.

An authorised officer should use professional judgement to decide whether premises, process, treatment or piece of equipment or its use involves an imminent risk of injury to health.

Further guidance can be found in Paragraph 3.3.9.

### **3.3.8: Seeking Additional Advice**

Authorised officers should seek expert medical or other advice if a process or treatment is producing food that appears to contain chemicals or other substances that may pose an imminent risk of injury to health, or where the process or treatment in question itself requires other specialist knowledge or expertise<sup>5</sup>.

An authorised officer exercising a right of entry under Regulation 14 of the Food Hygiene (England) Regulations 2005 or Section 32 of the Food Safety Act 1990 may be accompanied by anybody else who is necessary, including an expert or experts.

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<sup>5</sup> The Institute of Food Science and Technology maintains a list of experts in particular fields.

It is, however, the authorised officer who must be satisfied that the health risk condition is fulfilled with respect to the food business.

### **3.3.9: Deferring Immediate Action**

There may be circumstances where immediate closure may be unnecessary, even though there would normally be an imminent risk to health.

The condition of retail food premises, for example, that would normally 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, for example, the food business operator / food business proprietor undertook to get a team of contract cleaners to improve the position during the night.

The risk in such circumstances would 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.

### **3.3.10: Serving the Notice or Order**

A hygiene prohibition order, a hygiene emergency prohibition order, a prohibition order or an emergency prohibition order – all of which are made by the Courts – need not necessarily be served by the authorised officer who initiated the action. It should, however, be served by an officer who is competent to explain the purpose of the order or deal with obstruction.

If a hygiene prohibition order, a hygiene emergency prohibition order, a prohibition order or an emergency prohibition order cannot be handed to the food business operator / food business proprietor in person, a copy of the document should be handed to whoever would be responsible for complying with immediate closure or prohibition action, e.g. the manager.

The authorised officer should ensure that the operator / proprietor is aware of the matters that constitute an imminent risk. Although this is included in the model hygiene emergency prohibition notice in the Code of Practice and the prescribed emergency prohibition notice, the operator / proprietor may not understand what steps need to be taken to remove the imminent risk and further explanation may be necessary.

### **3.3.11: Methods of Serving the Notice or Order**

Every effort should be made to serve a hygiene prohibition order, a hygiene emergency prohibition order, a prohibition order or an emergency prohibition order by delivering it to the food business operator / food business proprietor, or each of the operators / proprietors in the case of a partnership etc, by hand.

The authorised officer may, 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, if the operator / proprietor is present.

The service of the notice or order on a number of partners may present difficulties, particularly where a partner is not in the United Kingdom at the time. As soon as the notice or order is properly served on any one of the partners it takes effect.

If it is not possible to serve the document by hand then the authorised officer should serve the document by a postal or courier service that includes proof of posting or despatch and, ideally, proof of delivery.

The document may be faxed to the operator / proprietor for information in advance of its formal service, but a hard copy must follow for it to be properly served.

It may be useful to record the time of service, even when the postal service is used.

Immediately the document has been legally served by one of the methods mentioned in Regulation 28 of the Food Hygiene (England) Regulations 2005 or Section 50 of the Food Safety Act 1990, the prohibition on the use of the premises, or equipment for the purposes of any food business, or a particular type of food business, or prohibition on a process or treatment, becomes effective under the order and the hygiene emergency prohibition notice or emergency prohibition notice ceases to have effect.

### **3.3.12: Evidence Required**

The authorised officer should collect sufficient evidence to produce to the Court in order to substantiate any proceedings.

It is important that contemporaneous notes, including sketches and photographs, are taken during an inspection as they may need to be used in evidence to a Court. Samples of insects, dirt or other contaminants may also be useful.

Although authorised officers do not need to 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.

If a note of an inspection is compiled by officers at the end of, or during a visit, they should satisfy themselves as soon as practicable afterwards that it is accurate, so they may rely on it in Court.

### **3.3.13: Hygiene Prohibition Orders / Prohibition Orders**

During an inspection of premises prior to a Court hearing for an offence under the Food Hygiene (England) Regulations 2005 or the Food Safety Act 1990, the authorised officer may discover that the matter(s) giving rise to the prosecution has either not been removed or has been removed but has recurred.

If the food business operator / food business proprietor is convicted, the Court's attention may be brought to the provisions of Regulation 7(1) of the

Food Hygiene (England) Regulations 2005 or Section 11(1) of the Food Safety Act 1990 in order that the Court may consider making a hygiene prohibition order or prohibition order on the premises, process or equipment, thus ensuring that the risk of injury to health is removed.

#### **3.3.14: Prohibition of a Person**

When the food business operator / food business proprietor has been convicted of an offence, the authorised officer may feel that it is appropriate to ask the Court to consider making an order in relation to that operator / proprietor.

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 unfit food.

#### **3.3.15: 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.

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 local Court practice to try and resolve potential difficulties of obtaining Court time at short notice. This could be initiated by informal contact with the Magistrates Clerk's Office to ensure that, if at all possible, applications for emergency prohibition orders are expedited.

The food business operator / food business proprietor must be notified that the authorised officer intends to apply for an emergency hygiene prohibition order or emergency prohibition order. A notice of application for the order must be served on the operator / proprietor at the latest on the day before the date of the application, giving details of the Court appearance.

#### **3.3.16: Action to be Taken Prior to the Hearing**

The authorised officer should organise monitoring of the premises between the service of the notice and the Court hearing. The officer who served the notice need not necessarily carry out the monitoring.

The premises should be re-inspected shortly before the hearing (preferably the day before or on the day of the hearing itself) by the officer who served the notice.

If this is not possible, an authorised officer with relevant experience should carry out the re-inspection. This should also be the case if any contravention was found during the monitoring.

The purpose of the re-inspection is to gather evidence as to the current condition of the premises or equipment for the Court hearing. If appropriate, more evidence may be gathered.

The authorised officer should note any changes that have taken place since the notice was served. For example, the circumstances which led to the service of the notice may have worsened, or other circumstances not present originally may now also pose a risk to health.

If the authorised officer is considering bringing the attention of the Court to Regulation 7(1) of the Food Hygiene (England) Regulations 2005 or Section 11(1) of the Food Safety Act so that a hygiene prohibition order or prohibition order is to be considered, it is important that suitable evidence is gathered to produce to the Court.

### **3.3.17: 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;
- Evidence that food business operator / food business proprietor had been involved in the commission of offences elsewhere, which tended to show weaknesses in management (the authorised officer may have to investigate to ascertain whether the operator / proprietor has been involved in convictions at previous food premises and what these convictions were for).

It is usual practice for those prosecuting to ascertain whether there have been any previous convictions or cautions and to obtain details for presentation to the Court in the event of the prosecution being successful. They may also be used in evidence if the requirements of Section 101 of the Criminal Justice Act 2003 are met.

Information on a trader's previous record may be held in the Office of Fair Trading's (OFT) Central Register of Convictions<sup>6</sup>, particularly if the trader operates from multiple sites in different Food Authority areas. Food Authorities are encouraged to use the register to discover relevant history when considering a prosecution or formal caution, and to notify the OFT of successful prosecutions and formal cautions so that they may be included in the Register.

### **3.3.18: Affixing the Notice or Order on the Premises**

Regulations 7 and 8 of the Food Hygiene (England) Regulations 2005 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

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<sup>6</sup> The Office of Fair Trading, Central Register of Convictions, Craven House, 40 Uxbridge Road, Ealing, London, W5 2BS.

order or notice should 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 premises have been closed or a process or piece of equipment prohibited from being used.

An authorised officer who is competent to explain the meaning and importance of the notice, should take this action. A witness need only accompany the officer if required by the Food Authority. The authorised officer who initiated the action need not necessarily be involved.

The authorised officer should, if possible, firmly affix the document inside the premises, but in a position where it can clearly be seen and read from the outside, preferably on the inside of the glass of a front display window.

If such a position is unavailable the officer should use professional judgement as to the best place available and if necessary affix a second copy of the document to the outside of the premises, making sure, as far as possible, that it is protected from the weather and possible vandalism. The Food Authority should arrange for periodic checks to be made on the document to establish that it is still there.

### **3.3.19: Unauthorised Removal or Defacement of Notices or Orders**

Neither the Food Hygiene (England) Regulations 2005 nor the Food Safety Act 1990 make any reference to defacing or removing a hygiene prohibition order, a hygiene emergency prohibition notice or order, a prohibition order, or an emergency prohibition notice or order. This is, however, covered by other legislation.

Section 1 of the Criminal Damage Act 1971 makes it an offence for any person to destroy or damage property belonging to another without reasonable cause.

An emergency prohibition notice is the property of the Food Authority. If the authorised officer discovers that a notice has been removed or defaced, he should replace the notice as soon as possible and consider starting proceedings for criminal damage.

Section 63 of the Magistrates Courts Act 1980 enables a Court making an order to make provisions ancillary to it, such as requiring that the order should not be defaced or removed. The breach of such a requirement is punishable by a £5,000 fine, or a fine of £50 per day where the breach continues after there has been a Court decision about the breach, or two months' imprisonment in either case. The authorised officer should ask the Court at the time of the making of an order to make provisions ancillary to it under Section 63 of the Magistrates Courts Act 1980.

Where an order has been removed or defaced the officer should start proceedings under Section 63(3) of the Magistrates Courts Act 1980 for disobedience to the Court's requirement that it should not be removed or defaced. Such proceedings can be started by making a complaint in writing to

the Court, stating when the order was made, what its terms were and how a requirement of the order had been broken.

### **3.3.20: Lifting the Notice or Order**

The food business operator / food business proprietor must apply in writing to the Food Authority for a certificate lifting a hygiene prohibition order, a hygiene emergency prohibition notice or order, a prohibition order or an emergency prohibition notice or order. On receiving such a request, the authorised officer should re-inspect the premises as soon as possible and determine as soon as is reasonably practicable, or in any event within 14 days, whether the notice or order can be lifted.

The decision on whether to issue the certificate or not should be made by the officer who initiated the action if this is possible or, if it is not, by another authorised officer with the relevant qualifications and experience.

If the 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 (England) Regulations 2005, or Section 11(6) or 12(8) of the Food Safety Act 1990 as appropriate to be issued as quickly as possible, and in any case within 3 days. The certificate may be sent by fax, although the proprietor may 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 (England) Regulations 2005, 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. The Food Authority must give reasons why it is not satisfied that the health risk condition has been removed.

Although a certificate lifting an hygiene emergency prohibition notice or emergency prohibition notice may be issued before the application for an hygiene emergency prohibition order or emergency prohibition order can be heard, the operator / proprietor may still be prosecuted for the offence(s) against the Food Hygiene (England) Regulations 2005 or the Food Safety Act 1990 as appropriate.

The Food Authority should ensure that the court is informed in this situation.

A hygiene prohibition order or prohibition order on the food business operator / food business proprietor can only be lifted on application by the operator / proprietor to the Court that made the order.

### **3.3.21: Breach of a Notice or Order**

A person who knowingly contravenes a hygiene prohibition order or a prohibition order is guilty of an offence under Regulation 7(5) of the Food Hygiene (England) Regulations 2005 or Section 11(5) of the Food Safety Act 1990, respectively. A person who knowingly contravenes a hygiene emergency

prohibition notice or order or an emergency prohibition notice or order is guilty of an offence under Regulation 8(5) or (6) of the Food Hygiene (England) Regulations 2005 or Section 12(5) or (6) of the Food Safety Act 1990, respectively.

The authorised officer should start proceedings for the offence under the appropriate legislation by laying information before the Magistrates Court.

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 may ask the authorised officer for their view as to whether to endorse the warrant with bail. The authorised officer should use their professional judgement and take into account all relevant circumstances in their decision.

The 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.

### **3.3.22: Appeals: Refusal of a Food Authority to Issue a Certificate That The Health Risk Condition No Longer Exists**

Regulation 20(1)(b) of the Food Hygiene (England) Regulations 2005 and Section 37 of the Food Safety Act 1990 allow anybody who is aggrieved by a decision of a Food Authority to refuse to issue a certificate that there is no longer a risk to health to appeal by way of a complaint to the Magistrates Court. The time limit for such an appeal is one month from the date when the 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.

### **3.3.23: Compensation**

Regulation 8(10) of the Food Hygiene (England) Regulations 2005 and Section 12(10) of the Food Safety Act 1990 provide for the Food Authority to compensate the food business operator / food business proprietor for losses arising from the service of a hygiene emergency prohibition notice or emergency prohibition notice if a hygiene emergency prohibition order or emergency prohibition order as appropriate is not applied for within three days.

Compensation is also payable if the Court is not satisfied that an imminent risk of injury to health existed at the time the notice was served.

Compensation is payable in respect of “any loss” which is directly attributable to the wrongful service of the notice.

The Food Authority may assess the amount of compensation due taking into account (among other things) the following aspects where applicable:



- The length of time the process or treatment was halted, or the use of premises or equipment was prohibited and for what purpose;
- Loss of trade;
- Value of spoiled food;
- Loss of goodwill;
- Loss of wages;
- How much of the damage to trade is repairable;
- Obligation of the operator / proprietor to mitigate their own loss;

or, if the operator / proprietor of the business is agreeable, a loss adjuster may be called in.

## **CHAPTER 3.4: SEIZURE AND DETENTION**

### **3.4.1: Introduction**

This Chapter concerns the use of the detention and seizure powers under the Food Hygiene (England) Regulations 2005 and the Food Safety Act 1990.

### **3.4.2: General**

It is presumed under food law that all food is intended for human consumption until it is proved to the contrary.

Detention powers should not be used in relation to food that has already been clearly identified by a food business as not being intended for human consumption.

An officer may assist or advise the person in charge of the food as appropriate. If there is any doubt about the food being used for human consumption, then the officer should use the statutory procedures.

### **3.4.3: When to Use Detention and Seizure Powers**

#### **3.4.3.1: Food Which Does Not Satisfy Food Safety Requirements**

An authorised officer who has reasonable grounds for suspecting that food does not satisfy food safety requirements for reasons of hygiene may, under Regulation 23 of the Food Hygiene (England) Regulations 2005, use Section 9 of the Food Safety Act 1990.

If food does not satisfy food safety requirements for other than hygiene reasons, Section 9 of the Food Safety Act 1990 should be used. Section 9 of the Act permits the service of a detention of food notice to prevent the use of the food for human consumption. The form of notice provided in the Detention of Food (Prescribed Forms) Regulations 1990<sup>7</sup> should be used in this regard..

#### **3.4.3.2: Food Not Produced, Processed or Distributed In Compliance With the Food Hygiene (England) Regulations 2005 or the European Community Hygiene Regulations**

Under Regulation 27 of the Food Hygiene (England) Regulations 2005, an authorised officer of a Food Authority may, on an inspection of any food, certify that it has not been produced, processed or distributed in compliance with those regulations or the European Community Hygiene Regulations. The food must then be treated for the purposes of Section 9 of the Food Safety Act 1990 as failing to comply with food safety requirements. A model certificate for this purpose can be found in Annex 7 of the Code of Practice.

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<sup>7</sup> SI 1990 No. 2614

### **3.4.3.3: Detention of Food Subsequent to the Issue of a Remedial Action Notice Under Regulation 9 of Food Hygiene (England) Regulations 2005**

In an establishment subject to Regulation 853/2004, where a remedial action notice has been served on the food business operator under Regulation 9 of the Food Hygiene (England) Regulations 2005, Regulation 9(5) allows a detention notice to be served requiring the detention of any food at the establishment for the purposes of examination. A model Remedial Action Notice / Detention Notice for this purpose can be found in Annex 7 of the Code of Practice.

### **3.4.4: Specific Powers of Seizure and Detention for County Council Food Authorities**

The following legislation gives powers of seizure and detention to County Council Food Authorities:

- The Tryptophan in Food Regulations 1990<sup>8</sup>
- The Food (Control of Irradiation) Regulations 1990<sup>9</sup>
- The Miscellaneous Food Additives Regulations 1995<sup>10</sup>
- The Colours in Food Regulations 1995<sup>11</sup>
- The Sweeteners in Food Regulations 1995<sup>12</sup>
- The Kava Kava in Food (England) Regulations 2002<sup>13</sup>
- The Food (Jelly Confectionery) (Emergency Control) (England) Regulations 2002<sup>14</sup>
- The Contaminants in Food (England) Regulations 2004<sup>15</sup>
- The Genetically Modified Food (England) Regulations 2004<sup>16</sup>
- The Food (Chilli, Chilli Products, Curcuma and Palm Oil) (Emergency Control) (England) Regulations 2005<sup>17</sup>

### **3.4.5: Detention of Food**

Authorised officers need to exercise careful judgement, and may need to seek expert advice, before using their powers to detain food pending further investigation.

Food that is suspected of causing food poisoning can often be readily identified, and the decision to detain can therefore be taken relatively easily.

The notice may specify that the food is either to be held where it is, or moved to a place specified by the officer, pending further investigations.

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<sup>8</sup> SI 1990 No. 1728

<sup>9</sup> as amended, SI 1990 No. 2490

<sup>10</sup> as amended, SI 1995 No. 3187

<sup>11</sup> as amended, SI 1995 No.3124

<sup>12</sup> as amended SI 1995 No. 2133

<sup>13</sup> as amended SI 2002 No. 3169

<sup>14</sup> as amended SI 2002 No. 931

<sup>15</sup> as amended, SI 2004 No.3062

<sup>16</sup> SI 2004 No. 2335

<sup>17</sup> SI 2005 No. 1442

Food that requires special storage conditions, such as refrigeration, may need to be moved elsewhere, in which case the decision to require the food to be moved should be discussed with the owner of the food.

The decision to detain a whole batch, lot, or consignment needs careful consideration before a notice is served (see paragraph 3.4.8).

### **3.4.6: Seizure of Food**

The officer may be required to prove that the food produced before the Justice of the Peace is the food that was seized. The food should only be left if the officer is confident that it will not be moved, used for human consumption, or the evidence destroyed.

### **3.4.7: Food Condemnation Warning**

A food condemnation notification giving details of the time and place of the appearance before a Justice of the Peace should be given to the owner of the food once the decision to seize food has been taken. This notification is purely administrative and may therefore be signed by any competent officer.

The officer delivering the notification does not need to hold the same qualifications as the officer who took the decision to detain or seize the food, but should be sufficiently competent to explain the purpose of the notification and to deal with any obstruction.

Notification to the owner of the food may 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 on any person who may 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.

### **3.4.8: Taking Action Without Inspecting**

The provisions of Section 9 of the Food Safety Act 1990 also apply to food that has not been inspected (Section 9(2)).

This could apply when the officer has reasonable grounds to suspect that consumption of the food would be likely to cause foodborne or other communicable disease, or that it was otherwise so contaminated that it would not be reasonable for it to be consumed in that condition.

Information from another reliable source, e.g. another Food Authority, the HPA, the CCDC, or the Agency etc. may 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 may nonetheless be prudent, if only for identification purposes.

### **3.4.9: Dealing With Batches, Lots or Consignments of Food**

Article 14(2) of Regulation 178/2002<sup>18</sup> defines unsafe food and is relevant to both the Food Hygiene (England) Regulations 2005 and the Food Safety Act 1990. Section 8(2) of the Food Safety Act 1990 as amended deals with food that fails to comply with food safety requirements, if it is unsafe within the meaning of Article 14(2) of Regulation 178/2002.

Article 14(6) of Regulation 178/2002 covers the situation where food is part of a larger batch, lot or consignment of food of the same class or description. In such circumstances it is presumed, until the contrary is proved, that all of the food in the batch, lot or consignment fails to comply with food safety requirements.

The authorised officer should use professional judgement to decide whether to detain or seize the whole of the batch, lot or consignment. Appropriate expert advice should be sought if necessary.

If a whole batch, lot or consignment is detained and it subsequently becomes clear that only part of the detained food is affected and needs to be seized, the remainder of the batch etc. may be released. The compensation provisions under Section 9(7) of the Food Safety Act 1990 should always be borne in mind if this course of action is taken.

### **3.4.10: Voluntary Procedures**

It should be borne in mind that the use of voluntary procedures might contribute to a defence in any subsequent prosecution. It could, for example, be argued that the food was not so contaminated that it had to be seized.

The fact that food had been condemned by a Justice of the Peace would be persuasive in any prosecution, but would not in itself necessarily establish an offence. It would still be necessary for a case to be proved beyond reasonable doubt. In this respect certificates of analysis or examination are of particular value.

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<sup>18</sup> Regulation (EC) No. 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety

## CHAPTER 3.5: TEMPERATURE CONTROL PROVISIONS

### 3.5.1: Introduction

This Chapter provides guidance on the enforcement of Regulation 30 / Schedule 4 of the Food Hygiene (England) Regulations 2005. In respect of circumstances to which this regulation is not applicable and where food is required to be kept under temperature control for safety reasons, the general requirements of Annex II, Chapter III Paragraph 2(g), Chapter IV Paragraph 7 and Chapter IX Paragraphs (5), (6) and (7), of Regulation 852/2004<sup>19</sup> would apply, as appropriate.

### 3.5.2: General Approach to Temperature Checks

#### 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 should 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, should normally be used as the next step in the enforcement process. This is done with a pre-cooled flat-headed probe, suitable for measuring surface or between-pack temperatures.

It is important to ensure good thermal contact between the product and the probe when taking between-pack measurements. A total tolerance of +2.8°C (0.8°C as specified for instrument accuracy and 2°C for the limitation of the methodology) should be allowed. Care should 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 should 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 may not be sufficiently accurate to give an indication of product temperature. In such instances it may be necessary to proceed directly to a destructive temperature measurement.

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<sup>19</sup> Regulation (EC) No. 852/2004 on the hygiene of foodstuffs

### 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 should normally be undertaken with the sample in its temperature-controlled environment. If this is not possible, the sample should be removed to an appropriately refrigerated environment, provided the transfer does not prejudice product temperature. Any transfer should take place prior to preparation of the sample. Transfer of products within the normal cold chain, e.g. from a vehicle to a cold store, is acceptable.

When a “stage 3” measurement is being carried out, insertion of the temperature probe into the food may render the food unsaleable. In such circumstances, the authorised officer should 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 should not normally be necessary to select large numbers of items for “stage 3” testing.

In the first instance, items should 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.

#### **3.5.3: Taking Temperature Measurements**

The temperature of a product should 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 should 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.

#### **3.5.4: Tolerances**

“Stage 2” temperature readings may be up to 2°C warmer than the true product temperature, especially product with thick packaging. They may also be affected by recent movement of goods, defrost cycles or instrumental inaccuracy as described below.

Authorised officers should use professional judgement in borderline cases to decide whether further “stage 2” measurements are necessary before proceeding to “stage 3”.

### **3.5.5: Checking and Calibration of Enforcement Measuring Thermometers etc**

The accuracy of the thermometer or other temperature measuring device, and any detachable probes, should be checked against a reference thermometer or calibrator that is certified to an appropriate standard, e.g. NPL, and the result recorded, before and after taking any temperature measurements that are likely to result in enforcement action.

The record of such a check should 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 should 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 should be broken up into very small pieces, packed into a wide-necked vacuum flask, wetted with cold water and stirred. The sensor should 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 should ensure accuracy at higher temperatures.

### **3.5.6: Pre-cooling of Instruments**

The thermometer or other temperature measuring device and the penetration probe should 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.

### **3.5.7: Preparation of Samples for Temperature Measurement**

Only temperature measuring probes that are specifically designed for the purpose should 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 should be used. The diameter of the hole should provide a close fit to that of the probe and its depth will depend on the type of product being tested (as described below).



### **3.5.8: Measurement of Product Temperature**

Preparation of the product for testing and its temperature measurement should take place with the product in its temperature-controlled environment. Measurement is as follows:

- (a) Where the product dimensions allow, insert the pre-cooled probe to a depth of at least 2.5cm from the nearest outside surface of the product.
- (b) Where (a) is not possible the probe should 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 should 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 should 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 should not be recorded until it has stabilised.

### **3.5.9: Equipment Used for Chilled Product Temperature Measurement**

Temperature measurement systems that are used for enforcement purposes should meet the following requirements:

- The system should reach 90% of its final reading within 3 minutes;
- The system should have an accuracy of  $\pm 0.5^{\circ}\text{C}$ , or better when the sensor is measuring within the temperature range  $-20^{\circ}\text{C}$  to  $+30^{\circ}\text{C}$ ;
- The accuracy must not change by more than  $\pm 0.3^{\circ}\text{C}$  when the instrument is operated in temperatures of  $-20^{\circ}\text{C}$  to  $+30^{\circ}\text{C}$ ;
- The instrument display should be readable to at least  $0.1^{\circ}\text{C}$ ;
- The system should be robust and shock proof;
- The temperature sensitive part of the system should be constructed to facilitate good thermal contact with the food and be easily cleaned.

A dry cell battery, not mains electricity, should power the measuring instrument. The instrument should incorporate a method of checking the

battery voltage to indicate when replacement or re-charging is necessary. The design of the probe depends on the type of temperature measurement:

- For product tests: a robust rigid stem with a sharpened point suitable for insertion into the product and capable of being sterilised;
- For between-pack tests: a flat head suitable for a between-pack measurement with good surface contact, low thermal mass and high thermal conductivity. If a suitable flat probe is not available, one can be constructed using a calibrated sensor crimped in the centre of a square, (approximately 4cm long) or circle (approximately 4cm diameter) or a double layer of aluminium foil. Any inter-connecting cables should be flexible between 0°C and +30°C.

## **CHAPTER 3.6: QUICK FROZEN FOODSTUFFS**

### **3.6.1: Introduction**

This guidance gives informal, non-statutory advice to Food Authorities on checking temperatures and temperature monitoring systems when enforcing the Quick-frozen Foodstuffs Regulations 1990<sup>20</sup>, as amended, (the Regulations).

Food is not subject to the Regulations unless it is specifically labelled or described as “quick-frozen”. A quick-freezing process can be regarded as any form of accelerated freezing such as blast freezing, plate freezing, liquid nitrogen freezing, etc.

### **3.6.2: Legislative Changes**

Commission Directive 92/1/EEC has been repealed and replaced by the directly applicable Commission Regulation 37/2005<sup>21</sup>. Necessary amendments to the Quick-Frozen Foodstuffs Regulations 1990 are still under consideration. Once these have been decided, consequent amendments to this chapter will be necessary.

There are three main points of difference between Directive 92/1/EEC and Regulation 37/2005. First, in the case of transport there is no longer a requirement for competent authorities to approve the temperature measuring instruments used. Also, from 1 January 2006 all measuring instruments, used in transport, warehousing, or storage of quick-frozen foodstuffs must comply with the relevant CEN standards<sup>22</sup>. Finally, from 1 January 2006, the legislation will apply to rail transport for the first time.

It is important to note, however, that there are significant transitional provisions. Measuring instruments installed up to 31 December 2005, which meet the legislative requirements at the time, can continue to be used until 31 December 2009.

### **3.6.3: Division of Enforcement Responsibility Between County and District Councils**

Regulation 7(2) makes each Food Authority responsible for enforcement of the Regulations within its area. The Regulations are primarily concerned with the physical quality of food, which is generally the responsibility of the County Council Food Authorities. However, in the interests of efficiency it is expedient for District Council Food Authorities to be involved in certain aspects of the enforcement of the Regulations.

Parts of Schedule 1 of the Regulations are concerned specifically with the safety and quality of raw materials and the nature of the quick-freezing process. The conditions laid down concern both County and District Council Food Authorities who should liaise closely over the enforcement of these aspects of the

<sup>20</sup> As amended, SI 1990 No. 2615

<sup>21</sup> Commission Regulation (EC) No 37/2005 of 12 January 2005 on the monitoring of temperatures in the means of transport, warehousing and storage of quick-frozen foodstuffs intended for human consumption

<sup>22</sup> European Committee for Standardization, [www.cenorm.be](http://www.cenorm.be)

Regulations. In particular they should liaise over the programme of inspections of premises where quick-frozen foodstuffs are processed and packaged. During such inspections the provisions concerning equipment used as required by Regulation 6 should also be enforced.

District Council Food Authorities are responsible for giving advice where a breakdown in refrigeration equipment raises doubt about the suitability of food for human consumption. Furthermore as District Councils have responsibility for checking temperatures in stores, vehicles, retail and catering establishments to enforce food hygiene legislation, it is cost effective for them to enforce the temperature of quick-frozen foodstuffs as laid down in Schedule 1, 1(f) of the Regulations, as varied by 2(c).

Regulation 4, which concerns the packaging of the food to protect it from microbial and other forms of contamination as well as dehydration, is primarily a safety matter and should be the responsibility of District Council Food Authorities.

The division of enforcement responsibilities between Food Authorities is set out in Paragraph 3.6.2 of the Code of Practice.

### **3.6.4: Temperature Requirements**

After quick-freezing, the Regulations require relevant food to be kept at, or colder than, -18°C.

It is necessary, however, to ensure that the temperature of food has stabilised after freezing and packing before the temperature requirements of the Regulations are applied. Permitted exceptions relating to the temperature of food apply during primary, secondary and local distribution as stated in Schedule 1 (2)(c) of the Regulations.

Catering outlets are *not* required to comply with these Regulations as the caterer does not sell the food as "quick-frozen" but prepares the food for sale in a chilled or heated form.

### **3.6.5: Staged Approach to Enforcement**

The staged approach to enforcement which is required by the Code of Practice, involves the following:

- Checking air temperature and air temperature monitoring records;
- A non-destructive check of food temperature if the first stage check raises reasonable doubt about compliance with the Regulations;
- A destructive temperature measurement of the food itself if doubt remains about compliance with the Regulations after the first two stages have been completed.

The initial stage of any check to monitor compliance with the Regulations should include a discussion with the proprietor or other responsible person about the position of temperature monitoring sensors, how temperatures that they record

relate to the actual temperature of the food, and how temperature control is achieved.

Destructive temperature measurement should normally only be undertaken when reasonable doubt remains that food is being held at the required temperatures, having regard to permitted fluctuations, after earlier steps in the staged approach have been completed.

Adopting this approach will also be less time consuming, and avoid food being rendered unfit for sale unnecessarily.

### **3.6.6: Air Temperature Checks**

A check of air temperature and any air temperature monitoring records should be the first step in the staged approach to enforcement.

Authorised officers should inspect air temperature monitoring records where they exist. Although operators are required to ensure that air temperatures are recorded, except in retail cabinets and local distribution, this does not preclude the use of supplementary systems based on temperature measurements other than air temperatures. Enforcement action should cease at this point if the air temperature check is satisfactory.

Air temperature monitoring is designed to indicate the performance of refrigeration equipment, and a single reading at any one time will not necessarily correspond directly to the temperature of the food.

Air temperature monitoring records will show temperature history, including any defrost cycles, door openings, breakdowns etc, and are a useful guide to how well a particular installation is functioning. The length of time that records should be kept in excess of one year (Regulation 6A(2)(b)) should be commensurate with the maximum shelf-life of the foods to which they relate.

#### **3.6.6.1: Air Temperature Checks: Cold Stores**

Enforcement at factory cold stores should primarily concentrate on the temperature of out-going product. The temperature requirements of the Regulations do not apply until the product has been thermally stabilised.

Authorised officers need to verify that a cold store is a holding store for quick-frozen foodstuffs and not merely used for temperature stabilisation, which is not covered by the Regulations.

Manufacturers may have off-site cold storage facilities that are used for temperature stabilisation, and transport to these sites prior to thermal stabilisation of the foodstuff will be necessary.

Authorised officers should be satisfied that the temperature monitoring sensors in cold stores have been appropriately positioned so as to give an accurate indication of product temperature, and may check whether the sensors are giving accurate readings by comparing them against their own calibrated instruments if necessary.

### **3.6.6.2: Air Temperature Checks: Transport**

Authorised officers should ascertain whether temperature measuring instrument(s) used in transport (excluding local distribution vehicles and railways) meet the specification set out in Schedule 2(e) of the Regulations, and that proper recordings are being made (Regulation 6A (2)).

This was to satisfy Article 2(1) of Directive 92/1/EEC, which required the competent authority to approve such measuring instruments. Instruments will be deemed to be approved if they comply with the appropriate specification in the Regulations.

Temperature sensors in a vehicle need to be sited so that they give an accurate indication of the air temperatures to which the load is subjected. In short or multi-compartment vehicles a sensor measuring the air-return to the refrigeration unit may be sufficient. In larger vehicles, an additional sensor positioned further down the chamber may be necessary to indicate adequate air circulation.

International transport of quick-frozen foodstuffs is sometimes achieved by conveying the product in insulated containers that have to be connected to independent refrigeration units ("clip-on units"). This refrigeration equipment is not an integral part of the container, and different systems can be used at different stages in the distribution chain. Temperature monitoring records may therefore not be immediately available for the whole of the journey, and authorised officers will have to make a professional judgement as to whether or not further inspection is necessary.

Local distribution vehicles are only required to be fitted with a visible thermometer (Schedule 2(g)). The sensor should be located so that it indicates the temperature of the air returning to the refrigeration unit. Air temperature monitoring records may not give a representative indication of product temperature because of the frequency of door openings in local delivery vehicles.

### **3.6.6.3: Air Temperature Checks: Retail Display Cabinets**

It may be necessary to discuss with the proprietor or representative how the retail cabinet temperature monitoring system operates and how its readings relate to the air temperature at the load line.

In many instances sensors will not be physically located at the load line. Authorised officers should therefore satisfy themselves that temperature sensors are positioned within cabinets so that their readings are indicative of temperatures at maximum load lines.

Although thermometers in retail display cabinets must be easily visible to the operator and to authorised officers, they do not necessarily have to be visible to consumers. A central readout at a control point that registers data from a number of cabinets in a system satisfies this requirement.

In open cabinets, including open vertical cabinets, thermometers have to be indicative of the temperature at the clearly marked maximum load line, although in open vertical cabinets the load line is not usually marked as it is normally regarded to be the front edge of the shelves.

Authorised officers should also be aware that there are many different types of temperature monitoring and measuring equipment, and that not all will give an instantly readable indication of temperature.

A display cabinet is a "point of retail sale" and therefore the temperature tolerance for local distribution also applies to back-up cold rooms in retail premises. The tolerance relating to retail display cabinets is a permanent tolerance which takes into account cabinet defrost cycles and the temperature gradient within a cabinet i.e. it allows for radiant heat and other such influences affecting the temperature of the top or outermost (warmest) packs in a cabinet.

### **3.6.7: Non-destructive Temperature Checks**

If an air temperature check leaves reasonable doubt that food to which the Regulations apply is being, or has been held at the required temperature, then a non-destructive between-pack temperature check should be undertaken. Enforcement action should cease if the result of the non-destructive temperature check is satisfactory.

Authorised officers should ensure that cartons or cases of quick-frozen foodstuffs that are opened for checking are re-sealed and appropriately labelled or marked with the date and time of the check, the name of the officer, and the name of the Food Authority. This is to show that the case was opened for an official check and to avoid any suspicion of malicious tampering.

Not all packs or packaging materials are suitable for this type of measurement. 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 non-destructive between-pack temperature measurement may not be sufficiently accurate to be indicative of product temperature. If the packaging of the food is not suitable for this type of measurement it may be necessary to proceed directly to a destructive temperature measurement.

When performing non-destructive between-pack temperature checks it is important to ensure good thermal contact between the product packaging and the probe. A total tolerance of +2.8°C (0.8°C for instrument accuracy, and 2°C for the limitation of the methodology) should be allowed.

Checks should be conducted so as to cause the minimum of disturbance to the product and its temperature-controlled environment, particularly to the airflow patterns in retail display cabinets. This can be achieved by using a pre-cooled, flat-headed probe that is suitable for measuring surface or between-pack temperatures.

Care should be taken to allow the reading to stabilise whilst ensuring that the temperature recorded is not that of the surrounding air, e.g. because the probe

is not properly sandwiched between the packs. For products within an outer casing it will be necessary to open the casing and insert the temperature probe between packs.

### **3.6.8: Destructive Temperature Measurement**

Destructive temperature measurement should only be undertaken where it has not been possible to carry out a non-destructive temperature check, or where reasonable doubt still remains after a non-destructive temperature check.

Sample preparation and temperature measurement should normally be undertaken whilst the sample remains in the refrigerated environment in which it was selected. If this is not possible it will be necessary to move the sample to an appropriately refrigerated environment prior to measuring its temperature, provided the transfer does not prejudice its temperature. Any transfer should take place prior to preparation of the sample. Transfer of products within the normal cold chain, e.g. from a vehicle to a cold store, is acceptable.

If internal product temperature measurement is to be undertaken, both the probe and the product penetration device should be pre-cooled. Only temperature measuring probes that are specifically designed for the purpose should be used to make a hole in the sample.

In other cases a separate pre-cooled product penetration implement must be used. Pre-cooling minimises any local rise in product temperature due to 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 10-15 minutes. Provided there is no significant rise in the temperature of the instrument or probe subsequent determinations can be made with a much shorter pre-cooling period.

If formal action is considered necessary, then determination of the actual temperature of the food must always be made since it is the temperature of the food that must comply with the Regulations.

The operator should witness the temperature measurement process and food temperature readings if possible.

If accurate internal product temperature measurement is not possible, e.g. because the product is fragile, the product should be treated in the same way as particulate foodstuffs (e.g. green peas etc). The surface product temperature should be determined by carefully removing the product from its packaging and firmly sandwiching a pre-cooled flat-headed probe between two products. This is regarded as equivalent to the method detailed in paragraph 6.3(c) of Annex II, Directive 92/2/EEC, and can be used for a prosecution.

### **3.6.9: Sampling**



Before a non-destructive or a destructive temperature measurement can be undertaken, the authorised officer should decide on the positions from which the samples to be measured should be taken.

#### **3.6.8.1: Sampling: Cold Stores**

It is necessary to establish that the product has been in the cold store long enough for temperature stabilisation to have occurred. Paragraph 1.1 of Annex 1 of Directive 92/2/EEC states:

"Samples should be selected from several critical points in the cold store, for example: near the doors (upper and lower levels), near the centre of the cold store (upper and lower levels), and near to the air return of the cooling unit."

It may be necessary to take several samples if there is any doubt about the warmest position or if it is not possible to take air temperature measurements from the desired area.

Depending on access within the cold store it may be possible to take several air temperature readings at various points to verify the chosen sampling position. Attention should be paid to the way in which product is stacked within the store, the height of stacks, and any other factor that may impede the free circulation of air around the store causing localised "warm spots".

#### **3.6.8.2: Sampling: Transport**

Particular care should be exercised when sampling from vehicles to ensure that the refrigerated environment is disturbed as little as possible.

Paragraph 1.2(a) of Annex 1 of Directive 92/2/EEC states that if it is necessary to select samples during transport they should be selected:

".. from the top and the bottom of the consignment adjacent to the opening edge of each door or pair of doors."

In circumstances where further investigation is required, or when unloading has already commenced, it may be necessary to select samples during unloading of a vehicle. Unloading of the vehicle should be carried out so that the product to be tested is marked, or can be identified, for subsequent examination under temperature controlled conditions, e.g. in a cold store.

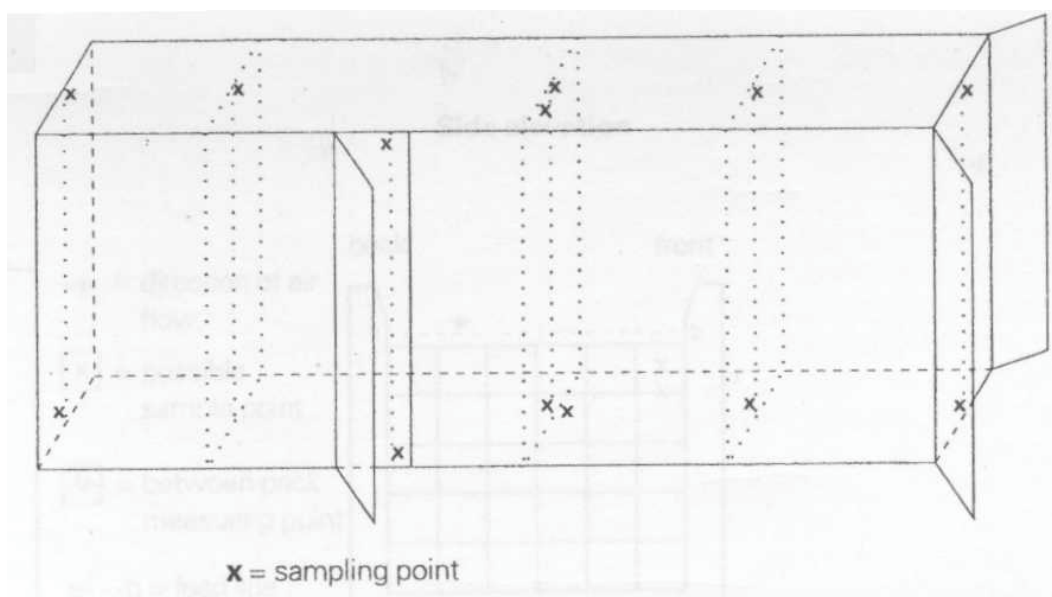
Paragraph 1.2(b) of Annex 1 of Directive 92/2/EEC states:

"Choose four samples from amongst the following critical points:

- top and bottom of the consignment adjacent to the opening edge of doors,
- top rear corners of the consignment (at a point as far away from the refrigeration unit as possible),
- centre of the consignment,

- centre of the front surface of the consignment (as close as possible to the refrigeration unit),
- top and bottom corners of the front surface of the consignment (as close as possible to the return air [inlet] to the refrigeration unit)."

This sampling plan may need to be modified for vehicles with more than one set of doors because the temperature distribution within the vehicle will be different. Four samples should be selected from amongst the suggested sampling points indicated in Figure 1.



**Figure 1. Sampling points for vehicles with more than one set of doors**

### 3.6.8.3: Sampling: Retail Display Cabinets

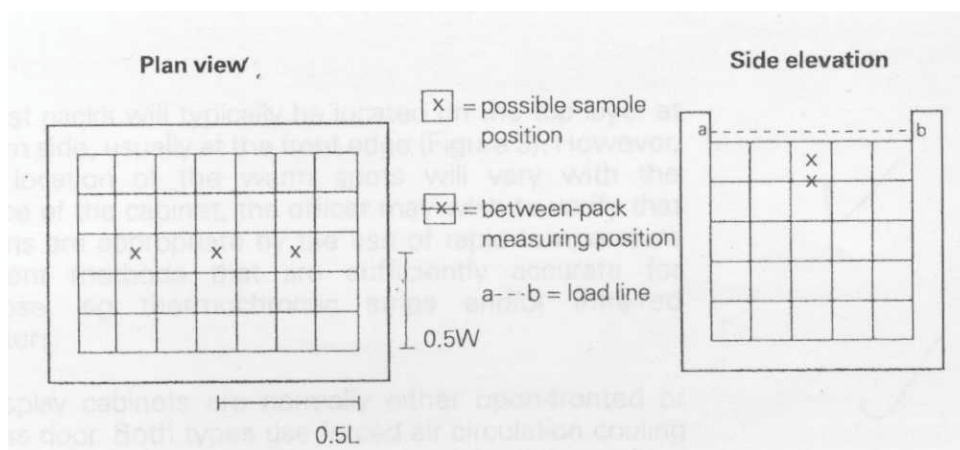
Paragraph 1.3 of Annex I of Directive 92/2/EEC states:

"A sample must be selected for testing from each of three locations representative of the warmest points within the retail display cabinet used."

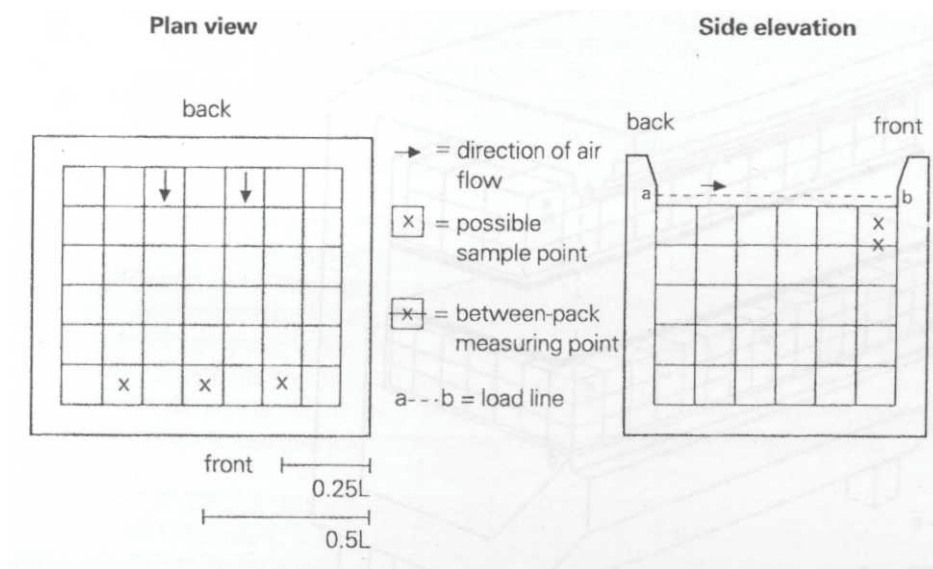
The temperature profile within a retail cabinet can be complex and even the same cabinet design may perform differently depending on its environment, the type of products it contains, and how these products are distributed within the cabinet.

External parameters such as draughts and lighting can also affect the temperature distribution within a cabinet. In horizontal cabinets the warmest packs will generally be located at the surface where they are exposed to radiant heat from the surroundings. Of these, packs furthest away from the cold walls of a contact cooling cabinet, normally down the centre, will have the warmest temperature (Figure 2). This will also be the case in combination cabinets.

In forced-air circulation cabinets the warmest packs will typically be located on the top layer at the air return side, usually at the front edge (Figure 3). However, since the location of the warm spots will vary with the performance of the cabinet, the officer may wish to verify that the positions are appropriate by the use of rapid temperature measurement methods that are sufficiently accurate for this purpose, e.g. thermochromic strips and/or an infra-red thermometer.



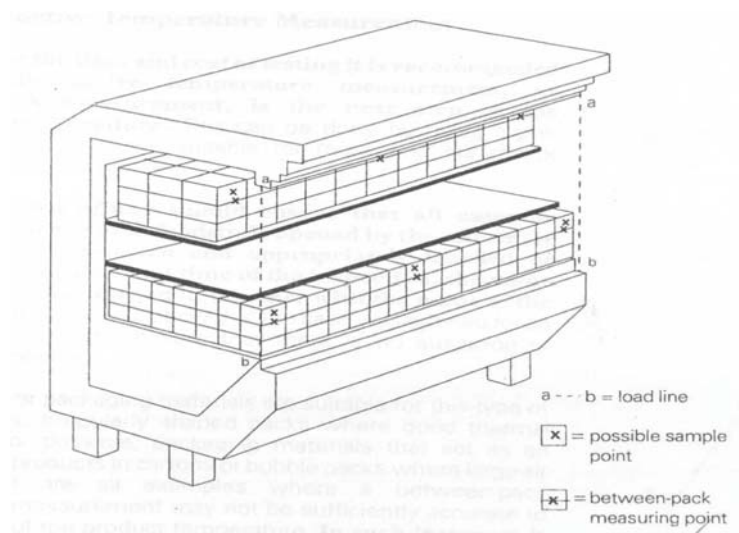
**Figure 2. Horizontal cabinet – contact cooling**



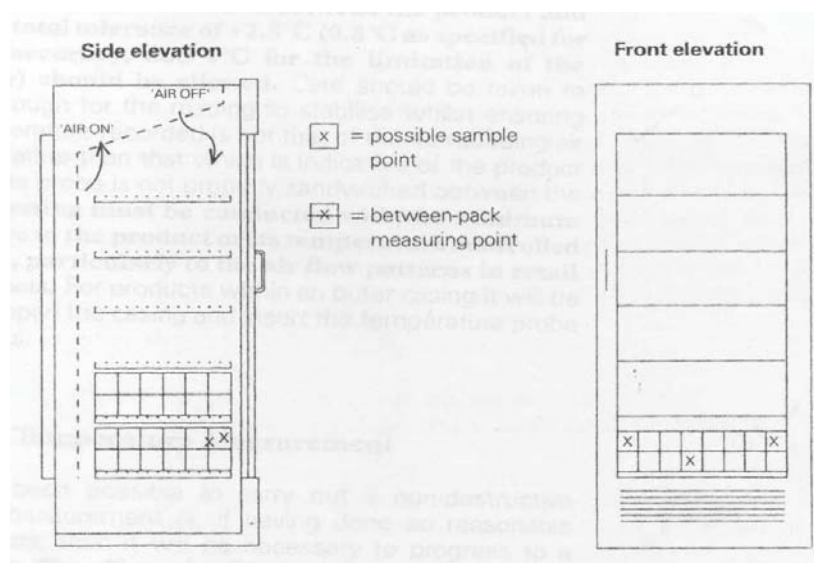
**Figure 3. Horizontal cabinet – forced air circulation**

Vertical display cabinets are normally either open-fronted or have a glass door. Both types use forced-air circulation cooling although design details vary and the exact pattern of the air flow will depend on the positioning of the fans. With open-fronted cabinets the warmest positions will generally be at the front of the top shelf (Figure 4). It is much more difficult to generalise the equivalent positions for glass door cabinets since the frequency of door openings and the

length of time they are left open throughout the day will greatly affect the temperature of the food. Typically, packs closest to the door, which are exposed to radiant heat and furthest from the cooling source, will be the warmest (Figure 5). The use of rapid temperature measurement methods can aid the identification of "warm spots".



**Figure 4. Open vertical cabinet**



**Figure 5. Vertical glass-fronted cabinet**

In large retail outlets, where several identical cabinet units that are holding products which are similar in type and packaging are joined together, it may be sufficient to sample only one unit, providing any temperature records and/or other rapid methods do not indicate large air temperature discrepancies between the units.

### 3.6.10: Procedure for Product Temperature Measurement

#### (i) Pre-cooling of instruments

The temperature measuring probe and the product penetration instrument, such as an ice punch, a hand drill or an auger should be pre-cooled before measuring the temperature of the product. The pre-cooling method used should ensure that both instruments equilibrate as close to the product temperature as possible.

### **(ii) Preparation of samples for temperature measurement**

The diameter of the hole made in a sample using the product penetration instrument should provide a close fit to that of the probe, and its depth will depend on the type of product (as described in (iii)). It is important to ensure that any instrument used for making a hole in a quick-frozen foodstuff is maintained in a sharp condition, and can be easily cleaned.

### **(iii) Measurement of product temperature**

The sample preparation and its temperature measurement should be undertaken whilst the sample remains in the selected refrigerated environment. Measurement is as follows:

(a) Where the product dimensions allow, insert the pre-cooled probe to a depth of at least 2.5 cm from the nearest outside surface of the product.

(b) Where (a) is not possible the probe should 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.

(c) Certain foods, because of their size or composition (e.g. green peas) cannot be drilled to determine their internal temperature. In these cases, the internal temperature of the food package should 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.

(d) Read the temperature indicated when it has reached a steady value.

### **3.6.11: Dealing with Food which is at a Higher Temperature than the Prescribed Frozen Temperature**

If a destructive temperature measurement confirms that the food is at a higher temperature than prescribed by the Regulations, it may not necessarily fail food safety requirements and may still be fit for consumption.

In most cases there will not be any need for action under Section 9 of the Food Safety Act 1990. The authorised officer should, however, advise the proprietor of the provisions of Section 14 of the Act, and discuss what action the proprietor proposes to take to deal with the quick-frozen foodstuff.

### **3.6.12: General Specification for Temperature Measuring Instruments**

Officers should check the accuracy of their temperature measuring instruments either prior to, or as soon as practicable after, any formal action. Officers should refer to Paragraph 3.5.5 of this guidance, and adapt the methodology to the range -20°C to +30°C.

Temperature measuring instruments that are used to gather evidence for a prosecution should be properly calibrated by a scientifically valid method and have a current certificate of calibration. This may include the use of a calibration tank, provided the tank itself has a current certificate of calibration.

Temperature measuring instruments used for enforcement purposes should meet the following specification:

- (a) The response time should achieve 90% of the difference between the initial and final reading within three minutes;
- (b) The instrument (readout and probe) must have an accuracy of +0.5°C within the measurement range -20°C to +30°C;
- (c) The measuring accuracy must not be changed by more than 0.3°C during operation in the ambient temperature range -20°C to +30°C;
- (d) The display resolution of the instrument should be 0.1°C;
- (e) The accuracy of the instrument (readout and probe) should be checked at regular intervals;
- (f) The instrument (readout and probe) should have a current certificate of calibration;
- (g) The temperature probe can be easily cleaned / disinfected;
- (h) The temperature-sensitive part of the measuring device must be so designed as to ensure good thermal contact with the product;
- (i) The electrical equipment must be protected against undesirable effects due to the condensation of moisture.

## **CHAPTER 3.7: FOOD WASTE**

### **3.7.1: Introduction**

This Chapter provides guidance to Food Authorities on the control of food waste.

The legislative framework that controls the identification, categorisation, segregation, collection and disposal of food waste includes regulations and orders that are made under both the Food Safety Act 1990 and the Animal Health Act 1981.

For the purposes of this guidance, “food waste” includes food material that is not fit or not intended for human consumption.

### **3.7.2: Inspection of Food Businesses**

Any inspection of a food business, including inspections of mobile establishments / premises, ships, aircraft and trains, should include a check on the arrangements that the business has for the collection and disposal of food waste.

Checks should also include the arrangements in ports and airports for the collection and disposal of imported food waste from ships and aircraft.

Checks should 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.

### **3.7.3: Major Investigations**

Food authorities may become aware of instances of apparent food fraud involving the misuse of food waste that could have potentially serious implications for public or animal health, e.g. unfit meat being diverted into the human food chain.

The investigation of such cases may 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 may 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 may 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 Agency as soon as practicable.

The Agency and the Food Authority will then be able to discuss options, including whether support may be available, or whether the Food Authority’s inspection programme should be re-prioritised to ensure that inspections of higher-risk premises are maintained.

## **CHAPTER 3.8: DISTANCE SELLING/MAIL ORDER**

### **3.8.1: Introduction**

This Chapter 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 this guidance, “the distance selling of food” means the advertisement of food for sale directly to consumers where the subsequent sale of the food to the consumer takes place without the buyer and seller meeting face-to-face. Examples of distance selling include the sale of food through internet websites, mail order transactions, and telephone sales.

The enforcement issues for Food Authorities that relate to the distance selling of food depend primarily on the location of the advertiser and/or seller.

### **3.8.2: 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.

If the seller is in the UK, the enforcement and consumer protection issues are likely to be within UK jurisdiction, and UK legislation will bind the seller.

Similarly, if the seller is based elsewhere in the EU, that Member State’s legislation, including EU legislation is likely to apply to the sale.

However, the difficulties are not so easily addressed when the seller is outside the EU because the enforcement powers of Food Authorities and consumer protection laws may not reach beyond the UK’s jurisdiction. There are, therefore, important distinctions between UK, EU and non-EU distance selling transactions.

### **3.8.3: Location of the Buyer**

The location of the buyer in a distance selling transaction is important only insofar as it affects the ease with which the buyer may be able to invoke an appropriate remedy, should there be a problem with the transaction, e.g. food not as described, food unfit for consumption on delivery etc.

### **3.8.4: Distance Selling of Food from the UK**

The distance selling of food from the UK takes place when the advertisement of food for sale or the sale transaction itself takes place within the jurisdiction of the UK legal system.



The distance selling of food from the UK is covered by relevant food law . Food that is sold by a distance selling method from the UK, and advertisements for such food, must therefore comply with exactly the same legal requirements as food sold from a high street supermarket or advertised in a UK national newspaper.

Food Authorities are therefore responsible for enforcing food law in relation to the distance selling of food from the UK, including food that is advertised or sold through UK-based internet sites.

Food Authorities should therefore have appropriate means of monitoring the distance selling of food by businesses for which they act as home authority.

Food Authorities should 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.

Food Authorities should also encourage distance sellers of perishable food that are based in their areas to adopt best practice by:

- Ensuring the maintenance of appropriate temperature controls during transit;
- Clearly marking consignments on the outermost packaging with the date of despatch and the appropriate durability indication.

### **3.8.5: Distance Selling of Food from the EU (Outside the UK)**

The distance selling of food from the EU takes place when the advertisement of food for sale or the sale transaction itself takes place outside the jurisdiction of the UK legal system, but within the jurisdiction of another Member State.

UK consumers who purchase food from a distant seller in another Member State cannot rely on the protection of UK food law.

However, as most UK food law derives from EU single market rules, similar provisions to those that apply in the UK will apply in the other Member State.

Food Authorities should generally use the liaison role of the Agency (See Chapter 2.4 of both the Code of Practice and of this Guidance) to resolve problems relating to the distance selling of food from the EU.

### **3.8.6: Distance Selling of Food from Third Countries**

The distance selling of food from third countries takes place when the advertisement of food for sale or the sale transaction itself takes place outside the jurisdiction of any EU Member State.

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<sup>23</sup> SI 2003 No. 2075

UK consumers who purchase food from a distance seller in a third country cannot rely on the protection of UK food law.

### **3.8.7: Generic Distance Selling Legislation**

Generic law regulating distance selling in the UK is set out in the Consumer Protection (Distance Selling) Regulations 2000<sup>24</sup>, which implement Council Directive 97/7/EC in the UK.

The primary aim of this legislation is to facilitate cross-border distance selling consumer transactions within the EU by laying down basic levels of consumer protection that apply throughout the EU, irrespective of the Member State that has legal jurisdiction over the transaction.

The Regulations lay down minimum levels of information that must be provided to the consumer by distance sellers of goods or services in the EU. These include:

- The name of the supplier and a geographical (rather than an internet) address;
- Description of the goods or services;
- The period that the offer remains open;
- The price (including all taxes);
- The right to withdraw;
- The arrangements for delivery of any goods.

The central UK competent authority with responsibility for these Regulations is the Department of Trade and Industry (DTI). Enforcement is the responsibility of the Office of Fair Trading (OFT) and Trading Standards Departments.

DTI, OFT and LACORS have each published guidance on the Regulations for businesses, consumers, and enforcement agencies. Copies of the guidance are available either directly from the LACORS website at [www.lacors.gov.uk](http://www.lacors.gov.uk) or via links from the LACORS website to the relevant DTI or OFT web addresses. If any further advice is required, officers should contact the Contract Regulation Unit at OFT.

### **3.8.8: Other References**

“Industry Guide to Good Hygiene Practice: Mail Order” [DN: due to be published in 2006].

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<sup>24</sup> SI 2000 No. 2334

## **CHAPTER 3.9: BOTTLED WATERS**

### **3.9.1: Introduction**

This Chapter provides guidance to Food Authorities on enforcement of the Natural Mineral Water, Spring Water and Bottled Drinking Water Regulations 1999<sup>25</sup>, as amended (the Regulations).

### **3.9.2: Legislation**

The Regulations transpose into UK legislation the provisions of: Council Directive 80/777/EEC, as amended by Directive 96/70/EC, relating to natural mineral water and spring water and Council Directive 80/778/EEC covering spring waters and bottled waters, as amended by Council Directive 98/83/EC, relating to the quality of water for human consumption.

The Regulations were amended by The Natural Mineral Water, Spring Water and Bottled Drinking Water (Amendment) (England) Regulations 2003<sup>26</sup> which implement, in relation to spring water and bottled drinking water, Council Directive 98/83/EC relating to the quality of water intended for human consumption.

A further amendment, The Natural Mineral Water, Spring Water and Bottled Drinking Water (Amendment) (England) Regulations 2004<sup>27</sup> came into force on 5<sup>th</sup> April 2004 and implement 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.

### **3.9.3: Natural Mineral Waters**

The Regulations require each UK 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.

It is not permitted to sell water as natural mineral water if the source has not been recognised.

A list of recognised UK sources is available on the Agency's website at [www.food.gov.uk/foodindustry/mineralwaters](http://www.food.gov.uk/foodindustry/mineralwaters).

The most recent list of all recognised sources within the EU is available on the EU's website.

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<sup>25</sup> SI 1999 No. 1540

<sup>26</sup> SI 2003 No. 666

<sup>27</sup> SI 2004 No. 656

### **3.9.4: Recognition of Natural Mineral Waters**

Applications for recognition of natural mineral waters in Great Britain 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 the Agency 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.

Food Authorities should also notify the London and Edinburgh Gazettes, of any recognition, withdrawal of recognition or change in the name of the source or trade description of a natural mineral water.

Natural mineral water cannot be tankered, unless it was tankered for the purposes of exploiting the *spring* before 15 July 1980. Hence transport of water from the spring to the packaging line must be in a closed pipeline made of a suitable material and the filling system must ensure that there is no microbiological contamination of the water before closure.

### **3.9.5: Labelling of Natural Mineral Waters**

The Regulations include detailed labelling requirements for containers of natural mineral water that must be met when natural mineral waters are packaged.

### **3.9.6: Spring and Other Bottled Drinking Water**

The recognition and monitoring procedures by Food Authorities that apply to natural mineral waters do not apply to spring and other bottled drinking waters, although these waters are subject to specific compositional and microbiological standards that are set out in the Regulations.

Spring water is normally extracted from a private water supply and is, therefore, also subject to the requirements of the Private Water Supplies Regulations 1991<sup>28</sup>, which specify the frequency of local authority monitoring of a range of compositional and microbiological parameters.

However, like natural mineral water, spring water cannot be tankered, unless it was being transported in tankers on or before 23 November 1996. The right to tanker is linked to the *spring*, not the bottler.

### **3.9.7: Labelling of Spring and Other Bottled Water**

Any bottled water that is described as “spring water” must meet the relevant labelling requirements in the Regulations.

Bottled drinking waters are subject to the general labelling requirements of the Food Labelling Regulations 1996<sup>29</sup>.

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<sup>28</sup> SI 1991 No. 2790

<sup>29</sup> as amended, SI 1996 No. 1499

## CHAPTER 3.10: MICROBIOLOGICAL CRITERIA REGULATION

[DN: Legislation on microbiological criteria for foodstuffs will be changing from 1 January 2006. The Regulation was adopted on 23rd September, as SANCO4198/2001 Rev 20, and is expected to be published in the Official Journal of the European Communities in the coming weeks.

Guidance on enforcement of this Regulation is still under development and will be included here when it is finalised. To assist the Agency in this task we welcome feedback on where the information you need to help you enforce this regulation. In the meantime, a summary of Agency guidance on the requirements of the new legislation for food business operators is set out below for information.

The full version of this draft guidance document can be found on the Agency's website (<http://www.food.gov.uk>) from 4 November. Further information is included in the Agency's Regulatory Impact Assessment for the Microbiological Criteria Regulation at:

<http://www.food.gov.uk/foodindustry/Consultations/ukwideconsults/microcriteria2005>].

### 3.10.1: DRAFT: Summary for Small Businesses

There are currently numerous pieces of legislation covering the hygiene of specific commodities and many of these include microbiological criteria. From 1 January 2006 a new package of food hygiene rules will replace the existing legislation. The existing microbiological criteria have been reviewed to produce a new Regulation (Regulation ---/2005) which supports that package. Many of the current criteria remain unchanged, but some no longer exist and criteria have been established in new areas where this is necessary e.g. pre-cut fruit and vegetables, infant formula, Salmonella on some meat carcasses and *Listeria monocytogenes* in some ready to eat products.

The Regulation applies to all food business operators involved in the production, distribution, handling and supply of foodstuffs, including retail and catering. Food business operators must ensure that foodstuffs comply with the relevant microbiological criteria and to comply with the regulation fully, they must also take the given action if a product is found to fail any of the criteria. Primary producers are unlikely to be affected directly by the Regulation, as there are no criteria for unprocessed fruit and vegetable products, except for sprouted seeds. They may however be affected by the food safety management procedures implemented by their customers.

Two types of microbiological criteria are to be introduced:

- food safety criteria which help indicate the microbiological safety of the products. These apply throughout the shelf-life and if they are exceeded the product must not be placed on the market or must be withdrawn from the market. In some cases a product recall may be required. The food safety management procedures should also be reviewed to ensure the products are likely to comply in the future.
- process hygiene criteria which help show that the production processes are working properly. These apply throughout every stage of manufacturing and handling. If a process criterion is exceeded this should lead to a review of current procedures to improve product hygiene. In two cases, further

testing may be required. These are when Enterobacteriaceae in infant formula or coagulase positive staphylococci in dairy products are found.

For most products, the Regulation does not require food business operators to carry out routine microbiological testing or to wait for the results of any testing carried out before the food is placed on the market. The criteria should be used to help show that the food safety management procedures are functioning correctly.

With the exception of certain meat and meat products, the Regulation allows Food business operators to use their food safety management procedures to establish an appropriate sampling regime. The level of sampling required will depend on considerations such as the food safety management procedures in place, the risk associated with the product, and the nature and size of the business.

It will not always be necessary to carry out microbiological testing to show compliance with the criteria. For example, routine monitoring of physical parameters associated with food safety management procedures (such as monitoring time/temperature profiles, pH, level of preservative and water activity) may provide adequate assurance that the criteria are being met. Evidence that the business is following guidance from the Food Standards Agency, Local Authorities or industry guides to good practice may also help demonstrate compliance e.g. adoption of schemes such as “Safer Food Better Business” in England and equivalent Agency schemes elsewhere in the UK.

Enforcement officers must ensure that food business operators are complying with the Regulation. In the UK this will be either Local Authorities or the Port Health Authority. Food business operators will be required to provide evidence that the necessary food safety management procedures are in place to ensure all relevant criteria are met. Enforcement officers will not routinely carry out testing to support their assessment of the evidence but there may be instances where they wish to do so, for example, if they identify a particular problem or where they are carrying out surveys.

Food safety criteria apply to trade between Member States and can be applied by enforcers to monitor imports from countries outside of the EU.

## **CHAPTER 3.11: IMPORT OF FOOD FROM THIRD COUNTRIES**

See Annex 14 of this Guidance.

## **SECTION 4: INSPECTIONS**

### **CHAPTER 4.1: INSPECTIONS**

All relevant material on inspections is contained in the Code of Practice.



## **CHAPTER 4.2: THE INSPECTION**

### **4.2.1: Introduction**

This Chapter deals with notice and co-ordination of inspections, and the monitoring of shellfish identification marks.

### **4.2.2: Notice of Inspection**

The general principle about pre-notification of inspections is set out in Regulation 882/2004 which states in Article 3(2) that *“official controls shall be carried out without prior warning, except in cases such as audits where prior notification of the feed or food business operator is necessary. Official controls may also be carried out on an ad hoc basis”*.

There will, however, be circumstances when it is advantageous to give advance notice, particularly when the purpose of inspection is to see a particular process in operation. Authorised officers should exercise discretion in this area guided by the overriding aim of ensuring compliance with food legislation.

### **4.2.3: Co-ordination of Inspections**

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

Wherever it is practicable and appropriate to do so, Food Authorities should co-ordinate inspections of food premises. The inspection team should include all the expertise necessary to inspect the premises in question and where appropriate further experts in particular fields of food technology<sup>30</sup>.

### **4.2.4: Shellfish Identification Marks**

As part of the monitoring of the use of shellfish identification marks, Food Authorities should, from time to time, select a batch or consignment from a retail outlet or restaurant and seek to trace the batch or consignment back through a dispatch centre, and any purification centre, to the original gatherers to establish that records relating to the batch and the identification mark are in order. Food Authorities should co-operate with other Food Authorities in any random check through the production and distribution chain.

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<sup>30</sup> The Institute of Food Science and Technology maintains a list of experts in particular fields.

If any checks suggest that registration documents, identification marks or records are not in order the Food Authority should carry out an investigation to establish where the procedures have not been properly observed. In such cases they should also consider increasing the frequency of random checks through the distribution chain until they are satisfied that the appropriate procedures are being followed.

## **CHAPTER 4.3: INSPECTION OF APPROVED ESTABLISHMENTS – ADDITIONAL REQUIREMENTS**

All relevant information is contained in the Code of Practice.

## **CHAPTER 4.4: INSPECTION OF SHIPS AND AIRCRAFT**

### **4.4.1: Introduction**

This Chapter supplements the information supplied in the corresponding Chapter in the Code of Practice to enable authorised officers to consider additional aspects relating to the inspection of ships and aircraft. It also provides, at Paragraph 4.4.7, an inspection template for aircraft, which may be adapted, where appropriate, provided that the procedures outlined in the Code are not overlooked. A Ship Sanitation and Food Safety Report template can be found on the LACORS website ([www.lacors.gov.uk](http://www.lacors.gov.uk)).

### **4.4.2: General**

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

Examples include:

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

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

The scale of food production on board vessels varies greatly, from large passenger vessels and cargo vessels with large crew and passenger numbers (e.g. some cruise liners with up to 900 passengers and 800 crew) to smaller vessels crewed by 10 to 15 personnel.

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

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

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

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

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

#### **4.4.3: Catering Waste**

The disposal of international catering waste to landfill is regulated by the Products of Animal Origin (Third Country Imports) (No. 4) Regulations 2004<sup>31</sup>. DEFRA has identified significant risks to animal health if this waste is not dealt with effectively at landfill. Specific measures are needed to ensure that disease is not introduced into the UK from landfill sites, which receive this waste. A mechanism for suspending or amending the conditions of a landfill site approved to deal with such waste is in place, in the event that the conditions of approval are not observed.

#### **4.4.4: Other Issues: Aircraft**

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

Such reports, where available, should form part of the authorised officer’s initial checks. Authorised officers should also give consideration, where appropriate, to these Guidelines, which were first published in February 2003<sup>32</sup>.

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.

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<sup>31</sup> SI 2004 No. 3388

<sup>32</sup> [www.ifcanet.com/teams/foodsafety](http://www.ifcanet.com/teams/foodsafety)

When it is necessary to board an aircraft, the actual time spent on board should be as short as possible, as most of the above issues should be standard operating procedures included in the airline's documentation. However, if there are any causes of concern relating to the above, the authorised officer should notify the relevant company and HA, if designated, that increased surveillance may be undertaken, e.g. assessment of galley cleanliness, increased water sampling for analysis/examination, etc.

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

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

#### **4.4.5: Other Issues - Ships**

If appointed, the HA for the shipping operator should ensure that all relevant documentation is made available to it, (see below for examples of relevant documentation), for liaison with and the information of other relevant Food Authorities. For military ships see paragraph 4.4.4 in the Code of Practice.

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) primary 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.

#### **4.4.6: Other References**

Industry Guide to Good Hygiene Practice: Catering Guide – Ships; Chamber of Shipping, published by Chadwick House Group (ISBN 1-904306-42-X).

Note: Article 8(5) of Regulation 853/2004 stipulates that guides to good practice drawn up pursuant to Directive 93/43/EEC shall continue to apply after the entry into force of that Regulation, provided that they are compatible with its objectives.

#### 4.4.7: Inspection Template: Aircraft - Food Safety Inspection Report Form

Local Authority:	Airport:		
Name of Authorised Officer:	Designation:	Tel. No:	
Date of Inspection:	Time of Inspection	Flight No:	
Airline Company or Airline operating the aircraft:			
Address:	Airline Tel. No:		
Airline Person interviewed/Designation:			
Aircraft Reg. No:	Aircraft type:	Home Authority:	
1. Date of previous inspection: (if known)		2. Return catered: Yes/No	
3. High risk foods served:	Yes/No	4. Hazard Analysis (√ tick box if satisfactory)	<input type="checkbox"/>
5. Training/Exclusion procedure	<input type="checkbox"/>	6. Pest control	<input type="checkbox"/>
7. Time/Temp control (outbound)	<input type="checkbox"/>	8. Temp control (return catering)	<input type="checkbox"/>
9. Cooking/Reheating	<input type="checkbox"/>	10. Galley hygiene/storage areas	<input type="checkbox"/>
11. Cleaning/Waste control	<input type="checkbox"/>	12. Toilets	<input type="checkbox"/>
13. Potable Water supply	<input type="checkbox"/>	14. Airline sampling (food/water)	<input type="checkbox"/>

Note: details of items 1 to 6 and 13 to 14 should be obtained from the airline (or Home Authority) prior to attending an aircraft.

Comments (including any samples procured)

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#### Summary of Action taken to be taken by Food Authority (√ tick box(es))

Satisfactory Outcome	<input type="checkbox"/>	Follow-up With Airline HQ/HA	<input type="checkbox"/>
Prosecution Detention/Seizure	<input type="checkbox"/>	Emergency Prohibition Notice	<input type="checkbox"/>
		Formal	<input type="checkbox"/>



Improvement Notice ☐

Letter to follow ☐

Verbal advice  
(not to cabin crew) ☐

Signature of Officer

Signature of Person interviewed

## **CHAPTER 4.5: ACTION FOLLOWING INSPECTION**

All relevant information on action following inspection is contained in the Code of Practice.

## **SECTION 5: PRODUCT-SPECIFIC ESTABLISHMENTS**

### **CHAPTER 5.1: APPROVAL OF PRODUCT-SPECIFIC ESTABLISHMENTS SUBJECT TO APPROVAL UNDER REGULATION 853/2004**

All relevant material on the approval of product-specific establishments subject to approval under Regulation 853/2004 is contained in the Code of Practice.

## **CHAPTER 5.2: ENFORCEMENT OPTIONS IN PRODUCT-SPECIFIC ESTABLISHMENTS SUBJECT TO APPROVAL UNDER REGULATION 853/2004**

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

## **CHAPTER 5.3: MATTERS RELATING TO LIVE BIVALVE MOLLUSCS**

Relevant material on live bivalve molluscs is contained in the Code of Practice and at Annex 6 of this guidance.

## **CHAPTER 5.4: MATTERS RELATING TO FRESH MEAT**

Relevant material relating to fresh meat is contained in the Code of Practice and at Annex 5 of this Guidance.

## **SECTION 6: SAMPLING<sup>33</sup>**

### **6.1.1: Introduction**

This Section concerns the procedures that should be followed when food samples are taken under Regulation 12 of the Food Hygiene (England) Regulations 2005 and Section 29 of the Food Safety Act 1990 / the Food (Sampling and Qualifications) Regulations 1990 (the Regulations)<sup>34</sup>.

### **6.1.2: Procurement of Samples**

The Food Hygiene (England) Regulations 2005 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 should offer an ex-gratia payment if samples are not purchased. The officer should 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.

### **6.1.3: Certificate Issued by Public Analyst or Food Examiner**

A Public Analyst or Food Examiner is required to analyse or examine samples as soon as practicable and, depending on local arrangements, to give the officer who submitted the sample a certificate specifying the result. Food Authorities should 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.

### **6.1.4: Avoiding Contamination**

Care should be taken to prevent contamination of samples and instruments, and containers used for samples should be clean and dry. It is important to avoid the use of cleaning and sterilising methods that may leave residues on instruments or containers that could, in turn, affect the results of the analysis or examination (e.g. alcohol).

### **6.1.5: Continuity of Evidence**

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 may therefore need to be reminded of the possibility of legal action, the need to treat food samples and faecal specimens as evidence, and to ensure the continuity of such evidence.

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<sup>33</sup> See also “Food Standards and Feeding Stuffs Sampling, Practical Guidance for Enforcement Officers” by the Food Standards Agency – published May 2004;  
<http://www.food.gov.uk/enforcement/foodsampling/guidance/>

<sup>34</sup> SI 1990 No. 2463

Records must therefore be kept of all stages of transport, including:

- Dates and times of transport;
- Identity of custodians;
- Date and time of receipt in the laboratory;
- Identity of the person receiving sample.

For food samples, the temperature of transport should be monitored, and recorded on receipt. If the sample has been posted, proof of posting or a record of the method of despatch to the Food Examiner or Clinical Microbiologist should be kept. The Food Examiner or Clinical Microbiologist should be made aware that the results of their examination of the food or faecal specimen(s) could be used as evidence in Court, and that by examining the sample/specimen, they may be required to produce a certificate of examination, give a sworn written statement, and/or give oral sworn testimony in court.

Other laboratory personnel may 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 should be a system at the laboratory for logging the sample or specimen's arrival, and its storage, which should be secure. For food samples, the temperature of storage should be such as to minimise microbial change, and be monitored using a calibrated thermometer or other similar device. Continuity preservation at the laboratory is vital so that there is certainty that the result relates to the sample/specimen submitted. There must be no possibility that the result could refer to a different sample or specimen. Neither must the results raise any doubt as to their reliability, or the reliability or accuracy of laboratory procedures. An individual in the laboratory should be capable of making a sworn statement and of providing sworn oral testimony on these points.

It should also be made clear that if the Food Examiner/Clinical Microbiologist does not carry out the actual examination, but has it conducted under their direction, the person who actually examines the sample or specimen may also be required to give evidence.

### **6.1.6: Samples for Analysis**

#### **6.1.6.1: Quantity of Samples for Analysis**

The nature and quantity of any sample should be such as to enable the required analysis to be made. The nature of the samples that are appropriate will depend on the purpose for which the analysis is being undertaken. The



quantity will vary according to the product and type of analysis to be carried out. The Public Analyst should be consulted in case of doubt.

National sampling protocols should be taken into consideration, where they exist. Some modification to the protocols may be necessary in the case of large consignments of imported foods.

#### **6.1.6.2: Containers for Samples for Analysis**

Samples of non-prepacked food or opened cans or packets, should first be placed in clean, dry, leak-proof containers such as wide-mouth glass or food quality plastic jars, stainless metal cans or disposable food quality plastic bags. Jars, bottles or cans should be suitably closed. Disposable food quality plastic bags should be sealed securely after filling, so that they cannot leak or become contaminated during normal handling. Samples of alcoholic drinks should be placed in glass bottles.

The contained final parts should 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, it should then be placed in a second container, such as a plastic bag, which should 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 should be submitted to the Public Analyst with a final part.

#### **6.1.6.3: Transport and Storage of Samples for Analysis<sup>35</sup>**

Final parts of food which are perishable should 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.

The final part to be submitted to the Public Analyst should be transmitted as soon as practicable after sampling, particularly where tests are to be made for substances which may deteriorate or change with time (e.g. certain pesticides, sulphur dioxide, etc). In any case, where doubt exists about suitable storage or transport arrangements for samples for analysis, the Public Analyst should be consulted. Since retained final parts may 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.

#### **6.1.6.4: 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 6(4) of the Regulations 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

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<sup>35</sup> The Campden and Chorleywood Food Research Association publication "Guidelines for the preservation of official samples for analysis" (Project 2000-45) includes further guidance.

where this procedure may be used will depend on the tests to be carried out but may include the following:

- Where there is insufficient product available to comply with the procedures in Regulations 6(1) or 6(2);
- There is no way of storing a final part for further analysis as with tests for previously frozen meat.

This situation may also arise where foods are not pre-packed and are not homogeneous and it is difficult to divide the food into three parts, so that each part contains the same proportion of each ingredient, e.g. meat products with lumps of meat, pies where it is difficult to divide the pastry and the filling into three, fruit cocktail/yoghurts with fruit where an ingredient is to be quantified.

In any case, where a single sample is taken in accordance with Regulation 6(4) the owner must be notified of its submission for analysis.

Regulation 6(2) sets out an exception from the general procedures where the sample consists of unopened containers and opening them would, in the opinion of the authorised officer, impede proper analysis. In these circumstances the authorised officer should divide the sample into parts by putting containers into three lots and each lot should be treated as a final part.

Where any doubt exists, the Public Analyst should be consulted.

#### **6.1.6.5: Certificates of Analysis**

The owner of the food and any person who has been notified in accordance with paragraph 6.1.7 of the Code of Practice is entitled, on request, to a copy of the certificate of analysis.

#### **6.1.7: Samples for Examination**

Samples for examination are not required to be divided into three parts, since the non-homogeneous distribution of bacterial contaminants means that no two samples will be the same. It is not appropriate to retain a part for examination later in the event of a dispute, as bacteria may not survive prolonged storage or conversely, may greatly multiply.

##### **6.1.7.1: Quantity of Samples for Examination**

The quantity of any sample procured should be such as to enable a satisfactory examination to be made. The quantity will vary according to circumstances, but should normally be at least 100 grams. In any case of doubt the Food Examiner should be consulted.

##### **6.1.7.2: Handling of Samples for Examination**

Full traceability in the taking and handling of the sample should be ensured, including the identity of those who have had dealings with the sample, and what they did with it. Samples of non-prepacked food, or from opened cans or

packets of food, should be first placed in sterile, leak-proof containers or disposable sterile plastic bags. Disposable sterile plastic sampling bags should be sealed securely after filling, so that they cannot leak or become contaminated during normal handling. Advice should 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, should be secured with a tamper evident seal and labelled, specifying:

- Type of food sample;
- Name of the Officer;
- The exhibit identification number (e.g.RG/1);
  - The date, place and time of sampling.

Containers that may be easily damaged, or that cannot themselves be made tamper-evident, should then be placed in a second container, such as a plastic bag, which should be sealed in a 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 should be given to the Food Examiner, e.g. food handling techniques/storage methods observed in respect of the food sampled.

For general sampling information see the LACORS “Guidance on Food Sampling for Microbiological Examination”, January 2002. Annex 3 of that Guidance contains details of information to be given to the Food Examiner, when samples are submitted.

Officers should 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 should be taken to avoid contamination of the sample and microbial growth or death during sampling, transport and storage. The temperature of transport should be monitored and recorded.

#### **6.1.7.3: Handling, Transport and Storage of Faecal Specimens for Examination**

On occasions, officers will be required to investigate reported or suspected cases of foodborne illness and obtain faecal specimens. Officers should therefore have a ready supply of appropriate leak-proof containers for the collection of faecal specimens.

Such specimens should 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 may 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.

#### **6.1.7.4: Request for Examination**

The officer should 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.

#### **6.1.7.5: Certificates of Examination**

The owner of the food and any person who been notified in accordance with paragraph 6.1.11 of the Code of Practice should, on request, be given a copy of the certificate of examination.

## **SECTION 7: MONITORING**

All relevant material on monitoring is contained in the Code of Practice.

## SECTION 8: ANNEXES

### ANNEX 1: GLOSSARY OF TERMS

ABPO	Animal By-Products Order 1999
BSE	Bovine Spongiform Encephalopathy
CCDC	Consultant in Communicable Disease Control
CDSC	Communicable Disease Surveillance Centre
CEFAS	Centre for Environment, Fisheries & Aquaculture Science
CIEH	Chartered Institute of Environmental Health
CPHM (CD/EH)	Consultant in Public Health Medicine (communicable disease/environmental health)
DEFRA	Department for Environment, Food and Rural Affairs
DH	Department of Health
DHI	Dairy Hygiene Inspectorate
DTI	Department of Trade and Industry
EC	European Community
EEA	European Economic Area
EMIs	Egg Marketing Inspectors
EU	European Union
FLEP	Food Law Enforcement Practitioners
Framework Agreement	Framework Agreement on Local Authority Food Law Enforcement
FVO	Food and Veterinary Office (of the European Commission)
HA	Home Authority
HACCP	Hazard Analysis and Critical Control Point
HPA	Health Protection Agency
LACORS	Local Authorities Co-ordinators of Regulatory Services
MSM	Mechanically Separated Meat
NAWDEPC	National Assembly for Wales
	Department of Planning, Environment and Countryside
OFT	Office of Fair Trading
OPOAO	Other products of animal origin
REHIS	Royal Environmental Health Institute of Scotland
SCIEH	Scottish Centre for Infection and Environmental Health
SEERAD	Scottish Executive Environment and Rural Affairs Department
SFI	Sea Fisheries Inspectorate
Seafish	Sea Fish Industry Authority
SFPA	Scottish Fish Protection Agency

SFSORB

The Agency  
TSE

UKAS  
VMHA

Scottish Food Safety Officers'  
Registration Board

The Food Standards Agency

Transmissible Spongiform

Encephalopathy

United Kingdom Accreditation Service

Veterinary Meat Hygiene Adviser

## **ANNEX 2: AGENCY GUIDANCE ON THE REQUIREMENTS OF FOOD HYGIENE LEGISLATION**

[DN: Generic Agency guidance for industry which provides a comprehensive overview of the new EU Food Hygiene Regulations will be inserted here to ensure that this useful reference is readily available for Food Authorities for the purposes of consistency. A draft of this guidance was originally issued for public consultation in October 2004 and was included as an Annex to the draft Practice Guidance which was issued for public consultation in May 2005. The guidance is currently being revised and updated to reflect developments which have occurred since it was originally drafted. The final version of the guidance will be included as an Annex in the final version of this Practice Guidance].



## **ANNEX 3: APPROVAL OF PRODUCT-SPECIFIC ESTABLISHMENTS SUBJECT TO APPROVAL UNDER REGULATION 853/2004 - GENERAL**

### **A.3.1: Introduction**

Article 4 of Regulation 853/2004 stipulates that establishments handling products of animal origin for which Annex III to that Regulation lays down requirements may not operate unless they have been approved (which includes conditional approval). This requirement is, however, subject to a number of exemptions which are outlined in Paragraph A.3.3, below.

Relevant requirements of both Regulation 852/2004 and Regulation 853/2004 apply to establishments subject to approval under the latter regulation. Some of the following paragraphs have been reproduced from the Code of Practice for completeness.

### **A.3.2: Division of Enforcement Responsibilities**

(From Code of Practice, Paragraph 5.1.2 / Paragraph 5.4.2)

Responsibility rests with Food Authorities for the approval of, and enforcement in relation to, establishments subject to approval under Regulation 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, 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, and will include certain cold stores and certain 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 Agency, through the Meat Hygiene Service, is responsible for the approval of, and enforcement in relation to, establishments subject to approval under Regulation 853/2004 where control falls to an official veterinarian in accordance with Article 4(7) of Regulation 854/2004<sup>36</sup>. Such establishments are slaughterhouses, game handling establishments and cutting plants. The Meat Hygiene Service is also responsible for such establishments in which Minced Meat, Meat Preparations, Mechanically Separated Meat and/or Meat Products are also produced.

The Agency is also responsible for enforcement in relation to the matters regulated by Schedule 6 of the Food Hygiene (England) Regulations 2005 in so far as it applies in relation to raw cows’ milk intended for direct human consumption.

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<sup>36</sup> Regulation (EC) No. 854/2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption

### **A.3.3: Exemptions from the Requirement for Approval**

#### **A.3.3.1: Introduction**

Exemptions from the requirement for approval are set out in Article 1 of Regulation 853/2004 which sets out the scope of the Regulation and in Article 4 which stipulates that establishments subject to approval under Regulation 853/2004 shall not operate unless they have been approved. The following paragraphs deal with the various exemptions from the requirement to be approved.

#### **A.3.3.2: Exemptions: Regulation 853/2004, Article 1 (Scope)**

##### **A.3.3.2.1: Article 1(2) of Regulation 853/2004: Food Containing Both Products of Plant Origin and Processed Products of Animal Origin**

(From Code of Practice, Paragraph 5.1.2.2)

*2. Unless expressly indicated to the contrary, this Regulation shall not apply to food containing both products of plant origin and processed products of animal origin. However, processed products of animal origin used to prepare such food shall be obtained and handled in accordance with the requirements of this Regulation.*

Article 1(2) of Regulation 853/2004 stipulates that “*Unless expressly indicated to the contrary, this Regulation does not apply to food containing both products of plant origin and processed products of animal origin*”. Food Authorities should be aware that the regulation does not set any minimum amounts of product of plant origin, or processed product animal origin, that such food must contain.

Establishments engaged solely in the production of such food by assembling products of plant origin with processed products of animal origin which enter the establishment in that processed state, will not therefore be subject to Regulation 853/2004 and, as such, will not require approval. Food Authorities will need to consider the definitions of “processed products”, “unprocessed products” and “processing” in Article 2 of Regulation 852/2004 in this regard.

Food Authorities should be aware that establishments benefiting from this exemption would, in addition to compliance with Regulation 852/2004, need to comply with Article 1(2) of Regulation 853/2004 which requires such establishments to obtain the processed products of animal origin they use in compliance with Regulation 853/2004 (i.e. from approved establishments) and that these products are handled in accordance with that regulation.

Food Authorities should also be aware that this provision can apply in an approved establishment. As indicated above, Article 1(2) of Regulation 853/2004 stipulates that this “*Regulation shall not apply to food containing both products of plant origin and processed products of animal origin*”. An establishment making such food by the processing of unprocessed products of animal origin, and hence not benefiting from the exemption, would need to handle such food in accordance with Regulation 852/2004 after the animal origin element of it has been processed (e.g. cooked) as Regulation 853/2004 would not apply to it.

#### **A.3.3.2.2: Regulation 853/2004, Article 1(3)(a) and (b): Private Domestic Use / Consumption**

3. *This Regulation shall not apply in relation to:*

*(a) primary production for private domestic use;*

*(b) the domestic preparation, handling or storage of food for private domestic consumption;*

Article 1(3) of Regulation 853/2004 replicates the exemptions at Article 1(2) of Regulation 852/2004 and emphasises the exclusion of these activities from the scope of the EC Hygiene Regulations.

#### **A.3.3.2.3: Definition of Retail**

The following paragraphs contain details of provisions in Regulation 853/2004 which either mention 'retail' or exclude retail activities from the scope of that regulation. It is therefore important, when considering such provisions, to be clear on the definition of 'retail' which is given in Article 3(7) of Regulation 178/2002 is as follows:

*'retail' means the handling and/or processing of food and its storage at the point of sale or delivery to the final consumer, and includes distribution terminals, catering operations, factory canteens, institutional catering, restaurants and other similar food service operations, shops, supermarket distribution centres and wholesale outlets;*

#### **A.3.3.2.4: Regulation 853/2004, Article 1(3)(c), (d) and (e): Direct Supply of Small Quantities**

3. *This Regulation shall not apply in relation to...*

*(c) the direct supply, by the producer, of small quantities of primary products to the final consumer or to local retail establishments directly supplying the final consumer;*

*(d) the direct supply, by the producer, of small quantities of meat from poultry and lagomorphs slaughtered on the farm to the final consumer or to local retail establishments directly supplying such meat to the final consumer as fresh meat;*

*(e) hunters who supply small quantities of wild game or wild game meat directly to the final consumer or to local retail establishments directly supplying the final consumer.*

#### **Article 1(3)(c)**

'Local' should be interpreted in the same way as 'Localised' (see Paragraph 3.3.2.6).

#### **Article 1(3)(d)**

Requirements in respect of those producers benefiting from the exemption afforded by Article 1(d) of Regulation 853/2004 are set out in Regulation 31/ Schedule 5 to the Food Hygiene (England) Regulations 2005.

#### **Article 1(3)(e)**

Guidance on the exemption afforded by Article 1(d) of Regulation 853/2004 is given in Annex 5, Paragraph A.5.3.1 of this Practice Guidance.

#### **A.3.3.2.5: Regulation 853/2004, Article 1(5)(a) and (b): General Retail Exemption**

5. (a) *Unless expressly indicated to the contrary, this Regulation shall not apply to retail.*

(b) *However, this Regulation shall apply to retail when operations are carried out with a view to the supply of food of animal origin to another establishment.....*

The intention of Regulation 853/2004 is to exempt businesses retailing products of animal origin to the final consumer (i.e. the public) and it is meant, in general, to apply to businesses that supply other businesses (e.g. caterers, pubs, restaurants, other retailers).

The effect of the Article 1(5) is that, in general, Regulation 853/2004 does not apply to retailers. The Regulation does, however, apply to a retailer if food of animal origin is supplied to another establishment unless the activities in Article 1(5)(b)(i) or (ii) are undertaken (see following paragraph).

#### **A.3.3.2.6: Regulation 853/2004, Article 1(5)(b)(i) and (ii): Other Retail Exemptions**

(b) *However, this Regulation shall apply to retail when operations are carried out with a view to the supply of food of animal origin to another establishment, unless:*

(i) *the operations consist only of storage or transport, in which case the specific temperature requirements laid down in Annex III shall nevertheless apply;*

or

(ii) *the supply of food of animal origin from the retail establishment is to other retail establishments only and, in accordance with national law, is a marginal, localised and restricted activity.*

#### **Article 1(5)(b)(i)**

Article 5(b)(i) affords an exemption for the supply of food of animal origin from a retail establishment to another establishment. However, retailers benefiting from this exemption must, nonetheless, ensure that there is compliance with relevant temperature requirements in Annex III of Regulation 853/2004.

#### **Article 1(5)(b)(ii)**

Article 5(b)(ii) affords an exemption for retailers otherwise exempt from the requirements of Regulation 853/2004 which allows them to supply food of animal origin from the retail establishment to other retail establishments, but only if this is a marginal and localised and restricted activity.

The concept is described in Recital 13 of Regulation 853/2002 as follows:

*...when the supply of food of animal origin from a retail establishment to another establishment is a marginal, localised and restricted activity. Such supply should therefore be only a small part of the establishment's business; the establishments supplied should be situated in its immediate vicinity; and the supply should concern only certain types of products or establishments.*

#### **'Marginal'**

'Marginal' is described in Recital 13 of Regulation 853/2004 as only a small part of the establishment's business.

[Draft] European Commission Guidance on Regulation 853/2004 provides that 'marginal' may also be interpreted as a "small amount of food of animal origin" in absolute terms, but an interpretation of this phrase in England has been limited only to meat (fresh or processed, excluding wild game meat) and fresh wild game meat [the latter is subject to consultation] (see Annex 5, Paragraph A.5.4.2).

In respect of products of animal origin other than these, Food Authorities should interpret "a small part of the establishment's business" as meaning

***up to a quarter of the business's turnover in terms of food;***

#### 'Localised' / 'Local'

'Localised' is described in Recital 13 of 853/2004 as in the immediate vicinity of the supplying establishment.

Food Authorities should interpret both 'localised' and 'local' as meaning:

***Sales within the supplying establishment's own county plus the greater of either the neighbouring county or counties or 30 miles/50 kilometres from the boundary of the supplying establishment's county.***

In this regard, Food Authorities should interpret "County" as meaning:

***Metropolitan or non-metropolitan counties in England and Wales as defined in the Local Government Act 1972 and London Government Act 1963<sup>37</sup> (e.g. Greater London, North Yorkshire, Leicestershire, Powys), a local authority in Scotland, or an administrative county in Northern Ireland (e.g. Co. Fermanagh).***

This makes allowance for the imbalance between closely spaced urban authorities and widely spaced remote populations, as well as those on the boundaries or bordered by the sea.

#### 'Restricted'

'Restricted' is described in Recital 13 of Regulation 853/2004 as concerning only certain types of products or establishments

Having to list establishments and products is seen as bureaucratic and a potential barrier to trade and there are other legal requirements for traceability of food products.

Food Authorities should interpret "restricted" as relating to either:

- ***Specified product categories (as referenced in Regulation 853/2004 (e.g. dairy products, fishery products))***

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<sup>37</sup> Except that the Isles of Scilly and the combined counties of Mid Glamorgan, South Glamorgan and West Glamorgan shall be regarded as one county each. For some larger authorities in Scotland a finite limit might be considered more appropriate.

- ***The type of establishment supplying the products (e.g. a baker)***
- ***The type of establishment(s) being supplied with the products (e.g. a restaurant).***

In the meat sector, however, the restrictions are in relation to the amounts of meat supplied and the requirement for a 'genuine' retail' outlet (see Paragraph A.5.4.2).

#### **A.3.3.3: Exemptions: Regulation 853/2004, Article 4 (Requirement for Approval)**

##### **A.3.3.3.1: Regulation 854/2004, Article 4**

*...establishments handling those products of animal origin for which Annex III to this Regulation lays down requirements shall not operate unless the competent authority has approved them in accordance with paragraph 3 of this Article, with the exception of establishments carrying out only:*

*(a) primary production;*

*(b) transport operations;*

*(c) the storage of products not requiring temperature-controlled storage conditions;*

*or*

*d) retail operations other than those to which this Regulation applies pursuant to Article 1(5)(b).*

Article 4(2) of Regulation 853/2004 excludes the above activities from the scope of the Regulation.

#### **A.3.4: Conditional Approval**

(Includes the text of Code of Practice, Paragraph 5.1.7)

Article 31(2)(d) of Regulation 882/2004 permits the granting of conditional approval to an establishment, following an on site visit, which does not fully comply with the requirements of food law, but only if the establishment meets all the infrastructure and equipment requirements.

In this context, Food Authorities should consider 'infrastructure' to relate not only to the physical structure of the establishment, but also to the systems and services necessary, for the food business to be able to produce safe food. Such systems would include a procedure or procedures based on the HACCP principles, in accordance with Article 5 of Regulation 852/2004.

Food Authorities should bear in mind that food business operators can only make applications for the *approval* of establishments under their control; the decision whether or not to grant conditional approval to an establishment which does not fully comply rests with the Food Authority. Professional judgement should be used in deciding whether it would be appropriate to grant conditional approval, on a case by case basis.

If conditional approval is granted, a further visit must be carried out within three months of the conditional approval being granted in accordance with Article 31(2)(d) of Regulation 882/2004. This visit should be a secondary inspection (see Paragraph 4.1.3 of the Code of Practice). In appropriate circumstances as

set out in Article 31(2)(d) of Regulation 882/2004, conditional approval may be extended, but this is restricted to a maximum of six months from the date of the initial grant of conditional approval. Professional judgement should be used in deciding whether it would be appropriate to extend conditional approval, on a case by case basis.

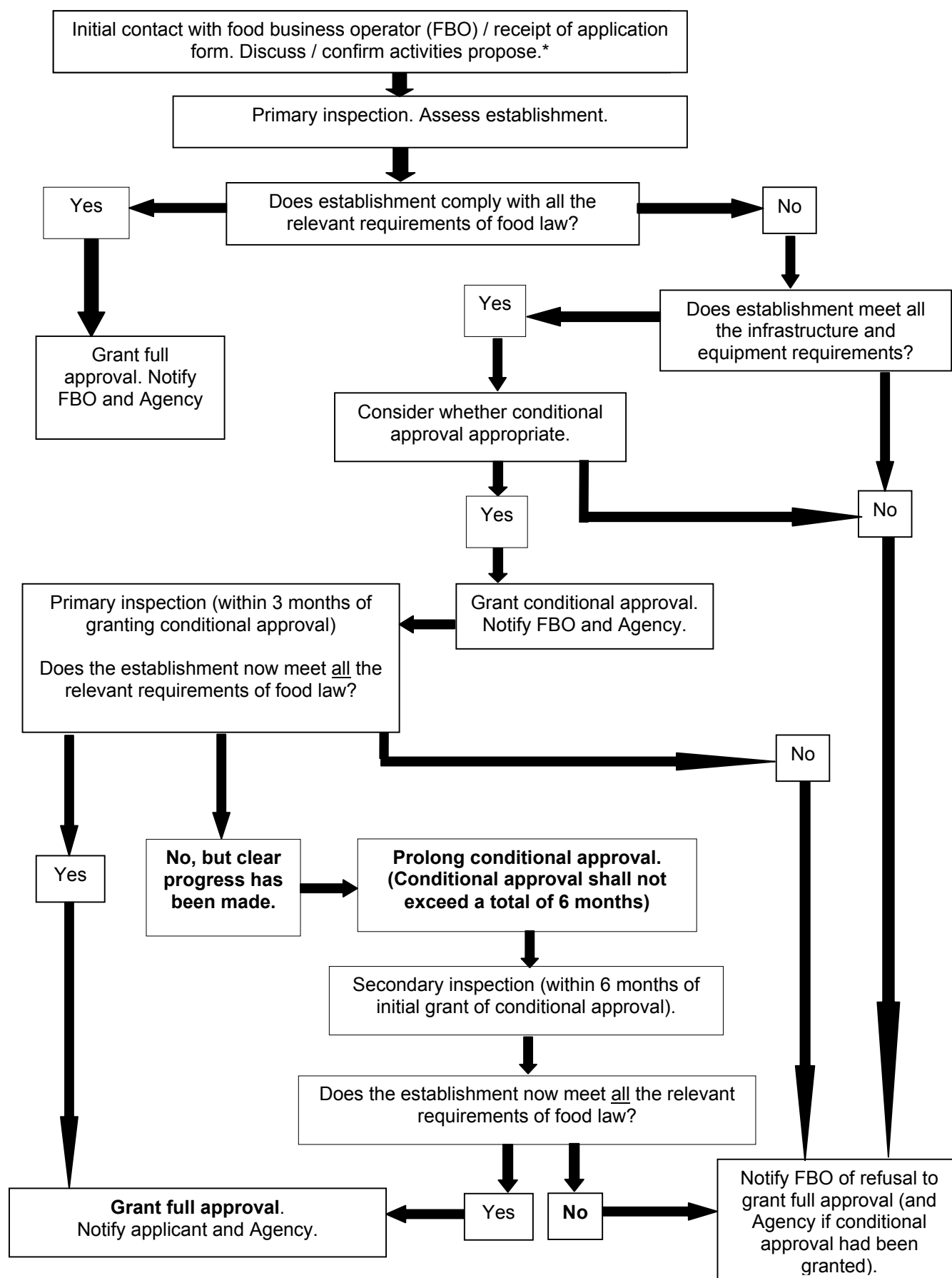
### **A.3.5: Approval Procedures**

(From Code of Practice, Paragraph 5.1.4)

Article 31(2)(a) of Regulation 882/2004 obliges competent authorities to establish procedures for food business operators to follow when applying for the approval of their establishments in accordance with Regulation 853/2004. Procedures for handling applications for approval are set out in Paragraphs 5.1.5 *et seq* of the Code of Practice. Food Authorities should ensure that they, and food business operators, follow these procedures as appropriate. Any deviations from these procedures should be recorded and retained by the Food Authority and should, where possible, be agreed with the Food Authority beforehand.

An overview of the approval process is set out in a flow chart at Annex 4. A series of template forms is also provided at Annex 11 to assist Food Authorities in the administration of approvals. Whilst the content of these documents should be regarded as the minimum required, Food Authorities may adapt them as necessary to meet local requirements.

## ANNEX 4: APPROVAL PROCESS FLOWCHART



\*If application relates to a live bivalve mollusc purification centre, copy application to the Agency for CEFAS consultation.



## **ANNEX 5: MEAT**

### **A.5.1: Guidance**

A Guide to the Food Hygiene and other Regulations for the Meat Industry has been produced for UK meat plant operators, in particular those whose premises require approval and veterinary control.

A working draft of the above Guide can be found on the Agency's website at <http://www.food.gov.uk/foodindustry/meat>.

### **A.5.2: Approval of Establishments**

The Agency will be responsible for approving establishments subject to veterinary control (i.e. slaughterhouses, cutting plants and game handling establishments) as well as any co-located cold stores, meat products, minced meat, meat preparations, mechanically separated meat premises and edible co-products plants. Food authorities will be responsible for approving these establishments when they stand alone, or for registering establishments that are exempt from approval.

### **A.5.3: Enforcement in Meat Establishments**

The Meat Hygiene Service (MHS) is responsible for enforcement in meat establishments that require veterinary control.

#### **A.5.3.1: Co-located Establishments**

The MHS is also be responsible for enforcement in meat products, minced meat, meat preparations, mechanically separated meat plants, cold stores or edible co-products plants that are co-located with an approved slaughterhouse, cutting plant or game handling establishment. (This is a change to the previous arrangement whereby meat products plants co-located with cutting plants were subject to dual Food Authority/MHS enforcement). However, where an establishment handling meat also handles fishery or dairy products, food authorities will retain responsibility for these products.

The term "co-located establishment" should be applied to establishments that require approval, e.g. a slaughterhouse and meat products plant. A butcher's shop attached to a slaughterhouse can be regarded as a separate establishment from the slaughterhouse and remain under Food Authority enforcement.

#### **A.5.3.2: Stand Alone Establishments**

Food authorities will be responsible for enforcement in stand alone establishments that produce meat products, minced meat, meat preparations and mechanically separated meat, and in establishments exempted from approval under Regulation 853/2004.

### **A.5.3.3: Cold Stores**

There is no requirement for veterinary control of cold stores and Food Authorities are responsible for enforcement except where cold stores are co-located with approved slaughterhouses, cutting plants or game handling establishments in respect of which the Meat Hygiene Service is responsible for enforcement.

European Commission guidance advises that cold stores require approval in so far as they are used in relation to activities for which Annex III of Regulation 853/2004 lays down requirements, and it is understood that other Member States intend to approve cold stores. It is therefore intended to ask Food Authorities to approve meat cold stores.

### **A.5.3.4: Wild Game**

Establishments that process wild game for the national market only have been subject to enforcement by Food Authorities. The regulations now require veterinary post-mortem but allow an application to be made to vary the presence of the competent authority.

[DN: The Agency expects to consult on an application to the EU Commission to vary the requirements for game handling establishments producing small quantities (0.5 tonnes per week) of wild game meat from carcasses sourced locally, examined by 'trained persons' and sold locally with a distinctive identification mark. A four year pilot would be proposed].

In the meantime, establishments meeting these criteria should be registered with the food authority and comply with Regulation 852/2004. All other plants require approval and veterinary control.

### **A.5.3.5: Edible Co-products**

Food Authorities are also responsible for enforcement in stand alone establishments producing edible co-products i.e. treated stomachs, bladders and intestines, rendered animal fats and greaves, gelatine and collagen.

Separate guidance on these products can be found on the Agency's website at <http://www.food.gov.uk/foodindustry/meat>.

## **A.5.4: Exemptions from Approval**

### **A.5.4.1: Retail Establishments**

The exemption is for retail establishments that supply products of animal origin to the final consumer, or supply other establishments (including caterers) on a marginal, localised and restricted basis.

A major change as far as butchers are concerned is that, whereas the current definition of "*final consumer*" in the meat hygiene Regulations includes caterers, the definition in the new Regulations does not. "*Final consumer*" is now 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. This means that establishments supplying caterers will be considered to be supplying other establishments as opposed to supplying the final consumer.

The Regulations require establishments that cut meat (that is placed on the market i.e. rather than supplied for further processing.) to be approved as cutting plants and subject to veterinary control, unless that supply is on a marginal, localised and restricted basis. Catering butchers who supply all or most of their production to the catering trade will therefore in principle be subject to approval, as well as retail butchers supplying caterers and/or other establishments in excess of the marginal threshold.

#### **A.5.4.2: "Marginal, localised and restricted"**

Recital 13 of Regulation 853/2004 interprets "marginal" as 'a small part of the establishment's business', but subsequent EU Commission guidance provides that it may also be interpreted as 'a small amount of food of animal origin in absolute terms'. In respect of fresh meat, the terms 'marginal', localised' and 'restricted' should be interpreted as follows:

- **'Marginal'** supply of food of animal origin:
  - (i) Up to a quarter of the business in terms of food; or
  - (ii) In relation to:
    - Meat (fresh or processed, excluding wild game meat) - up to 2 tonnes a week;
    - Fresh wild game meat - up to [0.5 tonnes a week]  
[DN: this is subject to consultation];

subject to the establishment being a genuine retail outlet supplying the final consumer with part of its production of meat or wild game meat. Supply to a final consumer can include mail order and internet sales.

If either applies, the establishment may be exempt from approval under regulation 853/2004 subject to the supply of food of animal origin satisfying 'Localised' and 'Restricted' criteria as below.

"Up to a quarter of the business in terms of food" should be calculated by measuring the amount of food of animal origin supplied to other establishments (including caterers) against the entire business in terms of food (this includes food of any type, e.g. drink, biscuits etc).

- **'Localised'**: supply within the supplying establishment's own county plus the greater of either the neighbouring county or counties or 30 miles/50km from the boundary of the supplying establishment's county;

NB: "County" would be interpreted here as meaning metropolitan or non-metropolitan counties in England and Wales as defined in the Local Government Act 1972 and London Government Act 1963<sup>(1)</sup> (e.g. Greater

London, North Yorkshire, Leicestershire, Powys), a local authority in Scotland, or an administrative county in Northern Ireland (e.g. Co. Fermanagh). This makes allowance for the imbalance between closely spaced urban authorities and widely spaced remote populations, as well as those on boundaries or bordered by the sea. <sup>(1)</sup> Except that the Isles of Scilly and combined counties of Mid Glamorgan, South Glamorgan and West Glamorgan shall be regarded as one county each.

and

- **‘Restricted’:** supply is limited to certain types of products or establishments. In the meat sector, the restrictions are in relation to the amounts of meat supplied and the requirement for a ‘genuine’ retail’ outlet (see ‘marginal’ above).

#### **A.5.4.3: Guidance on the cutting of meat for direct sale by farmers (e.g. at farmers' markets)**

The "marginal, localised and restricted" exemption will 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. As this has a similar effect to the "*Guidance on the cutting of meat for direct sale by farmers*", this guidance becomes obsolete on 1 January 2006.

#### **A.5.4.4: Wild Game**

The exemption is for primary producers supplying small quantities of wild game carcasses either directly to the final consumer or to local retail establishments directly supplying the final consumer. Primary producers can be individual hunters or shooting estates. There is an additional exemption for supply of small quantities of wild game meat supplied either direct to the final consumer or to local retail establishments directly supplying the final consumer. This exemption is available only to the individual hunter who prepares meat from carcasses he has shot himself. Supply to a final consumer can be via mail order and internet sales as well as by delivery/collection. The final consumer does not have to be local to the primary producer.

The UK is interpreting ‘small’ as under 10,000 small wild game and under 300 large wild game a year. The interpretation of “local” is the same as for “localised” (see Paragraph A.4.4.3, above).

The summary table in Appendix 1 to this Annex, provides information on what elements of the various regulations apply to the hunting of wild game and its placing on the market.

Separate guidance on the supply of wild game outside approved premises can be found on the Agency website at <http://food.gov.uk/foodindustry/meat>.

#### **A.5.4.5: On farm slaughter and cutting of small quantities of poultry and lagomorphs**

Article 1(3)(d) of Regulation 853/2004<sup>38</sup> states that the Regulation does not apply to the direct supply, by the producer, of small quantities of meat from poultry or lagomorphs slaughtered on the farm to the final consumer or to local retail establishments directly supplying such meat to the final consumer. Article 1(4) goes on to say that the rules governing the persons and activities benefiting from this exemption (in addition to those set out in Regulation 852/2004) will be set out in national law. These national rules are set out in Schedule 5 to the Food Hygiene (England) Regulations 2005.

##### **A.5.4.5.1: Which producers benefit from this exemption?**

The exemption applies to producers of poultry (i.e. farmed birds except ratites) or lagomorphs (i.e. rabbits, hares and rodents) 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 not be applied absolutely. Annual fluctuations in slaughterings around the 10,000 level are acceptable provided that annual slaughterings are typically no more than 10,000. The limit of 10,000 should be applied to the total number of poultry or lagomorphs slaughtered. For example, a producer slaughtering 6,000 chickens and 2,000 turkeys would be exempt, while another slaughtering 6,000 chickens and 6,000 turkeys would not be exempt.

Although there is no limit to the number of birds or lagomorphs that producers in the second category may slaughter, the Agency anticipates that the restrictions will limit production to relatively small quantities. The purpose of the restrictions on those slaughtering over 10,000 is to allow the exemption to apply only to those producers where the assessed public health risk is likely to be low.

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 Agency can advise in cases of doubt.

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<sup>38</sup> As amended by Article 3 of the Transitional Measures Regulation [Regulation (EC) xxxx/2005]

#### **A.5.4.5.2: Where can the meat be sold?**

Meat produced under this exemption may be supplied:

- direct to the final consumer,
- or
- direct to local retail establishments directly supplying such meat to the final consumer.

In the first category, direct supply to the final consumer would include 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' (see paragraph A4.4.2 above) and, in addition, anywhere within the UK in the two weeks preceding Christmas and Easter and (for geese) Michaelmas (*late September*).

#### **A.5.4.5.3: What rules apply?**

Regulation 852/2004 applies to producers who benefit from this exemption. This includes, among other things, the requirement to maintain procedures based on the HACCP principles and to register the establishment with the local food authority, as well as to comply with general hygiene and training requirements. In addition to this, the national rules in Schedule 5 to the Food Hygiene (England) Regulations 2005 apply. These set out rules on labelling and record keeping.

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 requirement is in addition to any labelling particulars required by the Food Labelling Regulations 1996.

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 fresh 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.

#### **A.5.5: 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, in that plant,

will need to comply with the relevant requirements of Annex III of Regulation 853/2004 for cutting plants, but will not need approval as cutting plants.

#### **A.5.6: Slaughter for private domestic consumption**

Where slaughter is carried out for private domestic consumption and the meat is not placed on the market (whether free of charge or not) such activity falls out of the scope of both Regulation 852/2004 and Regulation 853/2004. However, it is unlawful to supply the meat of cattle, sheep and goats to any third party, including family members, unless the TSE Regulations 2005 and the EU Animal By-Products Regulations 1774/2002 have been complied with. In practice this is only possible if the meat has been slaughtered in an approved slaughterhouse. A more detailed guide is at Appendix 2 to this Annex.

## ANNEX 5, APPENDIX 1: The Wild Game Sector - Which Regulations Apply to Which Activities?

### THE WILD GAME SECTOR: WHICH REGULATIONS APPLY TO WHICH ACTIVITIES?

WHICH REGULATION IS APPLICABLE?	Regulation 852/2004	Regulation 853/2004	Regulation 854/2004
<b>ACTIVITY</b>			
Shooting for own consumption	No Art 1.2a exemption	No Art 1.3a exemption	No
<b><u>Supply direct to final consumer or to local retailers (directly supplying final consumer) of small quantities of:</u></b>			
<i>a) whole carcasses by primary producer (hunter or estate)</i>	No Art 1.2c exemption National rules apply <sup>1</sup>	No Art 1.3c exemption	No
<i>b) meat from carcasses (produced by hunter from own shooting)</i>	Yes Premises to be registered as food business <sup>4</sup> and to operate under Annex II	No Art 1.3e exemption National rules apply <sup>1</sup>	No
<i>c) meat from carcasses (produced by estate, shot by others)</i>  • This is a type of approved game handling establishment (AGHE)	Yes	<b>Yes<sup>2</sup></b> Premises to be approved by CA <sup>3</sup>	<b>Yes<sup>2</sup></b>
1. <b><u>Supply of whole carcasses to approved game handling establishments (AGHEs) either direct from shoot or from game larder operated by primary producer</u></b>	Yes Premises to be registered as food business <sup>4</sup> and to operate under Annex I	Parts relating to primary producer ("trained person" <sup>5</sup> ) requirements and hygiene practices e.g. initial handling, temperature controls and transport)	Parts relating to primary producer's documentation and hygiene practices, including OV <sup>6</sup> examination of "trained person" <sup>5</sup> information
2. <b><u>Supply of whole carcasses to approved game handling establishments (AGHEs) not by the primary produce</u></b>	Yes Premises to be registered as food business <sup>4</sup> and to operate under Annex II (including any game larders and vehicles)	Parts relevant to documentation originally supplied by "trained person" <sup>5</sup> , plus temperature controls, hygienic handling and transport	Parts relevant to supplier's hygiene practices, plus OV <sup>6</sup> to check supply of documentation from "trained person" <sup>5</sup>
3. <b><u>All other (non-retail) establishments preparing wild game meat for placing on the UK domestic or export market</u></b>  • These are approved game handling establishments (AGHEs)	Yes	Yes Premises to be approved by CA <sup>3</sup>	Yes

<sup>1</sup> Food Safety Act 1990 (as amended by General Food Law Regulation 2005). "Small quantities" limits currently set by Food Standards Agency (after consultation with stakeholders) as 10,000 small wild game carcasses per year or 300 large wild game carcasses per year (subject to review in due course)

<sup>2</sup> [Insert derogation details when/if appropriate]

<sup>3</sup> Competent Authority (i.e. the Food Standards Agency)

<sup>4</sup> By the Local Authority

<sup>5</sup> Either the gamekeeper or game manager on the hunting party/in the immediate vicinity or a hunter who has completed training provided to the satisfaction of the Competent Authority (see H2, Annex III, Section IV, Chapter I)

<sup>6</sup> Official Veterinarian



## **ANNEX 5, APPENDIX 2: Private Slaughter of Livestock - Guidance for Food Authorities In England**



### **PRIVATE SLAUGHTER OF LIVESTOCK GUIDANCE FOR FOOD AUTHORITIES IN ENGLAND**

#### Introduction

Private slaughter is the killing of an animal for the personal consumption of the owner. Such slaughter and consumption is often considered to be a human right of the animal's owner, although the lawful options for carrying this out have not always been clear either for the owner or for the enforcement authorities.

2. It is fundamental to the operation of the Hygiene Regulations<sup>39</sup> that the slaughter of animals intended for placing on the market for human consumption must, in almost all cases, take place in an approved slaughterhouse or, in the case of farmed game and poultry, in an authorised on farm farmed game and poultry slaughter facility. Such slaughter would, among other things, be subject to ante mortem and post mortem inspection by the Meat Hygiene Service or, in the case of on farm slaughter, to an ante mortem inspection by an approved veterinarian. Private slaughter in an approved slaughterhouse is lawful. It does not necessarily follow, however, that all private slaughter outside an approved slaughterhouse would be unlawful. That is because the Hygiene Regulations apply to meat intended for placing on the market for human consumption. Thus private slaughter outside an approved slaughterhouse would in principle be lawful if it was not intended that placing on the market of the meat should take

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"Regulation A" means Commission Regulation (EC) No. [ ]/2005 implementing Regulation (EC) No. 853/2004 of the European Parliament and of the Council as regards special guarantees concerning salmonella for consignments to Finland and Sweden of certain meat and eggs<sup>(39)</sup>;

"Regulation B" means Commission Regulation (EC) No. [ ]/2005 on microbiological criteria for foodstuffs<sup>(39)</sup>;

"Regulation C" means Commission Regulation (EC) No. [ ]/2005 laying down implementing measures for certain products under Regulation (EC) No. 853/2004, for the organisation of official controls under Regulations (EC) Nos. 854/2004 and 882/2004, derogating from Regulation (EC) No. 852/2004 and amending Regulations (EC) Nos. 853/2004 and 854/2004<sup>(39)</sup>;

"Regulation D" means Commission Regulation (EC) No. [ ]/2005 laying down specific rules on official controls for *Trichinella* in meat<sup>(39)</sup>; and

"Regulation E" means Commission Regulation (EC) No. [ ]/2005 laying down transitional arrangements for the implementation of Regulations (EC) No. 853/2004, (EC) Nos. 854/2004 and 882/2004 of the European Parliament and of the Council and amending Regulations (EC) Nos. 853/2004 and 854/2004<sup>(39)</sup>.

place. This guidance therefore explains what placing on the market means in this context. The guidance also explains how Transmissible Spongiform Encephalopathy (TSE) controls affect the lawful options for private slaughter.

Food Authorities are responsible for enforcing the Regulations which in England provide for the enforcement of the Hygiene Regulations, namely the Food Hygiene (England) (No.2) Regulations [state SI No. once available] (“the No.2 Regulations”) outside approved premises. They may, when carrying out inspections pursuant to those Regulations outside approved premises, certify that meat has not been produced, processed or distributed in accordance with those Regulations. Such meat would then be treated as failing to comply with food safety requirements under section 9 of the Food Safety Act and an order for its condemnation could therefore be obtained from a Magistrates’ Court. In carrying out this enforcement role, Food Authorities may on occasion need to liaise either with the Meat Hygiene Service (in relation to activities in approved plants) and with the Food Standards Agency (in relation to approval status). A list of contact points for both is at Annex A.

### **Public Health Risks**

4. Slaughter outside approved premises is likely to carry a greater public health risk than slaughter in approved premises. There are a number of reasons for this:

- (a) such slaughter would take place without official Meat Hygiene Service ante mortem and post mortem inspection and supervision;
- (b) such slaughter might also be carried out without observing the TSE controls.
- (c) the skill levels of the personnel involved may be lower;

In addition, such slaughter is difficult for enforcement authorities to monitor given that they will often not know where and when it might take place. This difficulty increases the risk that (supposedly) privately slaughtered meat could be unlawfully diverted for placing on the market for human consumption. This increased risk is of particular concern when, as noted at (b) above, some private slaughter might not observe the TSE controls.

### **The Legal Position**

5. The guidance on the legal position that follows represents the Agency’s best understanding of a complex area of law. It is, of course, subject to the caveat that only the Courts can determine the true meaning of the law in this area. However, several convictions and other court rulings have now been secured on the basis of the Agency’s understanding of the law.

4. Article 4 of EC Regulation 853/2004 provides that no person shall carry on the business of a slaughterhouse or place on the market products of animal origin for human consumption unless the premises are approved under that Regulation (exception – see paragraph 10 below). The legality of slaughter outside approved premises therefore depends on whether placing on the market is intended. “Placing on the market” is widely defined for the purposes

of the Hygiene Regulations to mean “the holding of food for the purposes of sale, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution and other forms of transfer themselves”. The transaction underlying a private slaughter (i.e. the supply of a carcase back to the owner) in general amounts to placing on the market under the above definition because:

- (a) in general there would be the supply of food in the course of a business;
- (b) such supply would in essence amount to a contract for the supply of goods, rather than of services, in that what is returned after slaughter (i.e. the carcase or dressed meat) is fundamentally different in kind from what was delivered to the slaughterhouse or slaughterman (i.e. the live animal); and
- (c) as already stated, the No.2 Regulations implement the Hygiene Regulations. The Hygiene Regulations apply to the production and placing on the market of all meat intended for human consumption and contain no derogation for private slaughter (other than that described in paragraph 11 below).

7. The TSE (England) Regulations 2005, which came into effect on 1 January 2006 make provision for the enforcement of EC Regulation 999/2001 on Transmissible Spongiform Encephalopathies (TSE). That Regulation in effect resulted in a change to the position as to private slaughter. Like all EC Regulations it is directly applicable in all Member States (i.e. it is automatically the law in those States with effect from the date from which it applies).

8. As far as private slaughter is concerned, the EC TSE controls apply to the extent provided for by Regulation 999/2001. That Regulation, like the Hygiene Regulations, applies to “placing on the market” and defines that term in a similar way to the corresponding definition applicable to the Hygiene Regulations as explained in paragraph 6 above. It applies not only when a sale of meat for human consumption takes place, but also where there is supply to a third party in the community. This means that the controls apply in all situations where a third party is involved. **It is, therefore, no longer lawful for the farmer to supply privately killed meat to the rest of his household without the TSE Regulations having been applied, as they are considered to be a third party.** The only exception is a truly private kill where a farmer slaughters the animal himself, processes it himself, and consumes it himself.

9. The TSE Regulation **only** applies to those TSE susceptible species under SRM controls: bovine, ovine and caprine species. Porcine species, poultry, farmed game species and rabbits are not under SRM controls and may be supplied by a farmer to the rest of his household - though not to any other third party. Neither the Hygiene Regulations nor the No.2 Regulations will change the requirements of Regulation 999/2001. This means that any slaughter of an animal for placing on the market for human consumption would need to take place in an approved slaughterhouse, as now.

10. There are some circumstances where poultry and lagomorphs do not have to be slaughtered in an approved slaughterhouse in order for their meat to be lawfully placed on the market for human consumption. Article 1(3)(d) of Regulation 853/2004 states that the Regulation does not apply to the direct supply, by the producer, of small quantities of meat from poultry or lagomorphs slaughtered on the farm to the final consumer or to local retail establishments directly supplying such meat to the final consumer as fresh meat. Article 1(4) goes on to say that the rules governing the persons and activities benefiting from this exemption (in addition to those set out in Regulation 852/2004) will be set out in national law. These national rules are set out in Schedule 5 to the No.2 Regulations. (Section 1 of On farm slaughter of small quantities of poultry and lagomorphs Meat Guidance)

11. There is also legislation to protect the welfare of farmed livestock (both red meat animals and poultry) during the slaughter or killing process. Whenever such livestock is slaughtered (death caused by bleeding after stunning) or killed (immediate death), it must be carried out in accordance with the Welfare of Animals (Slaughter or Killing) Regulations 1995 (as amended). This is enforced by the Meat Hygiene Service in approved slaughterhouses. . Outside approved premises i.e. on farm, the Regulations are enforced by the State Veterinary Service. These Regulations make it an offence to cause or permit any avoidable excitement, pain or suffering to any animal or bird during the slaughter or killing process. They also require everyone carrying out such operations to have the knowledge and skill necessary to perform the tasks humanely and efficiently in accordance with the Regulations. Only the permitted stunning and killing methods laid down in the Regulations may be used. The Regulations also require most people involved in the slaughter or killing process to be licensed, although there are a number of exemptions from this requirement. These exemptions include:

- (i) the slaughtering or killing of an animal or bird by the owner for his/her private consumption;
- (ii) the use of a free bullet to kill an animal in the field; and
- (iii) the killing of a bird by dislocation of the neck on premises on which the bird was reared.

The Department for Environment, Food and Rural Affairs is responsible for legislation on animal health and welfare. The relevant contact point is at Annex A. Furthermore, the Humane Slaughter Association has produced a leaflet entitled On-farm slaughter of Livestock for Consumption. This provides detailed information on legislation and best practice for farmers on humane slaughtering on farm. The relevant contact point is also at Annex A.

### **Examples illustrating what the legal requirements mean in practice**

12. The following examples illustrate the consequences of the legal requirements in practical terms. In the examples in paragraphs 13 to 17, the competent enforcement authority would be the relevant Food Authority. The Meat Hygiene Service would be the enforcement authority in the example in paragraph 18 in respect of slaughter and dressing in approved premises.

### **Slaughter on-farm by the Farmer for his own consumption only**

13. This is **lawful**. There is no placing on the market here. Thus the Hygiene Regulations and TSE Regulations would not apply. This means that it would be lawful for the farmer to slaughter his animal for his own consumption (even if it was born or reared in the UK before 1 August 1996 in the case of a bovine). At its most extreme this means that a farmer could lawfully slaughter his own pre - 1 August 1996 cow without BSE testing and consume any part of it, including those parts of it which would otherwise have been classed as SRM (e.g. the brain), notwithstanding the risks to his health that this might entail. Nevertheless any part of the carcass (including blood) that the farmer chose not to consume would be classed as animal by-products under the EC Animal By-Products Regulation (1774/2002). The waste material would have to be disposed of in line with that Regulation. (As with the SRM controls, it is local authorities that have enforcement responsibility for the Animal By-Products Regulation outside approved premises. However, depending on local circumstances, these functions may be carried out separately by Environmental Health and Trading Standards Departments, thus necessitating effective liaison. Guidance was issued for local authorities by the FSA on specified risk material and other BSE controls in April 2004 [DN: A review of the guidance is currently underway so a revised version may be issued before the end of 2005]. The Department for Environment, Food and Rural Affairs is responsible for legislation on the disposal of animal by-products. Contact point: see Annex A). It would be **unlawful** for the farmer to place on the market any part of such an animal, as it would not have been subject to any of the general meat hygiene and TSE controls and would not have been health marked. It would also be **unlawful** for the farmer to have an animal that he had slaughtered on farm cut up by a butcher.

### **Slaughter on-farm by the Farmer for consumption by his immediate family living in the same household**

14. Under EC Regulation 999/2001 this option is in effect unlawful for TSE susceptible species i.e. bovines, ovines and caprines. This is because, as already stated, the Regulation applies not only when a sale takes place, but also where there is supply to a third party, (which includes supply to the farmer's family). That means that the Regulation applies in all situations where a third party is involved - i.e. the only exception is a truly private kill where a farmer slaughters the animal himself and consumes it himself. **It is, therefore, no longer possible for the farmer to supply privately slaughtered meat to the rest of his household without the TSE controls having been applied.**

### **Slaughter on-farm by the Farmer for consumption at his bed and breakfast enterprise**

15. This is **unlawful** (other than in the case described in paragraph 10). The farmer is supplying the meat in the course of his business i.e. he is carrying out the slaughter of his animal with the intention of supplying it to the guests in his bed and breakfast business. This would amount to the offence of contravention of Article 4 of EC Regulation 853/2004.

### **Slaughter on-farm by an Itinerant Slaughterman**

16. It is **unlawful** for a farmer to use the services of an itinerant slaughterman both to kill his animal and to dress it. This is because (as explained at paragraph 6(b) above) the slaughterman would be supplying goods (i.e. a dressed carcass) in the course of his business. The slaughter and the supply of the dressed carcass back to the farmer would give rise to a number of offences under Article 4 of EC Regulation 853/2004, as would any subsequent placing on the market. If, however, the slaughterman did no more than kill the animal for the farmer, leaving the farmer to dress and cut the carcass, the Courts might be less likely to conclude that the slaughterman was supplying goods (and more likely to be supplying services). If so, this activity might be held to be **lawful**, (i.e. neither the Hygiene Regulations nor the TSE Regulations would prohibit it) although the issue is far from clear.

### **Slaughter in Other Unapproved Premises**

17. This is **unlawful** (other than in the case described in paragraph 10). Unapproved premises here could include any place used for slaughtering animals other than an approved slaughterhouse (e.g. field, barn, warehouse, vehicle, unapproved slaughterhouse). Other than in the example quoted at paragraph 13 (where the farmer is slaughtering an animal for consumption by himself), the operator of the unapproved premises would be supplying goods (i.e. meat) back to the farmer in the course of the operator's business. There would therefore be placing on the market. The slaughter would then amount to an offence, as would any subsequent sale under Article 4 of EC Regulation 853/2004.

### **Private Slaughter in an approved Slaughterhouse**

18. This is **lawful**. Private slaughter of an animal (excluding a bovine born before or reared in the UK before 1 August 1996) may lawfully take place in an approved slaughterhouse. The slaughterhouse is supplying the farmer with the meat from his animal in the course of its business, so there is placing on the market. The Hygiene Regulations and, where relevant, the SRM controls and the OTM BSE testing therefore apply, and these are all enforced within approved slaughterhouses. This means, furthermore, that should the farmer decide not to consume the meat from his animal but rather to place it on the market (e.g. in his farm shop or bed and breakfast enterprise) it would be **lawful** for him to do so as the meat would have been produced lawfully and would have been health marked as fit for human consumption. This would, however, be subject to compliance with the relevant provisions of the Hygiene and TSE Regulations as well as the No.2 Regulations. This includes the requirement that any subsequent cutting for placing on the market should take place in an approved cutting plant.

19. A Question and Answer brief is attached at Annex B. This attempts to answer some of the questions which local authorities are likely to be asked by the public more frequently.

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**Food Standards Agency  
October 2005**

## ANNEX 5, APPENDIX 2, ANNEX A

### Contact Points

#### **Meat Hygiene Service Regional Directors**

**Northern Region** (part of Cumbria, Durham, Humberside, Lancashire, Greater Manchester, Northumberland, Tyne and Wear, Yorkshire)

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**Central Region** (part of Bedfordshire, Cambridgeshire, Cheshire, Derbyshire, Essex, Hertfordshire, Leicestershire, Lincolnshire, Merseyside, West Midlands, Norfolk, Northamptonshire, Nottinghamshire, North Shropshire, Staffordshire, Suffolk, Warwickshire)

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**South and West Region** (Avon, part of Bedfordshire, Berkshire, Buckinghamshire, Cornwall, Devon, Dorset, part of Gloucestershire, Hampshire, Kent, Greater London, Oxfordshire, Wiltshire, Surrey, Somerset, Sussex)

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**Wales** (including parts of Gloucestershire, Hereford & Worcester, Shropshire)

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**ANNEX 5, APPENDIX 2, ANNEX B**

**PRIVATE SLAUGHTER OF LIVESTOCK**

**QUESTIONS AND ANSWER BRIEF**

**Consumers**

**1. *Is meat from privately slaughtered animals safe?***

Meat slaughtered outside an approved slaughterhouse is likely to carry a greater public health risk than that slaughtered inside, for a number of reasons:

- (a) such slaughter would take place without official Meat Hygiene Service ante- mortem and post-mortem inspection and supervision;
- (b) such slaughter might also be carried out without observing the TSE controls;
- (c) the skill levels of the personnel involved may be lower.

**2. *Can someone supply me with privately slaughtered meat?***

No. Under the TSE (England) Regulations 2005, a farmer can only supply beef, sheep or goat meat to you if the EC Regulation 999/2001 has been observed. In practical terms the 2005 Regulations can only realistically be complied with in approved slaughterhouses.

If, however, the farmer had his or her animal slaughtered in an approved slaughterhouse, it would be lawful for the farmer to supply the resulting meat direct to you e.g. as a gift or through his or her farm shop or bed and breakfast enterprise (see below).

**3. *How can I be sure that the meat I buy wasn't slaughtered illegally?***

If meat was slaughtered and prepared lawfully in approved premises, it will bear the health mark. Where meat is pre-packed (e.g. in a supermarket) the identification mark will normally be printed on the packaging. The health mark is applied to the carcass before it is cut. The health mark has "UK" at the top, "EC" at the bottom, and the approval number of the plant in the middle. Emergency slaughter meat must bear "a special health mark" which cannot be confused with health mark or identification mark.

Where meat is placed on the market unpackaged, for example in a butcher's shop or delicatessen, the health mark will not usually be visible to the purchaser. You could, however, ask to see evidence of the health mark, for example on the packaging that was used to deliver the meat to the shop or on parts of the carcass that have not yet been cut.

## **Farmers**

### **4. *Can I eat any meat from my own animals?***

Yes, but you must ensure that your animal is slaughtered and prepared lawfully (see below).

### **5. *How should I have my own animals slaughtered for my own consumption?***

There are two lawful ways in which to have your animals slaughtered and prepared for your own consumption:

- (a) in an approved slaughterhouse; or
- (b) on your farm by *yourself*.

The Food Standards Agency advises that option (a) would generally carry a lower risk to your health than option (b).

If you choose option (b), it would be unlawful in all cases to employ anyone else - including a slaughterman. It would also be unlawful to have the animal slaughtered anywhere else away from the farm, other than in an approved slaughterhouse.

### **6. *What should I do with the waste material?***

If you chose option (b) above and slaughtered the animal yourself on your farm, any part of the carcass you chose not to consume would be classed as animal by-products under the EU Animal By-Products Regulation (EC) No.1774/2002. The waste material would have to be disposed of in line with the Regulation, for example by arranging for the material to be rendered or incinerated. Your local Animal Health Office or local authority trading standards department (or, in some cases, environmental health department) can advise on what your options would be.

### **7. *Can I place on the market the meat from my own animals?***

No, not if you have chosen option (b) above – furthermore, you would not, realistically, be able to even offer your beef, sheep or goat meat to members of your immediate family living in your household, or to colleagues within your business – e.g. partners – or their immediate family living within their household.

If however you have chosen option (a) above, it would be lawful for you to retail the meat, for example in your farm shop or your bed and breakfast enterprise.

**8. *Does the restriction of supplying privately slaughtered meat apply to partnerships or joint owners?***

(This covers two separate areas of law; national legislation concerning partnerships, and EC law as regards private kills and dealing with SRM in certain types of animals)

Yes. It is unlikely that a Court would decide that a private kill (which, but for the involvement of a partnership, would be unlawful under the EC Regulation 853/2004 and, the TSE (England) Regulations 2005) would be rendered lawful, simply because the supply was carried out within a partnership.

In considering the legislation defining 'partnerships' and 'persons' it is recognised that, whilst a partnership is a separate entity, it is comprised of individual partners. They would be considered 'persons' for the purposes of the Regulations. Furthermore, it is thought likely that the courts would be mindful of their obligation to construe national legislation in line with EC requirements wherever possible.

Therefore, whilst the owner of an animal is free, if he so wishes, to privately slaughter and consume the meat from that animal himself, he cannot lawfully provide any of that meat to any other person, even a co-owner of that animal, as this would still constitute supplying a third party and would therefore be unlawful.

**9. *What about controls for privately slaughtered pigs?***

The TSE Regulation **only** applies to those TSE susceptible species under SRM controls: bovine, ovine and caprine species. Porcine species, poultry, farmed game species and rabbits are not under SRM controls and may be supplied by a farmer to the rest of his household - though not to any other third party. Neither the Hygiene Regulations nor the No.2 Regulations will change the requirements of Regulation 999/2001. This means that any slaughter of an animal for placing on the market for human consumption would need to take place in an approved slaughterhouse, as now.

**10. *Why did the position change?***

The TSE (England) Regulations 2005 provide the arrangements for the enforcement of directly applicable EC Regulation 999/2001 as amended. Under that Regulation supply against payment or free of charge to a third party is regarded as "placing on the market". If placing on the market takes place the TSE Regulations must be applied to the kill. Therefore from April 2002 you are not realistically able to offer beef, sheep or goat meat from animals slaughtered on your farm to your immediate family or household as it is not possible to comply with the TSE Regulations outside of an approved slaughterhouse.

EU Regulation 999/2001 was introduced to provide harmonised rules for the prevention, control and eradication of certain TSEs which are applicable in all Member States.

**Approved slaughterhouse operators**

**11. *Can I undertake a private kill for a farmer?***

Yes. A private kill would be subject to exactly the same rules and procedures as a conventional (commercial) kill.

**12. *Can a farmer have an animal privately slaughtered other than in an approved slaughterhouse?***

No, other than by himself or herself on farm (see Question 5 above). There is, however, an exemption which allows a farmer to slaughter on his holding small quantities of poultry or lagomorphs reared there and place them on the market for human consumption, subject to certain conditions. (*See On farm slaughter of small quantities of poultry and lagomorph Meat Guidance*).

**Food Standards Agency  
October 2005**

## **ANNEX 6: LIVE BIVALVE MOLLUSCS**

### **A.6.1: Introduction**

This Annex provides specific guidance to Food Authorities on the application and enforcement of the live bivalve mollusc aspects of Regulations 852/2004, 853/2004 and 854/2004. In line with Annex III, Section VII(1) of Regulation 853/2004, references to live bivalve molluscs in this Annex also include live echinoderms, tunicates and marine gastropods, with the exception of guidance on the provisions on the purification of live bivalve molluscs.

### **A.6.2: Competent Authority**

The Food Standards Agency is the UK central competent authority with lead responsibility for these Regulations. Food Authorities are responsible for enforcement of the Regulations at local level.

### **A.6.3: The Local Market Exemption**

Regulation 853/2004 does not apply to the direct supply of small quantities of live bivalve molluscs to the final consumer or to local retail establishments directly supplying the final consumer. For live bivalve molluscs, a small amount is a total amount of not more than 25 tonnes of fishery products in a calendar year. The total amount may be made up of any species with the exception that the total amount shall not exceed the maximum amount for the following species:

### **A.6.4: Table**

<b>Species</b>	<b>Annual Maximum amount</b>
Cockles	25.0 tonnes
Oysters	5.0 tonnes
King Scallops	5.0 tonnes
Queen Scallops	10.0 tonnes
Mussels	20.0 tonnes
Other Live Bivalve Molluscs	10.0 tonnes
Marine Gastropods	20.0 tonnes

While Regulation 853/2004 does not apply to this allowance it is still the responsibility of the harvester to ensure that the live bivalve molluscs meet the end product standards set down for placing them on the market. Any amount of the catch which include live bivalve molluscs must have originated from an 'A' class area, which designates the product as suitable for placing on the market with no further treatment required.

### **A.6.5: Heat Treatment**

Live Bivalve Molluscs which are to undergo an approved heat treatment process or other processing, e.g. freezing, are subject to the requirements of Regulation 853/2004 that relate to live bivalves up to the point where

processing begins in an approved establishment. After that point they are considered to be fishery products.

The controls that must be exercised over any heat treatment process for bivalve molluscs from Class B or Class C areas are set out in Annex II, Section VII, Chapter II of Regulation 853/2004.

#### **A.6.6: Shellfish Liaison Arrangements**

The Food Authority's shellfish liaison officer will be the Agency's first point of contact in relation to non-routine matters concerning the enforcement of the Regulations.

It is essential for the effective enforcement of the Regulations that adjoining Food Authorities, including Port Health Authorities, in England and Wales maintain effective liaison arrangements.

All Food Authorities in England and Wales in areas in which there are commercial live bivalve mollusc harvesting activities should maintain, participate in, and be represented at a local shellfish liaison group.

Each local shellfish liaison group should also include representatives of other relevant local and national organisations, including the Chief Fishery Officer of the local Sea Fisheries Committee, the Environment Agency, the DEFRA Sea Fisheries Inspectorate and the Health Protection Agency (or a representative of the microbiology laboratory used by the Food Authorities if it is not an HPA laboratory).

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 live bivalve mollusc relaying areas (if any) (working with the industry);
- Joint sampling plans to monitor the quality of live bivalve molluscs from designated areas (and new production areas);
- Arrangements for the issue of registration documents;
- Arrangements for the making of Temporary Prohibition Orders covering waters from more than one Food Authority area;
- Arrangements for the detention/recall of bivalve molluscs affected by any Temporary Prohibition Order;
- Effective local notification procedures to advise interested parties of action taken under the Regulations (where such notification is required by the Regulations);

- Co-ordination of local monitoring procedures to ensure compliance with the requirements of the Regulations.

### **A.6.7: Notification of Designated Live Bivalve Mollusc (LBM) Production Areas and Relaying Areas**

The Agency will supply a list of designated live bivalve mollusc production and relaying areas to Food Authorities annually and, where necessary, additions and changes to the lists during the year.

Food Authorities should forward relevant details of designated LBM production areas and approved relaying areas to members of the local shellfish industry, including harvesters, handlers, operators of dispatch and purification centres and other individuals and organisations likely to be substantially affected by the designation of bivalve mollusc production areas and approved relaying areas.

It may be necessary from time to time for the Agency to re-classify a bivalve mollusc production area. Relevant Food Authorities will be informed by the Agency whenever this is done. Food Authorities should forward all public information concerning the re-classification of production areas to members of the local shellfish industry as described above.

### **A.6.8: Monitoring of Registration Documents**

Food Authorities should be aware of the commercial advantages of abusing the registration document procedure, e.g. by suggesting that live bivalve molluscs have been taken from waters producing molluscs with a better microbiological quality.

It is not possible for Food Authorities to monitor every landing in their areas, or to detect abuses in the use of registration documents by concentrating resources at this point.

An appropriate system of monitoring for batches described as being from class A, B and C areas is to take samples and consider the test results against the standards referred to in Section VIII of Chapter V of Regulation 853/2004. On a cautionary note, it should be recognised that shellfish *E. coli* monitoring from any one production area may show significantly variable results, both temporally and spatially, due to environmental and other factors e.g. class C areas may 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 should not be considered conclusive proof that the batch originated from the same class of production area.

Food Authorities will find that liaison with other statutory inspectorates e.g. the Sea Fisheries Inspectorate and the local Sea Fisheries Committee is helpful in monitoring the harvesting of live bivalve molluscs and other shellfish.

The registration document in respect of each batch of shellfish must be date stamped on delivery of the batch to a dispatch centre, purification centre, relaying area, or processing plant by the operator of the centre or area.



Operators are required to retain registration documents for at least 12 months. Gatherers are also obliged to keep a copy of completed movement documents for the same period.

#### **A.6.9: Sampling by Operators**

Operators of approved purification / dispatch centres should also have adequate laboratory arrangements to ensure that the live bivalve molluscs comply with the microbiological standards set out in Section VIII of Chapter V of Regulation 853/2004.

Officers should be aware that the Regulations do not prescribe a frequency for these microbiological tests.

In determining what level of sampling is appropriate, Food Authorities should have regard to any advice issued by the Agency or LACORS or contained in voluntary guidelines produced by relevant trade associations.

#### **A.6.10: Laboratories Used in Connection with Dispatch or Purification Centres**

Laboratories used by operators of dispatch or purification centres to examine samples to meet their obligations Section VIII of Chapter V of Regulation 853/2004 must be recognised by the Food Authority. The laboratory may be directly associated with the approved centre, or may be a Health Protection Agency (HPA) Food Examiner, or any other appropriate laboratory.

However, recognition by the Food Authority will depend on the laboratory using methods for microbiological examination that are acceptable to the Agency. The current recognised method 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. Food Authorities may also wish to consider whether the laboratory is/should be accredited for the relevant method(s) and participates in a recognised external quality assurance scheme such as is run by the HPA. The current method specified in the Regulation is a five tube, three dilution, Most Probable Number (MPN) test.

#### **A.6.11: Sampling of Live Bivalve Molluscs by Food Authorities**

Sampling by Food Authorities should be aimed at verifying the results of tests carried out by producers and operators of centres. Test results that are inconsistent with those shown in the centre’s own records should be followed up by further investigations and tests.

#### **A.6.12: Information on Standards to be Applied**

Information on the standards required by the Regulations may be found in a series of operating manuals for the different types of purification system used in the UK and a further guidance document “Procedures to Minimise Risks to Food Safety in Bivalve Mollusc Purification” published by the Sea Fish Industry Authority (Seafish). These documents contain recommendations designed to

help shellfish processors achieve high quality standards, as well as to comply with the requirements of the Directive. 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 [www.seafish.org](http://www.seafish.org).

Food Authorities may refer to the guidelines to establish a consistent approach to the requirements of the Regulations but should avoid using, in support of formal enforcement action, those parts that are directed towards the achievement of good industry practice and high quality standards.

#### **A.6.13: Molluscs and Other Shellfish Which Fail to Satisfy Requirements**

In accordance with Regulation 27 of the Food Hygiene (England) Regulations 2005, any live bivalve molluscs or other shellfish that have not been produced, processed or distributed in accordance with the Regulations may be treated, for the purposes of Section 9 of the Food Safety Act 1990 as failing to comply with food safety requirements and may be seized and taken before a Justice of the Peace to be condemned, implementing Directive 91/67/EEC on the animal health conditions governing the placing on the market of aquaculture animals and products.

#### **A.6.14: Transfer of Seed Molluscs to Designated Production Areas**

Live bivalve molluscs may be transferred from areas that are not designated as production areas for “growing on” within a production area of any Class. Such molluscs must be genuine “seed shellfish”. 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.

Transfers of “seed bivalve molluscan shellfish”, i.e. immature bivalve molluscs taken from an unclassified area, to be used to seed a classified production area are permitted, provided that they remain in the designated production area for a period of not less than six months before they are harvested for human consumption. This does not permit the movement of adult or partially developed bivalve molluscan shellfish from an unclassified area for further short-term growth before marketing. It is restricted to the seeding of new areas or the re-seeding of existing classified production areas. If new areas are seeded they must be classified before harvesting can take place. Harvesters should inform the relevant Food Authority if any such movements are contemplated.

#### **A.6.15: Temporary Prohibition Orders**

(See also Chapter 5.3 of the Code of Practice)

A Food Authority may make a Temporary Prohibition Order to prohibit the collection of any live bivalve molluscan shellfish from a production area. An Order may be made if the Food Authority is satisfied that the consumption of bivalve molluscan shellfish taken from the area is likely to cause a risk to public health. A Temporary Prohibition Order will cease to have effect 28 days after

the making of the Order. Such an Order might be considered appropriate where, for example, the designated mollusc production area was subject to sudden or accidental pollution which affected the quality of the production area. Temporary Prohibition Orders may also be appropriate where there is a local problem with chemical contamination or toxin producing plankton

There may also be circumstances when it would be appropriate for the Food Authority to consider seeking the opinion of appropriate experts such as the consultant in communicable disease control and consultant microbiologist at the HPA.

A model Temporary Prohibition Order can be found at Annex 9 to the Code of Practice.

## **ANNEX 6, APPENDIX 1: Guidance Note for Food Authorities in England – Live Bivalve Molluscs / Shellfish**

### **GUIDANCE NOTE FOR FOOD AUTHORITIES IN ENGLAND**

#### **LIVE BIVALVE MOLLUSCS / SHELLFISH**

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3. Are separate approval numbers needed for dispatch and purification centres operating from the same site?
4. What locations are considered suitable for dispatch centres and purification centres?
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##### **Registration documents**

6. Can a Food Authority issue registration documents to gatherers of shellfish in another Food Authority's area?

##### **Identification Marking**

7. If a dispatch centre is selling live shellfish to individual consumers on a retail basis, does the identification mark need to be applied to each sale?

##### **Seed Shellfish**

8. What is the minimum period of on-growing of seed mussels before they can be harvested for human consumption?

## **Approval of Establishments**

### **1. When does a harvester or handler of shellfish need to consider becoming an approved dispatch centre?**

Regulation 853/2004, Annex 1(2) defines a dispatch centre as ‘any on-shore or off-shore establishment for the reception, conditioning, washing, cleaning, grading and wrapping and packaging of live bivalve molluscs fit for human consumption.’ All dispatch centres must be approved. As fishing vessels are considered primary production, fishing vessels do not need approval for washing and grading live bivalve molluscs at sea. Though fishing vessels will need to be registered.

The Regulation (853/2004/EC, Annex III, Section VII) requires all live bivalve molluscs destined to be placed on the market to enter the market via a dispatch centre. At the dispatch centre they are wrapped, identification marked and sampled. The dispatch centre need not be on the shoreline but could be some distance away, even in another Member State.

### **2. May inland markets become dispatch centres?**

Yes. The market would need to meet the approval conditions in the same way as other dispatch centres. Approval as a dispatch centre is not necessary to enable a market to unwrap parcels of live shellfish already sent from a dispatch centre and to split up the parcels for sale to retailers or consumers.

### **3. Are separate approval numbers needed for dispatch and purification centres operating from the same site?**

No. Where both exist on the same premises then the same number should be used for the dispatch centre and for the purification centre. Different suffixes (D and PC) are no longer used to separately identify dispatch and depuration centres.

### **4. What locations are considered suitable for dispatch centres and depuration centres?**

Regulation 853/2004, Annex III, Section VII, Chapter III requires dispatch and purification centres to be located on land that is not subject to flooding by ordinary high tides or run-off from surrounding areas.

### **5. Does the dispatch centre working area need to be physically identifiable from the purification centre working area, when both activities are carried out on the same premises?**

The need to separate clean from contaminated live shellfish would dictate this. It would also be in the interests of the business to have separate areas in the event of enforcement action on either the dispatch or purification centre. In small plants this is subject to a risk assessment by the Food Authority.

## **Registration documents**

**6. Can a Food Authority issue registration documents to gatherers of shellfish in another Food Authority's area?**

Registration documents should generally be issued by the Food Authority with responsibility for the harvesting area. This ensures that up to date information about any public health issues relating to the harvesting area may be given to gatherers. However, a Food Authority may allow gatherers to apply to it for registration documents for gathering in another Food Authority's area. In these circumstances the two Food Authorities should liaise regarding the issue of the registration documents and ensure that arrangements operate effectively to assist industry and avoid abuse. Inter-authority arrangements of this kind should normally be restricted to adjoining Food Authorities.

**Identification Marking**

**7. If a dispatch centre is selling live shellfish to individual consumers on a retail basis, does the identification mark need to be applied to each sale?**

Regulation 853/2004 does not, generally, apply to retail. Under this regulation there is only a requirement for identification marks to accompany consignments of live shellfish prior to retail sale. After live shellfish are sold the retailer should retain a copy of the registration document for at least 12 months, or for as long as the competent authority requires. Therefore, where a dispatch centre is acting as a retailer, record keeping of the dispatch of batches of live shellfish through the retail outlet may suffice. The position is similar for live shellfish sold by mail order.

**Seed Shellfish**

**8. What is the minimum period for on growing of seed mussels before they can be harvested for human consumption?**

The minimum period for growing on genuine seed mussels should be six months.

## ANNEX 6, APPENDIX 2: Model Registration Document

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### LIVE BIVALVE MOLLUSCS / LIVE SHELLFISH REGISTRATION DOCUMENT

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Registration Document

No.....

Issued by: .....

Date of Issue: .....

Name of gatherer

Signature of gatherer

.....

Food Authority where shellfish landed

Address of gatherer

.....

Date of gathering

Location of production area  
[described in as precise detail as  
practicable] and, if live bivalve molluscs,  
class of production area (A, B\* or C\*)

.....  
Name of shellfish species being moved  
(common and scientific name) and  
quantity of shellfish being moved

.....  
Place of destination and (if applicable)  
approval number

.....

\*When shellfish originate from a production area classified as B or C:

Relaying area .....

Duration of relaying .....

OR

Address of Purification Centre

.....

Date of Receipt .....

Place of Receipt .....

[Date of Signature] .....

**REMINDER – This document is to be kept by the person receiving the shellfish for a period of not less than 12 months and the gatherer is to keep a copy for the same period.**

## **ANNEX 7: FISHERY PRODUCTS**

### **A.7.1: Introduction**

This Annex provides specific guidance to Food Authorities on the application and enforcement of the fishery products aspects of Regulations 852/2004, 853/2004 and 854/2004.

### **A.7.2: Competent Authority**

The Agency is the UK central competent authority with lead responsibility for these Regulations.

Food Authorities are responsible for enforcement of the EU food hygiene Regulations at their local level, and therefore approve fishery products establishments, register certain markets and fishing vessels, and otherwise enforce the EU food hygiene Regulations.

### **A.7.3: Scope of Approval**

The Regulations do not apply to retail unless expressly indicated. They would however apply when operations are carried out to supply fishery products to other establishments.

Auctions and wholesale markets are required to have approval and should be inspected at regular intervals to check for compliance with hygiene and temperature requirements and subject to Regulation 853/2004 Annex III Section VIII Chapter II.

### **A.7.4: Direct supply of small quantity of Fish.**

The Regulations do not apply the direct supply of small quantities of fishery products to the final consumer or to local retail establishments directly supplying the final consumer. For the purposes of fishery products (not including live bivalve molluscs) a small amount is a total amount of not more than 25 tonnes of fishery products in a calendar year. While the Regulations do not apply to this allowance it is still the responsibility of the harvester to ensure that these products meet the end product standards set down for placing these fishery products on the market. Any amount of the catch which include live bivalve molluscs must have originated from a class 'A' area, which designates the product as suitable for placing on the market with no further treatment required.

### **A.7.5: Conditions During and After Landing**

One of the public health and quality measures in the Regulations is periodic inspection and checks on the fitness for human consumption of fish at the time of landing or before the first sale. Where fishery products are sold at a market associated with the landings, these inspections should take place in that auction hall or wholesale market. It should not normally be necessary for any inspections to be carried out at the time of landing. An organoleptic examination of the fishery products would normally satisfy this requirement.



A Food Authority may authorise the transfer of fishery products from the landing (ex-quay) into containers for immediate delivery to an approved establishment or auction or wholesale market for the checks to be carried out there. Deferring the checks to be carried out later in an auction or wholesale market should not normally 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 should be withdrawn if there is any suspicion of non-compliance with the requirements of the Regulations.

If an organoleptic examination of any product raises doubt as to the freshness of the product, the Food Authority may 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 may be required under EC marketing standards regulations by other statutory agencies.

Authorised officers should, where necessary, liaise with other statutory inspectors, e.g. the DEFRA Sea Fisheries Inspectorate, or the Scottish Fish Protection Agency (SFPA) to ensure that any enforcement action taken is appropriate

#### **A.7.6: Information on Standards to be applied**

Guidance on the requirements of the Regulations may be obtained from the Sea Fish Industry Authority (Seafish).

Food Authorities may use the guidance as a reference in establishing a consistent approach to the requirements of the Regulations. Food Authorities should, however, exercise caution and avoid using, in support of formal enforcement action, those parts of the Seafish guidance that is directed towards the achievement of good industry practice and high quality standards.



## **ANNEX 7, APPENDIX 1: Guidance Note for Food Authorities in England – Fishery Products**

### **GUIDANCE NOTE FOR FOOD AUTHORITIES IN ENGLAND FISHERY PRODUCTS**

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## **Approval of Establishments**

### **1. What establishments need an approval number?**

Article 6(2) of Regulation 852/2004 states that all food businesses shall notify the competent authority with a view to being registered however under Article 6(3)(b) food business operators shall ensure that all establishments requiring approval are approved when required Regulation 853/2004. Under Article 4 of Regulation 853/2004 establishments handling products of animal origin for which the Annex lays down requirements shall require approval by the competent authority. However, establishments carrying out 'primary production', 'transport or storage with temperature controls' or certain 'retail' activities are exempt from the requirements of the Regulation. 853/2004.

To decide whether a retail activity is, or is not exempt Article 1(5) of 853/2004 should be considered. The regulations will apply to retail when food operations are conducted with the purpose of supplying another establishment. However, if the retail operation consists of transport and storage only then they will not require approval. If the other establishment is in itself a retail operation then the regulations will not apply if this activity can be classified as local, marginal and restricted. In respect of these conditions food businesses claiming exemption must be considered on a case by case basis.

Fishery Products establishments carrying out the following will require approval:

- All fishery product establishments handling and processing live bivalve molluscs or fish.
- Fishery Products establishments that handle processed fish for storage only and where temperature controls are required.
- Auction and Wholesale Markets (see question below on retail) where handling and storage requires temperature control.
- Factory Vessels where fishery products are processed on board.
- Freezer Vessels

### **2. What is a retailer?**

'retail' means the handling and/or processing of food and its storage at the point of sale or delivery to the final consumer and includes distribution terminals, catering operations, factory canteens, institutional catering, restaurants and other similar food service operations, shops and supermarket distributions centres.

### **3. Who is the Final Consumer?**

'final consumer' means the ultimate consumer of a foodstuff who will not use the food as part of any food business operation or activity.

**4. In what circumstances would auction or wholesale markets need to become establishments?**

Under Article 2 (c) of Regulation 852/2004 an establishment is defined as ‘any unit of a food business’. However, 852/2004 does not cover food business activities relating to ‘primary production for private domestic use or any domestic preparation of food for domestic consumption’.

It is the case that wholesale outlets are included under the definition of retail in Regulation 178/2002 (see above). However, for wholesale units to fall within this definition they must be selling to the final consumer. When looking at the meaning of final consumer (see Q&A 3, above) it is apparent that it allows for wholesale units that could not be classified as retail, i.e. those that sell on for use in other food business operations or activities. Under these conditions auction or wholesale markets that do not sell primarily to the ‘final consumer’ cannot be considered retail. Therefore wholesale markets that supply to other food business operations or activities will need to be approved.

Under this definition fish auctions and units of wholesale markets are establishments and may require approval under the conditions as specified in the answer to question 1 above.

**5. Should individual stalls in auction halls and wholesale markets, where heading and gutting of fish is carried out, be approved establishments?**

Individual stalls in auction halls are classed as establishments and will need to meet the hygiene requirements of Regulation 852/2004, where appropriate. Regulation 853/2004 will only apply if the stall does not qualify for retail status (see Q&A 1, above). Should it be the case that the stall is not selling as a retail operation then it may still need be subject to approval under Regulations 853/2004, especially if temperature controls are required. In addition to the allocation of an approval number to the wholesale market itself, Food Authorities may issue sub-approval numbers to individual units or groups of units within wholesale markets may. Each unit would be responsible for meeting the hygiene requirements.

**6. Should retailers who also sell wholesale be approved establishments?**

Retailers who also sell wholesale to those not considered to be the final consumer may fall within the scope of Regulation 853/2004 and may require approval (see Q&A 1, above).

**7. Are retailers engaged in preparation of fish covered by the Regulation?**

Yes, unless they are only selling prepared fish to the final consumer.

**8. Do cold stores need to be approved establishments, even though they are not involved in the handling and processing of fishery products?**

The Agency interprets article 1.5(b)(i) of Regulation 853/2004 as exempting cold stores from approval where storage of fishery products is the only activity carried out at the establishment. If additional activities, such as freezing, cutting or processing are carried out, the exemption does not apply and cold stores that are involved in these activities would need to be approved either as a stand alone establishment or as part of the approval of another establishment. All cold stores have to comply with regulation 852/2004 and the temperature requirements in Annex III of Regulation 853/2004.

#### **9. Do cash and carries need to be approved?**

Retail establishments, such as cash and carry outlets, are generally exempt from the requirements of Regulation 853/2004. However, where a cash and carry is not just selling to final consumers, but other food establishments as well, they will require approval if their sales to other establishments involve operations beyond transport or storage. If the other establishment is in itself a retail operation then the regulations will not apply if this activity can be classified as local, marginal and restricted. Cash and carry outlets claiming exemption under these conditions will therefore need to be considered on a case by case basis.

Where only transport and storage is carried out the temperature control conditions laid down in Annex III, Section VIII, Chapters VII and VIII of Regulation 853/2004 will still apply.

#### **10. Are sandwich makers covered by the Regulations and do they need to be approved establishments?**

Sandwich makers, owing to the exemption provided by Article 1(2) of Regulation 853/2004, will not require approved status if the fishery products they use to make the sandwiches are processed before they enter the sandwich maker's establishment. However, the processed fishery products used in the production of the sandwiches should be obtained and handled in accordance with the requirements of Regulation 853/2004. Sandwich makers will still need to comply with the relevant requirements of Regulation 852/2004.

#### **11. Do fishmongers who also smoke or process fish and, if applicable, supply fish vans, need to be approved establishments?**

Fishmongers that sell their own smoked or processed products, but only to the final consumer would not require approval under the Regulations. However, where appropriate, they will need to comply with Regulation 852/2004.

If a Fishmonger sells smoked or processed products to other establishments it will require approval under Regulation 853/2004, unless the other establishment is retail and the activity can be classified as a marginal, localised and restricted activity. Those fishmongers claiming exemption under these conditions will need to be considered on a case by case basis.

#### **12. Are fishmongers who sell retail, but who keep fish live covered by the Regulations?**

Regulation 853/2004 does not apply if they sell only to their final consumers.

**13. If a retail outlet only has upright or chest freezer cabinets, does it need to be approved to comply with the requirements laid down for cold stores?**

There is no need for the premises to be approved where the only storage activity with fishery products is in upright or chest freezer cabinets for display for retail sale. However, where appropriate, they will need to comply with Regulation 852/2004.

**14. Do premises storing only cans and jars of fishery products need to be approved?**

No.

**15. Are airport caterers who supply fishery products to companies, which supply airlines, covered by the Regulations and do they need approval?**

If the airport caterers are supplying their fishery products by carrying out operations in relation to the fishery products beyond transport and storage then they will require approval. However, if the food they supply contains processed product of animal origin and product of plant origin as described in Article 1(2) of Regulation 853/2004, then approval would not be required. In this situation the airport caterers would only have to ensure that the processed products of animal origin being used to prepare their food products is obtained and handled in accordance with Regulation 853/2004. Therefore the fishery products must originate from an approved establishment and the company would need to comply with Regulation 852/2004.

**16. If a business has been approved under the Regulations and changes hands, does the new owner need to apply for approval and the business be reassessed?**

Under the Regulations, an approval is in relation to the premises and not the business occupying the premises or the operator. So the new owner of the premises does not have to seek approval. However, the new owner is obliged to comply with any terms or limitations attached to the approval and with the general requirements of the Regulations. Where a new owner of a previously owned business changes the name or activities of that business the Food Authority must be informed and the premises re-assessed.

**17. If a business supplies a company or a contractor, who then supplies the final consumer would it be covered by the Regulations?**

Yes. The first business is not supplying its own final consumers.

**Conditions of Approval**

**18. Do all the requirements of Regulation 853/2004 in relation to fishery products apply to all fishery products establishments?**



No. Under Regulation 852/2004 there are general conditions applicable to both businesses involved in primary production and those for manufacturing food businesses. However, the regulations indicate where separate conditions apply. Similarly under Regulation 853/2004 the different operations for establishments such as purification centres, fishing vessels, factory vessels and fishery product processing establishments.

**19. Could such facilities as wash basins and lavatories be communal to a number of establishments?**

Regulation 852/2004 covers the general hygiene requirements for food business establishment. With regards to wash basins and lavatories in, for example, wholesale markets, it is for the Food Authority to decide whether separate facilities, for different establishments, is in the public's health interest.

**20. When the Regulations refer to temperature recording devices, does this mean that readings can be taken and logged manually?**

Regulation 852/2004 Annex II, Chapter I, stipulates that it should be possible to monitor and record temperatures at which foodstuffs are maintained. The Regulations do not stipulate that the recording of temperatures should be done automatically, which implies that manual recording is allowed. However, for freezer vessels or establishments on land where the freezing of fishery products is undertaken the requirement is that a temperature recording-device be installed.

See Regulation 853/2004 Annex III, Section VIII, Chapter one, I (C) – Requirements for Freezer Vessels and Chapter III, B Requirements for Frozen Products (on land).

**21. Are communal filleting premises permissible?**

The Regulations do not specify whether or not communal filleting premises are permissible. Provided that control arrangements are adequate, ensuring that filleting is carried out to avoid contamination or spoilage then communal filleting premises would not be precluded by the Regulations. However, a separate establishment for communal filleting is likely to require approval and meet the other hygiene requirements of the Regulations.

**22. The Regulations require that operations such as filleting and slicing must be carried out in a place other than that used for heading and gutting operations. How should this be interpreted?**

The main requirement under Regulation 853/2004 is to avoid contamination of fillets. There may be a number of ways in which this can be achieved, one of which is to separate operations by time rather than place. As long as the Food Authority is content that contamination of the fillets is prevented then this separation by time may be allowed. We would assume that filleting and slicing is carried out where necessary at a different time or a place other than that where heading and/or gutting is carried out.

**23. Is there a list of approved detergents and similar substances for maintaining general conditions of hygiene in establishments and on equipment?**

No. Chemicals suitable for use in the food industry are governed by other legislation.

**Fish Farms**

**24. Are fish farms covered by the Regulations?**

Yes, Farmed fish are classified as primary production, which is covered by Regulation 852/2004, Annex 1. Although fish farms are covered by other animal health legislation Annex 1 lays down hygiene provisions, which stipulate primary products must be protected against contamination with respect to further processing. Various hygiene requirements to achieve this are laid down.

**Identification marks**

**25. Where should the identification mark appear in the case of fresh fish sold by an auction or wholesale market to a person who is not a retail customer?**

Regulation 853/2004 Annex II (c) allows for the identification mark to be applied in either of these ways; directly on the product, the wrapping or packaging, a label affixed to the product, its wrapping or packaging and be an irremovable tag of resistant material. Under these provisions approval number of the market (and the individual trader if applicable) can appear on the crate or whatever other container is being used as well as the accompanying documentation. The documentation may be in the form of a receipt or other proof of purchase e.g. some wholesale markets use a docket system to ensure that sold fish goes to the right buyer.

**Landings of fishery products**

**26. Do EHOs have to carry out histamine checks on other compounds listed in Regulation 854/2004 on all consignments of fish?**

According to Regulation 854/2004 random checks for histamine are to be carried out to verify compliance with permitted levels. Food Authorities will decide when these are necessary, which are likely to take place should the freshness of the product be in doubt.

Other checks are required under Annex III, Chapter II. Corresponding checks must also be carried out by food business operators.

**27. Do quaysides where fish are landed need to comply with the Regulations?**

There are no structural requirements for quays laid down in the regulations, however Annex II of Regulation 852/2004 does lay down general hygiene requirements for premises which will be applicable to auction and wholesale markets. Additionally handling practices for the unloading and landing of fish and some requirements relating to equipment are specified in Regulation 853/2004. Seafish Guidelines for Facilities and Equipment during Landing, Storage, Auction, and Dispatch from the Landing Area contains recommendations for quaysides.

- The proposed laboratory arrangements for the purpose of carrying out sampling in accordance with the Regulations;
- Documented cleaning schedules with details of any checks, including sampling, carried out by the occupier to establish the efficacy of proposed cleaning and disinfection methods;
- Documented maintenance schedules. These should specify the checks to be carried out and any reporting arrangements;
- Documented pest control arrangements, including copies of any contracts with external pest control companies;
- Details for calibrating and monitoring automatic temperature control equipment, where required by the Regulations;
- Proposed staff hygiene training programme, including records of training undertaken to date;
- Written company policy on staff illness and exclusion from work;
- Medical certificates for all staff;
- Details of traceability system, including checks on incoming raw materials, arrangements for controlling application of the health mark and correct use of commercial documentation. Details should include arrangements for documenting these procedures. It may also be appropriate to request examples of identification marked labels;
- Emergency withdrawal procedure;
- Up to date list of suppliers;
- Up to date list of customers (National, EU, 3rd Country).

## **ANNEX 8: RAW MILK AND DAIRY PRODUCTS**

### **A.8.1: Introduction**

This Annex provides specific guidance to Food Authorities with regard to Raw Milk and Dairy Products.

### **A.8.2: Enforcement**

Food Authorities approve dairy establishments, and otherwise enforce the Regulations except in the cases listed below:

Requirements in Regulation 5(1)(a) of the Food Hygiene (England) Regulations 2005 relating to the approval of production holdings and the subsequent supervision and inspection of approved production holdings (apart from animal health checks - see below). These are dealt with on behalf of the agency by the Dairy Hygiene Inspectorate (DHI) of the Rural Development Service in DEFRA. Separate guidelines are issued for enforcement of these requirements;

Controls in Regulation 32 of the Food Hygiene (England) Regulations 2005 on the sale of raw cows' drinking milk, i.e. cows' milk that is supplied raw to the final consumer or to distributors, from farms direct to consumers, temporary guests or distributors and standards for such milk in Schedule 6. These are also dealt with by the DHI (the separate guidelines mentioned above also cover enforcement of these requirements); The Department of Environment, Food and Rural Affairs (Defra) is responsible for carrying out official tests for tuberculosis and brucellosis where appropriate.

Food business operators whose operations are both production holdings and processing establishments are approved by the agency as a production holding, and approved by the Food Authority as a dairy establishment.

### **A.8.3: Food Business Operators Selling Raw Milk and Cream**

Article 10(8) of Regulation 853/2004 allows member states to retain national rules on the retail sale of raw milk and cream. Food businesses that are on-farm processors of raw cows' drinking milk (i.e. those wrapping/packing/bottling raw milk) who sell such products exclusively direct to the final consumer (including from their own milk van and at Farmers Markets) are exempt from approval. Article 1(2)(c) also allows for the supply of small quantities to local retail establishments directly supplying the final consumer.

However, such premises still need to meet the relevant requirements for processing establishments in Regulation 853/2004 and the relevant requirements of Regulation 852/2004.

Processors selling to cash and carry's etc. or to other retail establishments or to distributors that are a separate business must be approved.

The restrictions on sales of raw cows' drinking milk are set out in Schedule 6 of the Food Hygiene (England) Regulations 2005 and are enforced by the DHI at farm level.

Food Authorities are responsible for enforcing the requirements of Schedule 6 of the Food Hygiene (England) Regulations 2005 in respect of sales of raw cows' drinking milk on milk delivery rounds and for enforcing the microbiological standards in respect of sales of raw drinking milk (including raw drinking milk from cows, sheep, goats, buffaloes and other species). Distributors have to be registered with the Food Authority as food businesses.

#### **A.8.4: Reusable Containers**

The requirements for equipment to be clean and to disinfect reusable containers mechanically may 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.

#### **A.8.5: Health Requirements for Raw Milk Production**

Food business operators are responsible for ensuring that the requirements of Regulation 853/2004, Annex III, Section IX, Chapter 1 are met through private veterinary inspections at regular intervals. The frequency of such inspections will be dependent on the individual circumstances. Such inspections can take place when a farmer's private veterinary surgeon is present for other purposes. Food business operators will need to keep evidence of such visits e.g. a receipt/invoice - and of any follow up action taken if problems occur – for checking by authorised officers. Purchasers (or processors) of raw milk are also required to ensure, e.g. through contracts, that checks have been carried out to assess compliance with relevant animal health standards. Immediate problems that may affect the safety of milk will normally be notified to Food Authorities by private veterinary surgeons or (more rarely) the State Veterinary Service. Longer-term issues arising from records could 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 purchaser/processor, or in the case of producer/retailers of raw milk with the producer direct, and advise them to take appropriate advice e.g. from their private veterinary surgeon.

#### **A.8.6: Criteria and Standards for Raw Milk**

In the case of the standards laid down in Regulation 853/2004, Annex III, Section IX, Chapter III, Paragraph 3 for plate counts and somatic cell counts, the Regulations specify a minimum frequency of sampling by the food business operator or the purchaser. Authorised officers need to ensure that food business operators are carrying out the specified sampling programme. Authorised officers should check Food Business Operators' records, and when they have concerns about the test results, consider random official checks to

satisfy themselves that the required standards are being met. Transitional arrangements relating to milk for heat-treatment are set out in Article 3 and Annex XI of Regulation xxx/2005<sup>40</sup>

### **A.8.7: Temperature Requirements for Milk Used for the Manufacture of Dairy Products**

Regulation 853/2004, Annex III, Section IX, Chapter II, Paragraph 1 stipulates that the acceptability of raw milk applies from the arrival of the milk at a processing establishments. Paragraph 2 allows temperatures and times specified for treatment of raw milk to be exceeded for "technological reasons". These reasons will include cases where higher temperatures may be essential to the manufacture of certain products e.g. cheeses and also instances over a weekend for example when establishments are unable to process milk within the specified period. Authorisation by the Food Authority is required whenever it is anticipated that these times will be exceeded.

### **A.8.8: Heat Treatment of Raw Milk and Milk Products**

Requirements for pasteurisation and ultra heat treatment are set out in Article 5 (1) (g) (ii) of Regulation xxx/2005.

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<sup>40</sup> Regulation (EC) No. xxx/2005 laying down transitional arrangements for the implementation of Regulations (EC) Nos 853/2004, 854/2004 and 882/2004 and amending Regulations (EC) Nos 853/2004 and 854/2004

**ANNEX 8, APPENDIX 1: Guidance to Food Authorities in England on Officially Tuberculosis Free Status and Dairy Hygiene Legislation**

**GUIDANCE TO FOOD AUTHORITIES IN  
ENGLAND ON OFFICIALLY  
TUBERCULOSIS FREE STATUS AND DAIRY  
HYGIENE LEGISLATION**

**(January 2006)**

<b>Contents</b>	<b>Paragraph / Annex</b>
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## Scope

1. This guidance has been produced by the Food Standards Agency in consultation with Food Authorities, Defra, The Specialist Cheesemakers' Association and the Institute of Animal Health and updates the version forwarded by the Department of Health to CEHOs with an accompanying letter of 13 March 2000.
2. It provides information and advice for Food Authorities in England who have dairy herds and/or dairy establishments in their area producing raw cows' drinking milk<sup>1</sup> (RCDM) and/or unpasteurised milk-based products. The guidance will be of assistance to those involved with investigations following notification from the Department for the Environment, Food and Rural Affairs (Defra) of the loss<sup>2</sup> of "Officially Tuberculosis Free" (OTF) status of dairy herds.
3. This guidance incorporates the changes resulting from the introduction of the Food Hygiene (England) Regulations 2005, which apply from 1 January 2006 and revoke the Dairy Products (Hygiene) Regulations 1995.

## Introduction

4. Tuberculosis (TB) is an infectious disease of humans and many animal species, caused by some bacteria of the genus *Mycobacterium*. Most cases of human tuberculosis are caused by *Mycobacterium tuberculosis* (*M. tuberculosis*). TB in cattle is primarily caused by *Mycobacterium bovis* (*M. bovis*), which unlike *M. tuberculosis* has a very broad host range.
5. Regular tuberculin testing of dairy herds ensures that most cases of TB in cattle are detected in the early stages of infection, before the development of clinical signs and the shedding of bacteria in milk. *M.bovis* is however responsible for some human infection and the introduction of pasteurisation in the 1930's helped minimise the transmission of TB to man via milk from infected cows. *M.bovis* in humans is now rare – around 40 cases a year which is less than 1% of all TB cases in the UK. Most, if not all of these cases are thought to be due to reactivation of disease acquired in the past.
6. EC Regulation 853/2004 requires that RCDM must come from animals belonging to a herd which is OTF (Annex III, Section IX, chapter 1,1,2(b)). Milk, which does not satisfy this condition, may only be sold for human consumption after it has been heat-treated (Annex III, Section IX, chapter 1, 3). The State Veterinary Service (SVS) will notify Food Authorities of conditions in a herd that result in the loss of OTF status.

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<sup>1</sup> In this context raw cows' milk also includes raw buffaloes milk.

<sup>2</sup> For the purpose of this guidance and for the purposes of Dairy Hygiene legislation, the herd will have lost OTF status if: a reactor is disclosed by tuberculin testing ("status suspended"); when a reactor is confirmed by post mortem examination and /or bacteriological culture ('status withdrawn'); disclosure of an inconclusive reactor within 3 years of a herd breakdown; or the tuberculin test has become overdue.



## **Food Authority Enforcement Issues**

### **Action to take on loss of OTF status of a dairy herd**

7. When a dairy herd is placed under TB movement restrictions for whatever reason the Divisional Veterinary Manager (DVM) will send a copy of the herd restriction notice (Form 'TB2') to the relevant Chief Environmental Health Officer (CEHO) with a covering letter. Service of the TB restriction notice effectively suspends the OTF status of that herd.

On receipt of the notification, the Food Authority should ensure that milk from the herd is no longer used for raw milk based products. Milk from the affected herd may be used for human consumption providing it has been pasteurised, or subjected to a stronger heat treatment. Processors making raw milk based products must not use milk from the affected herd and will only be able to continue their production of such products by obtaining an alternative source of supply from an OTF herd. From 1 January 2006, milk from individual reactor animals within a herd may not be used for human consumption in any circumstances.

To give effect to this Local Authority Enforcement Officers will need to:

- a) liaise with the first buyer(s) of the milk (primary wholesaler) to establish where the milk from the affected herd is being transported and delivered;
  - b) confirm the use of the milk and the cleaning in place systems for the means of transport ;
  - c) ensure that all the milk from the affected herd, and any milk with which it may be mixed, will receive adequate heat treatment before consumption or use for milk based products;
  - d) establish whether milk from the herd is being sold as raw cows' drinking milk (RCDM);
  - e) establish whether the milk is being offered as part of an on-farm B&B business, or in a farm shop, or at a market stall or to a distributor selling raw milk direct to the ultimate consumer; and
  - f) establish whether the milk is being used to make unpasteurised milk-based products either on the particular farm or elsewhere.
8. These investigations may be facilitated by contacting the appropriate regional office of the Dairy Hygiene Inspectorate (DHI) and if necessary the producer and the milk buyer. This may involve liaison with other Food Authorities, including the Food Authority of the first buyer where appropriate.
  9. Where the affected farm has heat treatment facilities installed, the Authority should confirm that all hazard analysis controls are in place and working effectively, including adequate heat treatment.

## Action to be taken on stocks of raw milk based products following loss of OTF status

10. Food Authorities will wish to consider the public health implications, via a risk assessment undertaken locally with the Consultant in Communicable Disease Control (CCDC) and the DVM, for products made prior to the herd losing its OTF status. Advice should also be obtained where appropriate from the local Health Protection Agency (HPA). If, as a result of the risk assessment, it is concluded that it would be appropriate to withdraw or destroy such products, a voluntary withdrawal/destruction should be pursued. Enforcement Officers will have to decide on appropriate action based on the circumstances of individual cases. The factors to be taken into account in the risk assessment will include:
  - 11.1 The reasons for the loss of OTF status. This can be due to the disclosure of test reactors, inconclusive reactors only, a slaughterhouse case, or an overdue TB test (see footnote 2).
  - 11.2 Number of reactors identified. This would be the number of reactors in relation to the total herd size and numbers of cattle tested. A single or a low number of reactors in a large herd may represent a lower risk, since it may indicate that the infection has not had time to spread within the herd. A large number of reactors in any herd could indicate either a long term spread within the herd or multiple infections linked to a common source. Herds with larger number of reactors at the initial test are more likely to have additional reactors disclosed at the next test.
  - 11.3 Types of cattle reacting to the test. For example, heifers or bullocks being non-milk-producing animals would be of less significance.
  - 11.4 The number and location of any lesions found at post mortem examination (PME) and tissue culture results.
    - a) If no TB lesions are found, or lesions are confined to one organ or one part of the body other than the mammary gland, the risk of TB bacilli being present in milk would be considered low. If TB lesions were found in the mammary gland or in more than one organ or part of the body in a lactating dairy cow, the risk of TB bacilli being present in milk would be considered significant. TB bacilli may be present in milk even in the absence of obvious udder disease when the disease has been distributed systemically.
    - b) Following PME tissue samples are collected from all reactors, including those where no visible lesions were found. Tissue culture takes a minimum of 6 weeks to positively identify *M. bovis*, with approximately 10% of reactors with no visible lesions at PME yielding a positive culture of *M. bovis*.
  - 11.5 Testing history of the individual herd. Aspects to consider include:
    - a) time elapsed since the last clear TB test;
    - b) previous TB history of the herd; and
    - c) the reason for the test.

- 11.6 The baseline testing frequency for the civil parish. This provides an indication of whether the herd is in a high TB prevalence area. The SVS case veterinary officer will provide expert opinion and judgement of the TB incidence in the locality.
- 11.7 General herd health and herd bio-security. Consideration should also be given to:
- a) milk somatic cell counts - higher cell counts may indicate a higher likelihood of TB organisms being present in the milk; and
  - b) animal trading record for the farm, highlighting numbers brought in, from where and their last TB test date (this is important because it takes a minimum of 6 weeks from the time of infection for an animal to react to the tuberculin test).
- 11.8 Type(s) of milk-based product and production process. For example, the use of bought in milk may make it more difficult to establish the necessary herd information. Consideration should be given to any scientific evidence, including that provided by the milk processors, that the production process may eliminate the pathogens and that TB organisms are absent from the product.
- 11.9 Fresh milk products. The shelf life of the product may have been exceeded by the time the post-mortem report or tissue culture results are received.
- 11.10 Size of the TB restricted herd. The likelihood, severity and duration of TB incidents tends to increase as herd size increases. Although this trend has been identified the affect is difficult to quantify and therefore the other factors detailed above are of greater significance for the risk assessment.
12. 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.
13. The Regulations<sup>3</sup> do not prohibit the marketing of products made before the removal of OTF status. If a voluntary solution cannot be concluded with the producer any action taken will need to be under the Food Safety Act 1990 (as amended) and the General Food Regulations 2004. Enforcement Officers may consider further action under Section 9 of the Act if they suspect that the products concerned fail to comply with food safety requirements as now defined in Article 14 of EC Regulation 178/2002 on general food law. It would however be necessary, for any prosecution to succeed, to prove that an offence had occurred under regulation 4 of the General Food Regulations 2004. This makes it an offence to contravene Article 14 of EC Regulation 178/2002.

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<sup>3</sup> From January 1 2006 EC Regulations 852/2004 and 853/2004 will apply

### **Action to take before OTF problems arise**

14. Food Authorities and the Dairy Hygiene Inspectorate (DHI) should liaise with DVMs to ensure that herds supplying RCDM and/or establishments or processors manufacturing unpasteurised dairy products are tuberculin tested annually. For example, Food Authorities and the DHI should notify DVMs when they become aware of the sale of RCDM for human consumption or the production of unpasteurised dairy products in their area. 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 dairy herds that are tested annually for TB and are classified with OTF status. Food Authorities should contact the DVM who will be able to supply further information about these issues.
15. Food Authorities may find it helpful to liaise with Local Authority Animal Health and Welfare Inspectors as their responsibilities include checking farm records under animal health legislation.

### **Contacts**

16. For detailed guidance on dealing with human cases or contacts please refer to the Department of Health's "Guidance on Management of the Public Health Consequences of TB in Cattle". For copies of the guidance telephone 020 7972 5672.
17. 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 Food Standards Agency Food Incident Branch, telephone number 020 7276 8448, who will work with the local investigation team.
18. If more information is required on Defra procedures concerning TB controls in England and Wales, you should contact the duty Veterinary Officer at the local Animal Health Divisional Office of the SVS.
19. Additional details may be found on the following web sites:

<http://www.defra.gov.uk/animalh/tb/index.htm>

<http://www.hse.gov.uk/hthdir/noframes/bovine.htm>

[http://www.hpa.org.uk/infections/topics\\_az/tb/infosheets/english.pdf](http://www.hpa.org.uk/infections/topics_az/tb/infosheets/english.pdf)

<http://www.lacors.gov.uk>

## **Legislative Background and Human Health**

### **Raw cows' drinking milk and unpasteurised milk-based products**

- 1.1 EC Regulation 853/2004, Annex III Section IX, chapter 1,1,2(b) requires that RCDM must come from animals belonging to a herd which is officially tuberculosis free. Annex III Section IX, chapter 1,1,3 requires that milk which does not satisfy this condition may only be sold for human consumption after it has been heat treated.
- 1.2 Where Food Authorities investigating a notification of the loss of OTF status become aware that milk is being sold raw for direct human consumption, they must consider taking action (Annex III Section IX, chapter 1,1.3 of EC 853/2004) to ensure that milk from herds that have lost their OTF status is heat treated. Annex 3 provides a draft form, which may be used by Food Authorities to remind milk producers of this requirement.
- 1.3 Heat treatment notices previously made under the Milk and Dairies (General) Regulations 1959 no longer apply as the Food Hygiene Regulations (England) 2005 revoke the Milk and Dairies (General) Regulations 1959.
- 1.4 While the law requires that raw milk based products may only be manufactured with milk from herds classified as OTF the Regulations do not prohibit the marketing of products made before the removal of OTF status. If a voluntary solution cannot be concluded with the producer any action taken will need to be under the Food Safety Act 1990 and the General Food Regulations 2004 (see paragraph 13).

### **Cases of human illness**

- 1.5 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 might indicate the infection could have been caught from an animal source or could be passed to animals. If so they should inform the Food Authority. If there is a risk that a herd and/or other farm stock could be infected then the enforcement officer should notify the DVM 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).

## Animal Health Issues and the Role of the SVS (Defra)

### ***M. bovis* infection in cattle**

- 2.1 Tuberculosis (TB) in cattle is caused by *Mycobacterium bovis* (*M.bovis*) and bovine TB can affect other species such as deer and badgers. Humans can also be affected, although this is now rare in the UK. In the past infection from raw milk occurred, but now with regular testing of herds, slaughter of reactors and milk pasteurisation, human cases are relatively rare and usually thought to be due to the reactivation of disease contracted earlier, for example before milk pasteurisation was widely in use, or, occasionally, infection contracted abroad. Regular testing of cattle on the farm detects most cases early, before the organism is shed in milk. The bacteria can be inhaled in aerosols from the lungs of infected cattle, or ingested through drinking contaminated raw milk or consuming contaminated unpasteurised milk-based products.
- 2.2 In recent years, TB in cattle has increased in the UK in both numbers and geographic spread. Since the early 1980s the number of herds reported each year where the OTF status has been withdrawn has steadily increased. This initially affected mainly the southwest of England, but in recent years has spread to parts of South Wales and the West Midlands.
- 2.3 The routine tuberculin skin testing of herds is a key part of TB control in cattle in the UK. Any animal showing a positive reaction (i.e. a “reactor”) to this test is slaughtered and compensation paid. Slaughtered reactors undergo post-mortem and lymph node and other tissue samples are collected for culture of the organism to identify the strain of *M. bovis* responsible for the incident. Less than half of positive test reactors are found to have visible lesions or a positive culture for *M.bovis*. The Meat Hygiene Service also routinely examines all carcasses at abattoirs for macroscopic lesions of TB as part of general meat inspection.

### **Routine testing of herds**

- 2.4 Most TB testing in Great Britain is carried out by Local Veterinary Inspectors (LVIs). These are veterinarians in private practice appointed by Defra to carry out specific statutory duties. Veterinary Officers of the SVS undertake some of the follow-up tests in herds under TB restrictions and the re-testing of inconclusive reactors. The SVS is responsible for the day to day administration of the tuberculin testing programme, the supervision of LVIs and the management of TB incidents. The latter includes notification of a new TB incident to the relevant environmental and public health officials. Where individual farmers have agreed with the local Defra DVM that they wish to pay for private testing outside of the routine testing, the farmer must notify the DVM of the results accordingly.
- 2.5 Farmers may wish to carry out private tests, for instance on purchased animals, to clarify their TB status. Additionally, more frequent testing could be viewed as providing an early indication of problems for producers of

unpasteurised cows' milk and raw milk-based products intended for consumption in that state. Pre-movement TB testing of any purchased cattle would provide an additional safeguard against the introduction of infection in the herd.

- 2.6 Most British cattle herds are routinely tested at 4-year intervals, but in some parts of the country, where the incidence of confirmed TB herd breakdowns is greater, TB testing is carried out more frequently. Cattle herds in Scotland, North Wales and most of the North and East of England remain on 4-yearly testing. There are some parts of the country where testing can be annually, 2-yearly or 3-yearly.
- 2.7 The frequency of routine TB testing is broadly based on the incidence thresholds set out in Council Directive 64/432/EEC (as amended). This testing is essentially for animal health/disease control purposes, and Defra is responsible for the testing policy. The default testing frequency in any given parish is set by the DVMs according to the number of confirmed TB herd breakdowns. In general, the higher the incidence of confirmed herd breakdowns of unexplained origin in a given parish, the shorter the interval between two consecutive routine TB tests for all the herds in that parish. Furthermore, DVMs can place individual herds on an annual TB testing regime on animal or public health grounds, regardless of the default routine testing frequency for their parish. Examples of such herds are: cattle dealers' and bull hirers' herds, herds with a regular intake of cattle from areas with a high incidence of TB, retailers of RCDM and, where this information is available to the DVM, suppliers of milk for the manufacture of unpasteurised dairy products.

### **Finding a TB reactor**

- 2.8 Disclosure of tuberculin test reactors at a routine herd test is the most common reason for the service of TB restrictions by the SVS, but other situations may also lead to the suspension of the OTF status of a herd. These include detection by the Meat Hygiene Service of suspect lesions of TB at routine meat inspection in the abattoir; disclosure of inconclusive reactors within three years of the resolution of a confirmed TB incident; or the tuberculin tests becomes overdue. Service of the TB restriction notice (Form TB2) effectively suspends the OTF status of that herd. When a dairy herd is placed under TB movement restrictions for whatever reason the DVM will inform the relevant Chief Environmental Health Officer (CEHO). Automated letter distribution systems are being introduced but EHOs and the DVM should develop strong working relationships to ensure effective communications at a local level are established.
- 2.9 All tuberculin test reactors are sent under licence for compulsory slaughter. When reactors are slaughtered and herd restrictions applied, the DVM will make arrangements to re-test the herd at 60 day intervals until negative herd tests are obtained (one test when disease is not confirmed, two tests when confirmed). Following a programme of clear skin testing, movement restrictions will be lifted, thereby restoring the herd's OTF status. The DVM will notify the CEHO when the OTF status of a dairy herd has been regained.

## Laboratory confirmation of TB

- 2.10 TB incidents (also known as herd breakdowns) are confirmed when at least one reactor animal in that herd presents with visible lesions of TB at post-mortem examination and/or when *M. bovis* is isolated by bacteriological culture from selected tissue samples. Additionally, a TB incident can also be confirmed when suspect lesions are found in carcasses of clear testing cattle during routine meat inspection and those lesions yield *M. bovis* on culture.
- 2.11 As indicated in 2.9 above, all reactors are slaughtered and undergo post-mortem examination for confirmation of infection. On average, less than half of these animals are found to have visible lesions on post-mortem examination. The remainder are called “no visible lesion” (NVL) reactors. A small proportion of those NVL reactors may be due to false positive tuberculin tests, but the majority represent cattle at an early stage of infection, where the lesions of TB are too small to be detectable by visual inspection of the carcass. The SVS will collect appropriate tissue samples for submission to the Veterinary Laboratories Agency, where bacteriological culture of *M. bovis* will be attempted. In NVL reactors, a pool of apparently normal lymph nodes is collected to attempt the isolation of *M. bovis* by bacteriological culture and thus confirm the infection. In reactors with visible lesions, infection is automatically confirmed and the main reason for taking samples of the lesions is to undertake molecular typing of the *M. bovis* strain responsible for the incident. The outcomes of the post-mortem and bacteriological culture determine the number of 60-day interval tests that must be carried out in the remainder of the herd before TB restrictions can be lifted. Laboratory confirmation of TB by culture will take a minimum of 6 weeks. It could take longer if samples are contaminated.
- 2.12 The DVM will notify CEHOs of all TB incidents (whether subsequently confirmed or not) in dairy herds so that checks can be made and action taken under food hygiene regulations<sup>4</sup>. The DVM will notify the CCDC of confirmed TB incidents in any herd, for human health screening purposes. A courtesy copy of the notification of confirmed TB is often sent to the CEHO. In the unlikely event of TB of the udder being found on post-mortem examination, both the CEHO and the CCDC will be notified by the DVM.

## Inconclusive Reactors

- 2.13 On occasions the result of the skin test on animals will be in an intermediate range between positive and negative. These animals are classed as inconclusive reactors (IRs). Cattle may react in this way for a number of reasons including stress or exposure to other diseases but experience has shown that the majority of inconclusive reactions are non specific and resolve at the first or second retest.
- 2.14 In herds where there has been a recently confirmed TB breakdown (within the last 3 years), finding an IR results in the whole herd being placed

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<sup>4</sup> EC Regulations 852/2004 and 853/2004



under restrictions and the OTF status of the herd is suspended. CEHOs will be notified of these situations and all milk from the herd must be heat treated.

- 2.15 In herds where there is no recent history (within the last 3 years) of confirmed TB, IR animals are isolated and re-tested after 42 - 60 days. There are no restrictions regarding milk from the animals and OTF status of the herd is not compromised. If the inconclusive cattle retest negative, the DVM will permit the animal to rejoin the herd. If the second test is also inconclusive a third and final test will be carried out after another 42 – 60 days and unless this test is clear the animal will be reclassified as a reactor and slaughtered. The herd will then be classed as a confirmed TB breakdown.
- 2.16 If IRs re-test positive at either stage they are classed as reactors, OFT status is lost and the animal(s) will be slaughtered. Post-mortem examinations are carried out on all carcasses at the slaughterhouse and samples will be sent for culture.

**ANNEX 3**

**Model form for use following loss of OTF status for milk producers  
(Only for use on or after 1 January 2006 if required)**

NAME OF OCCUPIER  
ADDRESS

NAME OF LOCAL AUTHORITY  
ADDRESS  
TELEPHONE NUMBER

Milk from herds that have lost their Officially Tuberculosis Free (OTF) Status and milk from TB reactor animals

When a dairy herd is placed under TB movement restrictions, the herd effectively loses its Officially Tuberculosis Free status. This occurred to your herd when the TB2 notice was served on [xxxx] by [xxxx]. Milk from the above premises must therefore be pasteurised or subjected to a stronger heat treatment before it may be sold for human consumption, or used in the manufacture of products for human consumption. Milk heat treated in such a way will show a negative reaction to the phosphatase test. In addition, milk from any individual reactor animal must be withheld and must not be used for human consumption

Further please be advised that any person who sells or uses milk or milk-based products in breach of Article 4 (1) of Regulation (EC) 853/2004 may be convicted of an offence under the Food Hygiene (England) Regulations 2005. The legislative rules detailing the herd health requirements for raw milk production are contained in Annex III, Section IX, Chapter I of Regulation (EC) No. 853/2004. Annex III, Section IX, Chapter I, 3(a) requires that raw milk from animals that do not belong to an Officially Tuberculosis Free herd may, with the authorisation of the competent authority, only be used for human consumption after having undergone a heat treatment such as to show a negative reaction to the phosphatase test.

To safeguard your own health, that of your family or staff it is strongly recommended that you do not drink or use unpasteurised milk in your home.

Signed .....

Environmental Health Services

Date .....

## **ANNEX 9: EGG PRODUCTS AND LIQUID EGG**

### **A.9.1: Introduction**

This Annex provides specific guidance to Food Authorities on the enforcement of Section X, Chapter II of Regulation 853/2004. This lays down the public health rules for the manufacture and placing on the market of egg products and liquid egg for human consumption.

The Regulations lay down requirements for:

- establishments;
- raw materials for the manufacture of egg products;
- special hygiene requirements for the manufacture of egg products;
- analytical specifications; and
- labelling and identification marking.

### **A.9.2: Scope of the Regulations**

The Regulations apply to establishments manufacturing egg products and liquid egg for human consumption, which would be 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; or
- liquid egg for onward transportation to approved processing establishments.

All establishments need to be approved if the Regulations apply to them.

None of the requirements in Section X, Chapter II of Regulation 853/2004 apply to retail, as defined by Regulation 178/2002, so establishments such as bakers and caterers that process eggs are not subject to any of the requirements of Regulation 853/2004.

[Draft] European Commission Guidance on Regulation 853/2004 confirms that it was never the intention, while developing the hygiene regulations, that the production of foods such as bakery products and pasta should be subject to the requirements of Regulation 853/2004. Hence, an establishment processing eggs for use as ingredients for foods produced in that establishment would not be subject to approval under Regulation 853/2004 for this activity.

### **A.9.3: Types of Approved Premises**

Premises requiring approval fall into two categories:

- (i) premises where egg products are manufactured and placed on the market, i.e. where processing takes place; and
- (ii) premises where liquid egg is produced for later processing by an approved egg product manufacturer, i.e. egg producers or packing centres.

Category (ii) exists because egg packing centres may prefer to break out eggs, including cracked eggs, to produce liquid egg rather than risk breakage before they are sent to a category (i) processing establishment. Such approvals must require that the eggs are broken out as soon as possible 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 agency of approvals, the Authority should specify whether the approval is for (i) or (ii) and if the premise is also a packing centre.

### **A.9.4: Dirty Eggs**

Eggs may not be broken out unless they are clean and dry. Dirty eggs may be cleaned, but Authorities must ensure that any washing, drying and disinfecting of eggs is separated from all other operations of the business.

### **A.9.5: 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 may 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 should 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.

### **A.9.6: Identification Marking**

The general requirements for identification marking laid down in Annex II, Section I of Regulation 853/2004 must be complied with and are set out in Chapter 5.1 of the Code. However, there are additional specific requirements for egg products. Regulation 853/2004, Annex III, Section X, Chapter II, Part V requires that consignments of egg products to be used as an ingredient in the manufacture of another product must have a label giving the temperature at which the egg products must be maintained and the period during which conservation may thus be assured.

### **A.9.7: 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 EC Regulations on microbiological criteria.

Where a non-standard process is proposed, the onus is on the occupier to show that adequate research has been carried out into its effectiveness.

In establishments where heat processing takes place, Food Authorities should establish that the operator of the heat process has an acceptable and appropriate level of expertise.

### **A.9.8: Analytical Specifications**

Part IV of Annex III, Section X, Chapter II of Regulation 853/2004 lays down analytical specifications that the end product must not exceed. Although there are no prescribed EU methods for testing for lactic or butyric acids, methods do exist. Where such methods are used, due consideration should be given to the reliability of the results. Where samples are tested, the results should be compared with the standards specified.

Authorised officers may help occupiers develop sampling plans since these also are not prescribed in the Regulations.

### **A.9.9: 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.

### **A.9.10: Storage and Transport**

Establishments must keep eggs and egg products separate to avoid contamination. If separate rooms are not available, egg products may be stored in separate containers and areas.

Storage rooms must be capable of maintaining any required temperature controls.

The Regulations do not cover egg products that are stored in separate establishments such as depots or warehouses outside approved egg products establishments. Such storage is covered by Regulation 852/2004.

#### **A.9.11: Egg Marketing** **(See also Annex 10)**

Egg packing centres, whether or not approved to produce liquid egg under the Regulations, are the responsibility of Defra in respect of egg quality and marketing regulations and are inspected by Egg Marketing Inspectors (EMIs).

It is recommended that authorised officers should liaise with EMIs prior to inspecting egg product facilities at egg-packing centres.

## **ANNEX 10: EGG PACKING CENTRES**

### **A.10.1: Introduction**

This annex provides specific guidance to Food Authorities for the enforcement of Annex III, Section X, Chapter 1 of Regulation 853/2004.

In addition to the relevant requirements of Regulation 852/2004, this part of the aforementioned Regulations lay down requirements for egg packing centres covering:

- hygiene and temperature requirements for the storage and transport of eggs
- the maximum time limit in which eggs must be delivered to the consumer

### **A.10.2: 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 & Retailers – the handling and storage of eggs.

The production and collection of eggs at the producer's premises are activities that take place at the primary production level. Enforcement of the Regulations at this level will be the subject of future guidance.

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. This has been confirmed in Commission guidance. Therefore, in addition to the specific egg hygiene provisions contained in Regulation 853/2004, egg-packing centres will be subject to the appropriate provisions of Regulation 852/2004, including the Article 5 HACCP requirements and the relevant chapters of Annex II. Egg packing centres will also need to be approved, as they will be covered by Article 4(2) of Regulation 852/2004. They will also be subject to the official controls set out in Article 4 of 882/2004.

Egg packing centres will be receiving 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 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. All of this is acceptable as long as the provisions of the food hygiene regulations are not breached. Packing centres have an important role to play in ensuring eggs are delivered to the consumer in good condition.

Egg wholesalers, while subject to the requirements of Annex III, Section X, Chapter 1 of Regulation 853/2004, are not required to be approved as European Commission guidance has indicated wholesaling comes within the definition of retail activity, which is exempt from approval. (DN: presumably if an egg packing centre sells the eggs on a wholesale basis, which they all probably do, then approval is not required?)

### **A.10.3: Specific Hygiene Requirements for Shell Eggs**

The specific requirements set out in the Regulations are:

- At the producer's premises, 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 and their packaging may be stamped with 'best before dates', 'use by dates' or 'date of minimum durability'. On the basis of this information, if an enforcement officer suspects eggs are being sold beyond the time limit required on food safety grounds, they should examine documentation from the egg producer to determine the age of an egg. He should also contact his egg-marketing inspector (EMI) for further guidance and help in taking the appropriate action.

### **A.10.4: Non-UK eggs**

Wholesalers or packers are allowed to source eggs from any country within the EU. All eggs from any EU country should comply with requirements in Annex III, Section X, Chapter 1 of Regulation 853/2004.

### **A.10.5: Egg Marketing**

Egg producers, packing stations, and wholesalers are also subject to egg quality and marketing regulations. These regulations are the responsibility of DEFRA/SEERAD. Inspections under these regulations are carried out by egg marketing inspectors. It is recommended that enforcement officers should liaise with their respective egg-marketing inspector prior to inspecting egg packing stations and wholesalers.



#### **A.10.6: Lion scheme and other industry-led quality assurance schemes**

There are a number of industry based quality assurance schemes operating throughout the UK, particularly the 'Lion Scheme'. The Lion Quality Code incorporates food safety procedures based on the Food Hygiene Regulations but also includes additional requirements. These include compulsory vaccination against *Salmonella Enteritidis* of all pullets destined for flocks producing 'Lion eggs'. The Lion scheme also has a "best-before" date stamped on the shell as well as on the pack. In addition, there is the "Laid in Britain" scheme offered to independent egg producers who are members of UKEP, the UK Egg Producers Association Ltd. 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 and the Eggs & Poultry Unit (EPU) of SEERAD inspections. Enforcement officers may wish to take into account these assurance schemes in developing a risk based approach to inspections.

## **ANNEX 11: APPROVAL OF PRODUCT-SPECIFIC ESTABLISHMENTS SUBJECT TO APPROVAL UNDER REGULATION 853/2004 - TEMPLATE FORMS**

Template forms which may be used by authorised officers in connection with the approval of product-specific establishments are provided from A.11.1 to A.11.6, as summarised in the following table:

<b>Location</b>	<b>Template Form</b>
A.11.1	Application for Approval
A.11.2	Notification of Grant of Approval / Conditional Approval
A.11.3	Notification of Refusal to Grant Approval
A.11.4	Notification of Withdrawal of Approval / Conditional Approval
A.11.5	Notification of Suspension of Approval / Conditional Approval
A.11.6	Notification of Amendment to Approval

As stated in Paragraph 5.1.4 of the Code of Practice, although the content of these documents should be regarded as the minimum required, Food Authorities may adapt them as necessary to meet local requirements.

# Application for Approval of a Food Business Establishment Subject to Approval under Regulation (EC) No. 853/2004

**PART 1 – TYPE OF PRODUCT(S) OF ANIMAL ORIGIN FOR WHICH APPROVAL IS SOUGHT**

<input type="checkbox"/>	<b>Minced Meat</b>
<input type="checkbox"/>	<b>Meat Preparations</b>
<input type="checkbox"/>	<b>Mechanically Separated Meat</b>
<input type="checkbox"/>	<b>Meat Products</b>
<input type="checkbox"/>	<b>Live Bivalve Molluscs (Shellfish)</b>
<input type="checkbox"/>	<b>Fishery Products</b>
<input type="checkbox"/>	<b>Dairy Products</b>
<input type="checkbox"/>	<b>Eggs (not Primary Production) / Egg Products</b>
<input type="checkbox"/>	<b>Frogs' Legs / Snails</b>
<input type="checkbox"/>	<b>Rendered Animal Fats and Greaves</b>
<input type="checkbox"/>	<b>Treated Stomachs, Bladders and Intestines</b>
<input type="checkbox"/>	<b>Gelatine</b>
<input type="checkbox"/>	<b>Collagen</b>
<input type="checkbox"/>	Raw material for the production of Gelatine or Collagen intended for human consumption (Collection Centre or Tannery)
<input type="checkbox"/>	<b>Meat (Stand-alone Cold Store)</b>

## Postcode:

## Postcode:

Full names of managers of The Premises	1.	2.	3.
	Job titles	1.	2.

Full Names of others In control of the business	1.	2.	3.
	Job titles	1.	2.

---

#### PART 4 – USE OF THE ESTABLISHMENT

---

Which of the following activities will be conducted in / from the establishment (tick all that apply)?

<input type="checkbox"/>	Wholesale market
<input type="checkbox"/>	Manufacture
<input type="checkbox"/>	Other processing (please specify)
<input type="checkbox"/>	Packing
<input type="checkbox"/>	Storage
<input type="checkbox"/>	Distribution
<input type="checkbox"/>	Cash and carry / wholesale
<input type="checkbox"/>	Catering (preparation of food for consumption in the establishment)
<input type="checkbox"/>	Retail (direct sale to consumers or other customers)
<input type="checkbox"/>	Market stall or mobile vendor
<input type="checkbox"/>	Other (please specify)

---

#### PART 5 – TRANSPORT OF PRODUCTS FROM THE ESTABLISHMENT

---

How will products be transported from the establishment (tick all that apply)?

<input type="checkbox"/>	Your own vehicle(s)
<input type="checkbox"/>	Contract / Private Haulier
<input type="checkbox"/>	Purchaser's own vehicle(s)
<input type="checkbox"/>	Other (please specify)

---

#### PART 6 – SUPPLY OF PRODUCTS FROM THE ESTABLISHMENT TO OTHER ESTABLISHMENTS

---

Which of the following will be supplied with products from the establishment (tick all that apply)?

<input type="checkbox"/>	Other businesses that manufacture or process food
<input type="checkbox"/>	Wholesale packers
<input type="checkbox"/>	Cold stores that are not part of the establishment to which this application relates
<input type="checkbox"/>	Warehouses that are not part of the establishment to which this application relates
<input type="checkbox"/>	Restaurants, hotels, canteens or similar catering businesses
<input type="checkbox"/>	Take-away businesses

- ☐ Retail shops, supermarkets, stalls, or mobile vendors that you own
- ☐ Retail shops, supermarkets, stalls, or mobile vendors that you do not own
- ☐ Members of the public direct from the establishment to which this application relates
- ☐ Other (please specify)

---

## PART 7 – OTHER ACTIVITIES ON THE SAME SITE

---

Will any of the following activities be conducted on the same site as, or within, the establishment to which this application for approval relates?

	YES	NO	APPROVAL CODE
Slaughter, including pigs, sheep, cattle, poultry, game etc:	<input type="checkbox"/>	<input type="checkbox"/>	
Cutting fresh (including chilled and frozen) meat, poultry meat or game:	<input type="checkbox"/>	<input type="checkbox"/>	
Storage of fresh (including chilled and frozen) meat, poultry or game:	<input type="checkbox"/>	<input type="checkbox"/>	

---

## PART 8 – INFORMATION AND DOCUMENTATION

---

The following information is required in order to process your application and should be sent with this application form if possible. Please indicate which information you are sending now (N.B. information that is not sent now will still be required before your application can be determined).

- ☐ A detailed scale plan of the (proposed) establishment showing the location of rooms and other areas to be used for the storage and processing of raw materials, product and waste, and the layout of facilities and equipment
- ☐ A description of the (proposed) establishment and equipment maintenance arrangements
- ☐ A description of the (proposed) establishment, equipment, and transport cleaning arrangements
- ☐ A description of the (proposed) waste collection and disposal arrangements
- ☐ A description of the (proposed) water supply
- ☐ A description of the (proposed) water supply quality testing arrangements
- ☐ A description of the (proposed) arrangements for product testing
- ☐ A description of the (proposed) pest control arrangements
- ☐ A description of the (proposed) monitoring arrangements for staff health
- ☐ A description of the (proposed) staff hygiene training arrangements
- ☐ A description of the (proposed) arrangements for record keeping
- ☐ A description of the (proposed) arrangements for applying the identification mark to product packaging or wrapping

---

## PART 9 – ACTIVITIES / PRODUCTS TO BE HANDLED IN THE ESTABLISHMENT

---

Which of the following activities will be conducted in the establishment? Indicate by giving the approximate quantities to be handled in kilograms or litres per week (tick all that apply).

---

### PART 9(1) – Minced Meat and Meat Preparations

---

- ☐ Handling minced meat

	Handling meat preparations
--	----------------------------

Full Details of Activities and Specific Products Handled

--

How many tonnes of minced meat in total will be handled in the establishment per week on average?	
---------------------------------------------------------------------------------------------------	--

How many tonnes of meat preparations in total will be handled in the establishment per week on average?	
---------------------------------------------------------------------------------------------------------	--

**PART 9(2) – Mechanically Separated Meat**

Full Details of Activities

--

How many tonnes of mechanically separated meat in total will be handled in the establishment per week on average?	
-------------------------------------------------------------------------------------------------------------------	--

**PART 9(3) – Meat Products**

Full Details of Activities and Specific Products Handled

--

How many tonnes of meat products will be handled in the establishment per week on average?	
--------------------------------------------------------------------------------------------	--

**PART 9(4) – Live Bivalve Molluscs (Shellfish) / Fishery Products**

Full Details of Activities and Specific Products Handled

--

How many tonnes of <b>Live Bivalve Molluscs (Shellfish) / Fishery Products</b> will be handled in the establishment per week on average?	
------------------------------------------------------------------------------------------------------------------------------------------	--

**PART 9(5) – Raw Milk / Dairy Products**

	Raw Milk
--	----------

	Dairy Products
--	----------------

Full Details of Activities and Specific Products Handled

--

How many litres of Raw Milk <b>will</b> be handled in the establishment per week on average?	
----------------------------------------------------------------------------------------------	--

How many tonnes of <b>Dairy Products</b> will be handled in the establishment per week on average?	
----------------------------------------------------------------------------------------------------	--

---

**PART 9(6) – Eggs (not Primary Production) / Egg Products**


---

Full Details of Activities and Specific Products Handled

--

How many tonnes of Eggs <b>will</b> be packed in the establishment per week on average?	
-----------------------------------------------------------------------------------------	--

How many litres of Egg Products <b>will</b> be handled in the establishment per week on average?	
--------------------------------------------------------------------------------------------------	--

---

**PART 9(7) – Frogs' Legs and Snails**


---

	Frogs' Legs
	Snails

Full Details of Activities and Specific Products Handled

--

How many tonnes of frogs' legs in total will be handled in the establishment per week on average?	
---------------------------------------------------------------------------------------------------	--

How many tonnes of snails in total will be handled in the establishment per week on average?	
----------------------------------------------------------------------------------------------	--

---

**PART 9(8) – Rendered Animal Fats and Greaves**


---

Full Details of Activities and Specific Products Handled

--

How many tonnes of Eggs <b>will</b> be packed in the establishment per week on average?	
-----------------------------------------------------------------------------------------	--

---

**PART 9(9) – Treated Stomachs, Bladders and Intestines**


---

	Frogs' Legs
	Snails

Full Details of Activities and Specific Products Handled

--

How many tonnes of frogs' legs in total will be handled in the establishment per week on average?	
---------------------------------------------------------------------------------------------------	--

How many tonnes of snails in total will be handled in the establishment per week on average?	
----------------------------------------------------------------------------------------------	--

---

**PART 9(10) – Gelatine**


---

Full Details of Activities

--

How many tonnes of gelatine in total will be handled in the establishment per week on average?	
------------------------------------------------------------------------------------------------	--

---

**PART 9(11) – Collagen**


---

Full Details of Activities

--

How many tonnes of collagen in total will be handled in the establishment per week on average?	
------------------------------------------------------------------------------------------------	--

---

**PART 9(12) – Raw Material for the Manufacture of Gelatine or Collagen for Human Consumption (Collection Centre or Tannery)**


---

Full Details of Activities and Specific Products Handled

--

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**PART 9(13) – Meat (Stand-Alone Cold Store)**


---

Full Details of Activities and Specific Products Handled

--

How many tonnes of product will be handled in the establishment per week on average?	
--------------------------------------------------------------------------------------	--

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**PART 10 – APPLICATION**


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Name of applicant	
Position in business	

Name of contact	
Position in business	
Tel (incl. Dialling code)	
Fax (incl. Dialling code)	
E-mail	

I hereby apply, on behalf of the business described in Part 2, for approval to use premises at the address specified in Part 2 for the purpose of handling products to which Regulation (EC) No. 853/2004 applies.



Signature

Date

Name in  
BLOCK LETTERS

---

If you need any help or advice about how to complete this form, or about the products to which the Regulations relate, or the circumstances in which approval under the Regulations is required, please contact the officer named below.

---

When you have completed this form and collected the other information required, please send it to:

Contact Name:

Telephone:

Fax:

E-mail:

**IMPORTANT**

Please notify any changes to the details you have given on this form, by writing to the address shown.

## A.11.2: Template Form: Notification of Grant of Approval / Conditional Approval

### Notification of Approval / Conditional Approval of a Food Business Establishment Subject to Approval under Regulation (EC) No. 853/2004

To be completed by the Food Authority and sent to the applicant.

---

#### PART 1 – Name and address of applicant

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TO:	<b>IMPORTANT</b> You must notify any change to the details on this form, including any changes in the operations carried out and products handled in the establishment, in writing to the approving Food Authority at the address shown.	[Food Authority Logo]
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#### PART 2 – Introduction

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Your application dated \_\_\_\_\_ for approval of your establishment which is subject to approval under Regulation (EC) No. 853/2004 has been approved / conditionally approved. This approval / conditional approval is granted in respect of the establishment or part(s) of the establishment shown in Part 3, and the scope of operations, activities and other matters set out in the relevant Parts of this document.

The approval code that has been allocated to this establishment is shown at the end of this document. It must be used, in the required format, and when required by the Regulations, on product labelling, packaging, and other documentation.

In accordance with Regulation 12 of the Official Feed and Food Controls (England) Regulations 2005, any person who is aggrieved by a decision of a Food Authority to Authority to grant a full approval may appeal against that decision to a Magistrates Court. The time limit for lodging an appeal is one month from the date on which this notice was served on you. You may wish to consult a legal adviser about the implications of this notice and your right of appeal against this Food Authority's decision on your application. The name and address of the Magistrates Court at which you should lodge your appeal is \_\_\_\_\_

---

#### PART 3 – Trading name and address

---

Trading name of establishment

Full postal address

Postcode:

This approval / conditional approval relates to:

- ☐ The whole of the establishment at this address.
- ☐ The following part(s) only of the establishment at this address:

**Conditional Approval Only:**

- ☐ The establishment has been conditionally approved in accordance with Article 31 of Regulation 882/2004

The requirements of the Regulations that you have failed to comply with are:

Regulation / Article No.	Requirement

**The reasons you have failed to comply with the requirements of the Regulation are:**

Regulation / Article No.	Details of non-compliance

**The measures you need to take in order to comply with the requirements of the Regulation are:**

Regulation / Article No.	Measures needed to secure compliance

In accordance with Article 31(2)(d) of Regulation (EC) 882/2004, this Food Authority will visit your establishment within three months of this conditional approval being granted in order to make an assessment of progress in complying with the above requirements.

#### **PART 4 – Food Business Operator and Management**

Name of applicant	<input type="text"/>
Position in business	<input type="text"/>
Name of contact	<input type="text"/>
Position in business	<input type="text"/>
Tel (Incl. Dialling code)	<input type="text"/>
Fax (incl. Dialling code)	<input type="text"/>
E-mail	<input type="text"/>
Name and full address of Food Business Operator	<input type="text"/>
	Postcode: <input type="text"/>

#### **PART 5 – SCOPE OF APPROVAL**

This approval authorises the handling of the following type(s) of product in the establishment shown in Part 3 of this document in respect of the specific activities and products detailed below:

- |                          |                             |
|--------------------------|-----------------------------|
| <input type="checkbox"/> | Minced Meat                 |
| <input type="checkbox"/> | Meat Preparations           |
| <input type="checkbox"/> | Mechanically Separated Meat |

<input type="checkbox"/>	Meat Products
<input type="checkbox"/>	Live Bivalve Molluscs (Shellfish)
<input type="checkbox"/>	Fishery Products
<input type="checkbox"/>	Dairy Products
<input type="checkbox"/>	Eggs (not Primary Production) / Egg Products
<input type="checkbox"/>	Frogs' Legs / Snails
<input type="checkbox"/>	Rendered Animal Fats and Greaves
<input type="checkbox"/>	Treated Stomachs, Bladders and Intestines
<input type="checkbox"/>	Gelatine
<input type="checkbox"/>	Collagen
<input type="checkbox"/>	Collection Centre or Tannery supplying raw material for the production of Gelatine or Collagen intended for human consumption
<input type="checkbox"/>	Stand-alone Meat Cold Store

**Full Details of Activities and Specific Products Handled**

**The establishment shown at Part 3 has been granted the following derogations:**

**Approval Code:**

**Date Approval /  
Conditional Approval  
Granted:**

**Signed:**

**Name:**

**Designation:**

**Date:**

Name and address of Food  
Authority:

Contact Name:

**IMPORTANT**

You must notify any change to the details on this form, including any change in the operations carried out and products handled in the establishment, in writing to the approving Food Authority at the address shown

Telephone:

Fax:

E-mail:

### A.11.3: Template Notification of Refusal to Grant Approval

## Notification of REFUSAL to Grant Approval to a Food Business Establishment Subject to Approval under Regulation (EC) No. 853/2004

To be completed by the Food Authority and sent to the applicant.

---

#### PART 1 – Name and address of applicant

---

TO:	<b>IMPORTANT</b> You must not use any part of the establishment detailed in Part 3 for any purpose which would render the establishment subject to approval under Regulation 853/2004 unless this Food Authority has granted approval.	[Food Authority Logo]
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#### PART 2 – Notification of decision

---

Your application dated \_\_\_\_\_ for approval of your establishment which is subject to approval under Regulation (EC) No. 853/2004 has been **REFUSED** in respect of the establishment, or part of the establishment shown in Part 3 of this document.

The decision to refuse your application was made for the reason(s) set out in Part 4 of this document.

The establishment, or any part of it, must therefore not be used for any purpose which would render the establishment subject to approval under Regulation (EC) No. 853/2004 **UNLESS THIS FOOD AUTHORITY HAS GRANTED APPROVAL.**

In accordance with Regulation 12 of the Official Feed and Food Controls (England) Regulations 2005, any person who is aggrieved by a decision of a Food Authority to refuse to grant an approval may appeal against that decision to a Magistrates Court. The time limit for lodging an appeal is one month from the date on which this notice was served on you. You may wish to consult a legal adviser about the implications of this notice and your right of appeal against this Food Authority's decision on your application. The name and address of the Magistrates Court at which you should lodge your appeal is \_\_\_\_\_.

---

#### PART 3 – Trading name and address of the establishment

---

Trading name of premises

Full postal address

Postcode:
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This refusal relates to:

- ☐ The whole of the establishment at this address.
- ☐ The following part(s) only of the establishment at this address:

---

#### PART 4 – Reasons for refusal

---

Your application for approval has been refused because you have failed to comply with the requirements of the Regulations as indicated below.

The requirements of the Regulations that you have failed to comply with are:

Regulation / Article No.	Requirement

The reasons you have failed to comply with the requirements of the Regulation are:

Regulation / Article No.	Details of non-compliance

**Signed:**  
**Name:**  
**Designation:**  
**Date:**


Name and address of Food Authority:

Contact Name:

Telephone:

Fax:

E-mail:

### IMPORTANT

You must not use any part of the establishment detailed in Part 3 for any purpose which would render the establishment subject to approval under Regulation 853/2004 unless this Food Authority has granted approval.

#### A.11.4: Template Form: Notification of Withdrawal of Approval / Conditional Approval

### Notification of WITHDRAWAL of the Approval / Conditional Approval of a Food Business Establishment Subject to Approval under Regulation (EC) No. 853/2004

To be completed by the Food Authority and sent to the applicant.

A separate notification must be completed for each approval that has been revoked in relation to this establishment.

---

#### PART 1 – Name and address of applicant

---

TO:	<b>IMPORTANT</b>  With immediate effect, you must not use any part of the premises detailed in Part 4 for any activities that were subject to the approval that has been withdrawn, and you must not use the associated approval code on any product.	[Food Authority Logo]
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---

#### PART 2 – Notification of decision to withdraw [approval / conditional approval]

---

This is formal notification that the [approval / conditional approval] granted by this Food Authority (or by a predecessor Food Authority) on \_\_\_\_\_ in respect of the establishment shown in Part 4 of this document, which is subject to approval under Regulation 853/2004, to handle products of animal origin indicated in Part 3 of this document, has been **WITHDRAWN**. The decision to withdraw the [approval / conditional approval] was made for the reason(s) set out in Part 5 of this document.

You must therefore cease all activities that were the subject of the specified [approval / conditional approval], and you must not use the approval code \_\_\_\_\_ for any products, both with immediate effect.

If you are handling other products in the establishment that is subject to a different approval but with the same approval code as the code shown above, and that approval has not also been withdrawn, you must contact this Food Authority without delay. The name of the person you should contact is at the end of this notice.

In accordance with Regulation 12 of the Official Feed and Food Controls (England) Regulations 2005, any person who is aggrieved by a decision of a Food Authority to withdraw an [approval / conditional approval] may appeal against that decision to a Magistrates Court. The time limit for lodging an appeal is one month from the date on which this notice was served on you. You may wish to consult a legal adviser about the implications of this notice and your right of appeal against this Food Authority's decision on your application. The name and address of the Magistrates Court at which you should lodge your appeal is \_\_\_\_\_.

---

#### PART 3 – Product(s) of animal origin for which [approval / conditional approval] has been **WITHDRAWN**

---

- |                          |                                   |
|--------------------------|-----------------------------------|
| <input type="checkbox"/> | Minced Meat                       |
| <input type="checkbox"/> | Meat Preparations                 |
| <input type="checkbox"/> | Mechanically Separated Meat       |
| <input type="checkbox"/> | Meat Products                     |
| <input type="checkbox"/> | Live Bivalve Molluscs (Shellfish) |
| <input type="checkbox"/> | Fishery Products                  |
| <input type="checkbox"/> | Dairy Products                    |



<input type="checkbox"/>	Eggs (not Primary Production) / Egg Products
<input type="checkbox"/>	Frogs' Legs / Snails
<input type="checkbox"/>	Rendered Animal Fats and Greaves
<input type="checkbox"/>	Treated Stomachs, Bladders and Intestines
<input type="checkbox"/>	Gelatine
<input type="checkbox"/>	Collagen
<input type="checkbox"/>	Raw material for the production of Gelatine or Collagen intended for human consumption (Collection Centre or Tannery)
<input type="checkbox"/>	Meat (Stand-Alone Cold Store)

---

**PART 4 – Trading name and address of the establishment**


---

Trading name of establishment

Full postal address

Postcode:

---

**PART 5 – Reasons for withdrawal**


---

The [approval / conditional approval] has been withdrawn because:

- |                          |                                                                                         |
|--------------------------|-----------------------------------------------------------------------------------------|
| <input type="checkbox"/> | The activities for which the approval was granted are no longer being undertaken.       |
| <input type="checkbox"/> | You have failed to comply with the requirements of the Regulations as identified below. |

The requirements of the Regulations that you have failed to comply with are:

Regulation / Article No.	Requirement

The reasons you have failed to comply with the requirements of the Regulation are:

Regulation / Article No.	Details of non-compliance

**Signed:**

**Name:**

**Designation:**

**Date:**

Name and address of Food  
Authority:

Contact Name:

Telephone:

Fax:

E-mail:

## **IMPORTANT**

**With immediate effect, you must not use any part of the establishment detailed in Part 4 for any activities that were subject to the approval that has been withdrawn, and you must not use the associated approval code on any product.**

## A.11.5: Template Form: Notification of Suspension of Approval / Conditional Approval

### Notice of SUSPENSION of Approval / Conditional Approval of a Food Business Establishment Subject to Approval under Regulation (EC) No. 853/2004

To be completed by the Food Authority and sent to the proprietor, with a copy sent to the Food Standards Agency.  
A separate notification must be completed for each [approval / conditional approval] that has been suspended in relation to these premises.

---

#### PART 1 – Name and address of proprietor

---

TO:	<b>IMPORTANT</b>  With immediate effect, you must not use any part of the establishment detailed in Part 4 for any activities that were subject to the approval that has been suspended, and you must not use the associated approval code on any product, until such time as the suspension is lifted.	[Food Authority Logo]
-----	---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-----------------------

---

#### PART 2 – Notice of decision to suspend [approval / conditional approval]

---

This is formal notice that the approval / conditional approval granted by this Food Authority (or by a predecessor Food Authority) on \_\_\_\_\_ in respect of the establishment shown in Part 4 of this document, which is subject to approval under Regulation 853/2004 to handle products of animal origin indicated in Part 3 of this document, has been **SUSPENDED**. The decision to suspend the [approval / conditional approval] was made for the reason(s) set out in Part 5 of this document

You must therefore cease all activities that were the subject of the specified approval, and you must not use the approval code \_\_\_\_\_ for any products, both with immediate effect, until such time as this Food Authority lifts the suspension.

If you are handling a product of animal origin in the establishment that is subject to a different approval but with the same approval code as the code shown above, and that approval has not also been suspended, you must contact this Food Authority without delay. The name of the person you should contact is at the end of this notice.

In accordance with Regulation 12 of the Official Feed and Food Controls (England) Regulations 2005, any person who is aggrieved by a decision of a Food Authority to Authority to suspend an [approval / conditional approval] may appeal against that decision to a Magistrates Court. The time limit for lodging an appeal is one month from the date on which this notice was served on you. You may wish to consult a legal adviser about the implications of this notice and your right of appeal against this Food Authority's decision on your application. The name and address of the Magistrates Court at which you should lodge your appeal is \_\_\_\_\_.

---

#### PART 3 – Product(s) of animal origin / type of establishment in respect of which approval has been SUSPENDED

---

- |                          |                                   |
|--------------------------|-----------------------------------|
| <input type="checkbox"/> | Minced Meat                       |
| <input type="checkbox"/> | Meat Preparations                 |
| <input type="checkbox"/> | Mechanically Separated Meat       |
| <input type="checkbox"/> | Meat Products                     |
| <input type="checkbox"/> | Live Bivalve Molluscs (Shellfish) |

<input type="checkbox"/>	Fishery Products
<input type="checkbox"/>	Dairy Products
<input type="checkbox"/>	Eggs (not Primary Production) / Egg Products
<input type="checkbox"/>	Frogs' Legs / Snails
<input type="checkbox"/>	Rendered Animal Fats and Greaves
<input type="checkbox"/>	Treated Stomachs, Bladders and Intestines
<input type="checkbox"/>	Gelatine
<input type="checkbox"/>	Collagen
<input type="checkbox"/>	Raw material for the production of Gelatine or Collagen intended for human consumption (Collection Centre or Tannery)
<input type="checkbox"/>	Meat (Stand-Alone Cold Store)

---

**PART 4 – Trading name and address of the establishment**


---

Trading name of establishment

Full postal address

<input type="text"/>  Postcode: <input type="text"/>
------------------------------------------------------------

---

**PART 5 – Reasons for suspension**


---

**The approval has been suspended because:**

<input type="checkbox"/>	You have failed to comply with a notice (copy attached) served on you on	under:
<input type="checkbox"/>		
<input type="checkbox"/>		

<input type="checkbox"/>	You have failed to comply with the requirements of the Regulations as identified below.
--------------------------	-----------------------------------------------------------------------------------------

**The requirements of the Regulations that you have failed to comply with are:**

Regulation / Article No.	Requirement

**The reasons you have failed to comply with the requirements of the Regulation are:**

Regulation / Article No.	Details of non-compliance

**The measures you need to take in order to comply with the requirements of the Regulation are:**

Regulation / Article No.	Measures needed to secure compliance

**Signed:**   
**Name:**   
**Designation:**   
**Date:**

Name and address of Food Authority:
----------------------------------------

Contact Name:

Telephone:

Fax:

E-mail:

## IMPORTANT

**With immediate effect, you must not use any part of the establishment detailed in Part 4 for any activities that were subject to the approval that has been suspended, and you must not use the associated approval code on any product, until such time as the suspension is lifted.**

## A.11.6: Template Form: Notification of Refusal to Grant Full Approval to an Establishment which is Conditionally Approved

### Notification of REFUSAL to Grant Full Approval to an Establishment subject to Approval under Regulation 853/2004, which is Conditionally Approved under Regulation 882/2004

To be completed by the Food Authority and sent to the applicant.

---

#### PART 1 – Name and address of applicant

---

TO:	<b>IMPORTANT</b>  You must not use any part of the establishment detailed in Part 4 for any purpose which would render the establishment subject to approval under Regulation 853/2004 unless this Food Authority has granted approval.	[Food Authority Logo]
-----	-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-----------------------

---

#### PART 2 – Notification of decision

---

Your establishment which is subject to conditional approval under Regulation 853/2004 to handle products of animal origin indicated in Part 3 of this document has been **REFUSED** full approval in respect of the establishment, or part of the establishment shown in Part 4 of this document.

The decision to refuse to grant full approval was made for the reason(s) set out in Part 5 of this document.

The establishment, or any part of it, must therefore not be used for any purpose which would render it subject to approval Regulations 853/2004 **UNLESS THIS FOOD AUTHORITY HAS GRANTED APPROVAL.**

In accordance with Regulation 12 of the Official Feed and Food Controls (England) Regulations 2005, any person who is aggrieved by a decision of a Food Authority to Authority to grant an approval may appeal against that decision to a Magistrates Court. The time limit for lodging an appeal is one month from the date on which this notice was served on you. You may wish to consult a legal adviser about the implications of this notice and your right of appeal against this Food Authority's decision on your application. The name and address of the Magistrates Court at which you should lodge your appeal is

---

#### PART 3 – Products of animal origin for which full approval has been REFUSED

---

- |                          |                                              |
|--------------------------|----------------------------------------------|
| <input type="checkbox"/> | Minced Meat                                  |
| <input type="checkbox"/> | Meat Preparations                            |
| <input type="checkbox"/> | Mechanically Separated Meat                  |
| <input type="checkbox"/> | Meat Products                                |
| <input type="checkbox"/> | Live Bivalve Molluscs (Shellfish)            |
| <input type="checkbox"/> | Fishery Products                             |
| <input type="checkbox"/> | Dairy Products                               |
| <input type="checkbox"/> | Eggs (not Primary Production) / Egg Products |
| <input type="checkbox"/> | Frogs' Legs / Snails                         |
| <input type="checkbox"/> | Rendered Animal Fats and Greaves             |
| <input type="checkbox"/> | Treated Stomachs, Bladders and Intestines    |

<input type="checkbox"/>	Gelatine
<input type="checkbox"/>	Collagen
<input type="checkbox"/>	Raw material for the production of Gelatine or Collagen intended for human consumption (Collection Centre or Tannery)
<input type="checkbox"/>	Meat (Stand-Alone Cold Store)

---

**PART 4 – Trading name and address of the establishment**


---

Trading name of establishment

Full postal address

Postcode:

**This refusal relates to:**

<input type="checkbox"/>	The whole of the establishment at this address.
<input type="checkbox"/>	The following part(s) only of the establishment at this address:

---

**PART 5 – Reasons for refusal**


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**Your application for approval has been refused because you have failed to comply with the requirements of the Regulations as indicated below.**

**The requirements of the Regulations that you have failed to comply with are:**

Regulation / Article No.	Requirement

**The reasons you have failed to comply with the requirements of the Regulation are:**

Regulation / Article No.	Details of non-compliance

**Signed:**

**Name:**

**Designation:**

**Date:**

Name and address of Food  
Authority:

Contact Name:

## **IMPORTANT**

**You must not use any part of the establishment detailed in Part 4 for any purpose which would render the establishment subject to approval under Regulation 853/2004 unless this Food Authority has granted approval.**



## **ANNEX 12: APPROVAL OF PRODUCT-SPECIFIC ESTABLISHMENTS SUBJECT TO APPROVAL UNDER REGULATION 853/2004 - FOOD AUTHORITY FILES**

### **List of Contents**

The following guidance is offered to Food Authorities in order to support and improve consistency in the content and structure of files produced for establishments which require formal approval.

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

Each file should contain:

- The application form;
- a plan or plans of the establishment indicating:
  - i. The layout of the establishment;
  - ii. The location of equipment;
  - iii. Work flows for each product line;
  - iv. Water distribution system within the establishment including all outlets and sampling points;
  - v. Drainage layout;
  - vi. Pest control - baiting and/or trapping points within the establishment and external areas;
- a synopsis of the establishment which briefly describes what type of establishment it is, products produced, volume of product, type of trade, number of employees, approval number and what it is approved for. This synopsis should be no more than one side of an A4 sheet;
- pre-approval inspection report;
- planned programme of works to achieve approval;
- approval notification document specifying:
  - i. Details of activities to which the approval relates;
  - ii. Approval number;
  - iii. Classification;
  - iv. Special hygiene direction(s);
  - v. Any derogations that have been granted;
  - vi. Any other conditions or limitations specified by the Food Authority;
  - vii. Any arrangements acceptable to the Food Authority;

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

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

## **ANNEX 13: APPROACH TO ENFORCEMENT - REQUIREMENT FOR FOOD SAFETY MANAGEMENT PROCEDURES BASED ON HACCP PRINCIPLES**

### **A.13.1: Introduction**

The requirement for food safety management procedures based on HACCP principles is a significant change for food businesses. The legislation is flexible and allows businesses to comply in different ways. This is particularly important for small, less developed and catering businesses where traditional HACCP is difficult to apply.

### **A.13.2: Enforcement Approach**

Enforcement should continue to be graduated and educative.

### **A.13.3: Regulation 852/2004**

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

Food premises that present a clear and imminent danger to public health should have formal enforcement action taken against them to secure improvement. This will not change from 1 January 2006.

For food premises that do not present a clear and imminent danger to public health, the focus of enforcement visits should be to help the business improve its standards of food safety. For enforcement, *in practice this means:*

- *Questioning the person responsible for food safety in the premises to ensure that significant hazards are understood and controlled, and where understanding and control is lacking – helping the business to improve.*

With limited time and resources, enforcers should concentrate on significant hazards to public health, ensuring that the person responsible for food safety understands these hazards and knows how to control and manage them. This is an educative approach. The expectation is that businesses improve their standards over time, taking account of the understanding they gain from the enforcement officer and other sources. Where a business does not improve – given reasonable time, after being offered guidance, improvement notices and other more formal enforcement activity can be used. This is a graduated approach.

### **A.13.4: Flexibility**

Regulation 852/2004 will not simply add documentation and record keeping to an existing requirement for hazard analysis. In fact, the Regulation is much more flexible, and requires food businesses to establish procedures in the

business that control food safety hazards, and integrate these procedures with documentation and record keeping appropriate to the size and nature of the business.

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

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

For enforcement, *in practice, compliance at a high level, means:*

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

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

Further guidance on flexibility is expected from the Commission by December 2005.

The key points are:

- Flexibility applies to all food businesses
- The manager of a business should have the skills necessary to maintain a food safety management system proportionate to their business, and not simply be trained in HACCP principles. These skills can be gained in many ways, formal training is not the only route.
- Staff in a business should have the skills needed to undertake their duties and follow the food safety procedures in the business. Training for staff should be proportionate and reflect the flexibility guidance. Formal training may not be necessary to achieve the objective of having the required competencies. In practical terms, on the job training might be appropriate, attendance at a formal training event is not necessary.

- Monitoring key activities in the business (critical control points) need not be numeric and can be based on sensory observation, craft skills and supervision.
- Incident recording is an appropriate and proportionate form of record keeping in many businesses
- Corrective actions must supplement incident recording.

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

The following chart breaks down the components of the legislation into the standard 7 principles of HACCP, with some of the flexibility in the legislation identified. Although guidance materials may use this 7-principle framework, it is not necessary for this approach to be used. Provided the same outcome is achieved, safe food being produced, this can be achieved by substituting, in a simplified but effective way, some or more of the seven principles. This is clarified in the further 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 Agency approach 'Safer food better business', but should be useable to identify compliance in a business using other similarly flexible tools, or where the business has devised its own procedures.

1.	<p><b>Identify any hazards that must be prevented eliminated or reduced;</b></p> <p>Mapping Hazard Analysis with tools such as flow-charts may not be suitable for all businesses. It is sufficient that the business has thought about its activities in a structured way. The effect of the analysis and the procedures produced should be to ensure that safe food is always produced.</p> <p>The traditional HACCP approach of controlling some hazards through pre-requisite programmes of Good Hygienic Practice and others through the HACCP system may not be appropriate, particularly in small businesses where it is not readily understood. Whatever the format of the guidance, the business must be managing all significant hazards including those traditionally controlled through Good Hygienic Practice.</p> <p><b>For enforcement, in practice, this means:</b></p> <ul style="list-style-type: none"> <li>• <i>Seeing some evidence that the person responsible for food safety has thought about their business and identified significant hazards and knows how to control them – for some businesses it may be appropriate to follow standard advice from the Agency, industry guides, advice from trade bodies etc.</i></li> </ul>
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<p>2.</p> <p>3.</p>	<p><b>Identify the critical control points (CCPs) at the steps at which control is essential;</b></p> <p><b>and Establish critical limits at CCPs;</b></p> <p>Critical control points and their limits may not always be helpful ways of thinking about food safety for small businesses and they may instead identify generic controls - like thorough cooking, together with the ways of ensuring they know this has happened.</p> <p>The legislation is flexible in stating the requirement that establishing a critical limit does not always imply that a numerical value must be fixed. This is in particular the case where monitoring procedures are based on visual observation, for example a business may 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 may be appropriate to use pre-validated procedures that follow established best practice, produced by the Agency, trade bodies or others.</p> <p><b>For enforcement, in practice, this means:</b></p> <ul style="list-style-type: none"> <li>• <i>Seeing some evidence that the business is following procedures that include steps where the significant hazards are controlled – for many businesses it may be appropriate to follow standard advice.</i></li> </ul>
<p>4.</p>	<p><b>Establish procedures to monitor the CCPs;</b></p> <p>Management of food safety through the procedures detailed above will need to be demonstrated. This can be shown in many ways. In some larger businesses this may be achieved by monitoring protocols and record keeping. In other businesses – particularly where the person responsible spends significant time in the food preparation areas, this may be demonstrated by their ability to supervise their operation – that their procedures are being followed. It will be important to establish that if the procedures are followed, safe food will result.</p> <p>Monitoring may in many cases be a purely sensory exercise, for example a regular visual verification of the temperature of cooked food by a colour change.</p> <p><b>For enforcement, in practice, this means:</b></p> <ul style="list-style-type: none"> <li>• <i>Seeing some evidence that the business is monitoring their procedures, either using physical checks such as noting temperatures or via sensory checks such as noting that a stew or sauce is bubbling. The person responsible for food safety should be able to explain the chosen method of monitoring.</i></li> </ul>

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

### **A.13.5: Role of Food Authorities**

The new legislation will require the industry to raise its standards to that already achieved by the best businesses. The flexibility means that all food businesses should be able to comply.

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

Proper implementation of the appropriate support model will constitute compliance with Article 5 of Regulation 852/2004. Correctly implemented, Safer food better business will allow a food business to demonstrate compliance.

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

- Has been given reasonable opportunity to implement food safety management;
- Has been directed to appropriate training, if needed; and
- Has been 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 Agency's advice, 'Safer food, better business', is broken down into the 4Cs (cooking, cleaning, chilling & cross-contamination) and it may be appropriate to set a business one of these 'Cs' at a time. Other guidance material can also be divided into 'chunks' like this. Where fundamental skills are missing, enforcers should point businesses at sources of the competencies – guidance materials, books, courses etc. Enforcers should look to the business to make reasonable progress through the material and make appropriate changes in their practices before the graduated approach progresses from education to more formal infraction methods.

A food safety management system should give assurance that the business knows how to produce safe food, has procedures in place that assure this, and repeatedly does produce safe food. Whether a business has an effective food safety management system in place is a judgement for enforcement officers. For enforcement, in practice, this means:

- *Judging whether the business has appropriate procedures in place so that it would continue to produce food safely if things went wrong – staff absences, unexpected demand etc., and seeing some evidence that this is the case.*



## **ANNEX 14: IMPORT OF FOOD FROM THIRD COUNTRIES**

# **GUIDANCE FOR FOOD AUTHORITIES ON THE IMPORT OF FOOD FROM THIRD COUNTRIES**

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**Appendix 1: Glossary of terms**

## **A.14.1: Introduction**

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

The guidance focuses on the principal legislation relating to the import of food not of animal origin (FNAO). From 1 January 2006, FNAO import controls are harmonised at Community level by Regulation (EC) No 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (EU Regulation 882/2004). The provisions of the EU Regulation are directly applicable but are given effect at national level by the Official Feed and Food Controls (England) Regulations 2005 (and parallel legislation in Scotland, Wales, and Northern Ireland). This legislation replaces the current legislation (principally, the Imported Food Regulations 1997) but the general approach in the new legislation is similar.

### **A.14.1.1: Scope**

The scope of this guidance extends to imported FNAO and imported products of animal origin (POAO). It has been revised in the light of EU Regulation 882/2004 on Official Feed and Food Controls. The guidance does not cover control activities for POAO at Border Inspection Posts, where central guidance produced by Defra is available<sup>1</sup>. However, it does provide enforcement guidance for local authorities relating to illegally introduced POAO. The guidance covers food controls only – animal feed is subject to separate enforcement guidance issued by the Food Standards Agency.

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

Local authorities (including Port Health Authorities) with a point of entry provide the first line of control on imported food to ensure it is safe and complies with EU and UK requirements. However, it is important that controls are also in place at Enhanced Remote Transit Sheds (ERTS), ships suppliers, international rail terminals, and other premises inland, as significant amounts of FNAO will not have been subject to checks at points of entry and there is a possibility that POAO may have entered the UK illegally. Further details of the roles and responsibilities of Port Health Authorities, local authorities and other government agencies and departments can be found in the Food Standard Agency’s Local Authority Resource Pack on Imported Food Control<sup>2</sup>.

This guidance incorporates relevant information from:

Good practice guides contained in the Syniad/APHA/FSA Benchmarking Study<sup>3</sup> into the port health function involving port health participants from seaports, LACORS and other Government Departments.

The Food Standards Agency's Local Authority Resource Pack on Imported Food Control provided to food authority delegates at national update training seminars<sup>2</sup>.

This guidance includes summaries of some statutory provisions. However, these are indicative and for general guidance only.

#### **A.14.2: Status of this Guidance**

This document should be considered as centrally issued guidance for the purpose of the Framework Agreement on Local Authority Food Law Enforcement (the latest version is available on the Agency's website<sup>4</sup>). Amendments have been made to the Standard in the Framework Agreement to clarify its application to imported food control (Amendment issued in June 2004).

This guidance should also be read in conjunction with the Food Law Code of Practice issued under Section 40 of the Food Safety Act 1990, which has been reviewed and re-issued under Regulation 24 of the Food Hygiene (England) Regulations 2005, and Regulation 6 of the Official Feed and Food Controls (England) Regulations 2005. The Code of Practice provides direction and guidance on the local authority approach to enforcement generally.

#### **A.14.3: Imported Food Legislation (FNAO)**

##### **A.14.3.1: EU Regulation 882/2004**

This introduces EU-wide harmonised rules for import controls for FNAO. The requirements (at Articles 15 to 25) extend to foods not already covered by Directive 97/78/EC (POAO Veterinary Checks regime). These cover controls in relation to materials and articles in contact with food as well as cleaning and maintenance products and processes, and pesticides.

##### **A.14.3.2: The Official Feed and Food Controls (England) Regulations 2005**

The Official Feed and Food Controls (England) Regulations 2005 give effect to Articles 15 to 25 of EU Regulation 882/2004 in England only. These Regulations replace the Imported Food Regulations 1997. Parallel legislation is in place in Scotland, Wales, and Northern Ireland.

The Official Feed and Food Controls (England) Regulations 2005 include a mechanism for ensuring that where there is a serious or imminent risk to public health, control measures may be put in place. In particular, it may be used to ensure that Emergency Decisions made at EU level are implemented without delay. It does so by giving the Food Standards Agency powers to make declarations regarding import conditions for particular products. These conditions would apply with immediate effect.

#### **A.14.3.3: Other legislation**

For certain areas, for example, contaminants, there are specific EU harmonised requirements for foods which can be applied at point of import as well as inland. These EU requirements are implemented in the UK by separate legislation but the powers to deal with non-conforming food at import are those contained in the Official Feed and Food Controls (England) Regulations 2005. Separate and detailed European Commission guidance on the contaminants legislation is available at:

[http://europa.eu.int/comm/food/food/chemicalsafety/contaminants/aflatoxin\\_guidance\\_en.pdf](http://europa.eu.int/comm/food/food/chemicalsafety/contaminants/aflatoxin_guidance_en.pdf).

#### **A.14.3.4: 'High risk' FNAO**

EU Regulation 882/2004 (Article 15(5)) provides that the Commission may issue a list of 'high risk' FNAO. These products will be identified on the basis of known or emerging risk, and will be subject to increased import controls at the point of entry. The frequency and nature of such checks will be specified by the Commission when the products are identified. The enhanced controls provided for by these arrangements include; prior notification, import through designated ports only, and specified documentary and physical checks at points of entry.

As the Commission had not yet issued a list of 'high risk' products, it is not possible at this stage to legislate for these products at a national level. It is proposed that once the list of products has been issued by the Commission, the national legislation will be amended appropriately.

In the meantime, current safeguard measures will continue to apply and further measures may be introduced under the provisions of the EU General Food Law Regulation (178/2002) such that public and animal health protection will not be compromised by the delay. These measures provide similar enhanced requirements such as specified checks and, where relevant, entry through designated ports.

#### **A.14.4: Service Planning**

The Framework Agreement on Local Authority Food Law Enforcement includes service planning guidance. Section 2.3 of the framework ("Scope of the food service") and Section 2.4 ("Demands on the food service") provide for local authorities to set out the scope of the responsibilities and service provided and to describe any external factors that may impact on their service. Where relevant, local authorities should include in these sections imported food responsibilities and the control arrangements in place.

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

#### **A.14.5: Documented Policies and Procedures**

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

Procedures relating to examination of imported food including deferred examinations under The Official Feed and Food Controls (England) Regulations 2005 should cover both food safety and food standards issues, where applicable.

Such procedures may be audited by the Food Standards Agency and should be suitable and sufficient for these purposes. They should make public, information on their control activities and their effectiveness.

#### **A.14.6: Authorisation**

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

For food safety and food standards matters this should include authorisation under the Food Safety Act 1990 and under hygiene and processing Regulations issued under it, including any relevant contaminants legislation.

Officers should also be authorised to enforce relevant Regulations issued under the European Communities Act 1972 (e.g. The General Food Regulations 2004). However, the European Communities Act does not contain the specific enforcement powers, its primary function is to provide a mechanism by which Regulations can be enacted. Powers of enforcement for Regulations made under the Act are usually contained in the Regulations themselves. Therefore, the Agency's view is that all Regulations relevant to imported food control should be specifically referred to in authorisation documents, including officers' credentials. As such these should, for example, include:

The Products of Animal Origin (Import and Export) Regulations 1996 as amended,

The Products of Animal Origin (Third Country Imports) (England) (no. 4) Regulations 2004,

Note: in POAO legislation the definition of "local authority" for enforcement purposes does not currently include County Councils.

Emergency Control Regulations e.g. The Food (Chilli, Chilli Products, Curcuma and Palm Oil) (Emergency Control) (England) Regulations 2005, and

The Official Feed and Food Controls (England) Regulations 2005.

The Agency's view is that officers do not need to be specifically authorised to enforce declarations made under Regulation 33 of the Official Feed and Food Controls (England) Regulations 2005.

General advice on the authorisation of officers has been developed by LACORS. Local Authorities may also wish to consult their own legal advisors on this matter.

#### **A.14.7: Qualifications / Experience of Authorised Officers**

Officers authorised to undertake imported food control work and enforcement action should be appropriately qualified, experienced and competent to carry out the range of tasks and duties they are authorised to perform, in line with the relevant requirements of the Food Law Code of Practice, and subsequent documents. Staff should be kept up to date in their area of competence and receive regular additional training as necessary.

All local authorities should have at least one officer competent in imported food controls. Relevant update training could include:

- Attendance at Food Standards Agency enforcement training on imported food control; and
- Familiarisation with the Agency's Local Authority Resource Pack on Imported Food Control 2; or
- Other relevant training of an equivalent content e.g. in-house training or cascade training relating to (a) & (b) above.

#### **A.14.8: Information**

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

- The port operator.
- Access to port/Customs areas, including Enhanced Remote Transit Sheds (ERTS).
- Stakeholders, including import agents and airlines/shipping operators.
- Trade type (volume, nature, and trade routes).
- Facilities where imported food inspection can be carried out and arrangements for storage of detained/seized goods. Defra have issued further specific advice on operating procedures for sharing facilities at BIPS 16.
- Equipment available for carrying out inspections and sampling of imported food.
- Details of appointed and specialist laboratories for analysis and/or examination of samples that are able to provide an appropriate service for sample analysis (in particular relation to the time-scale of analysis and issue of results).
- Health and safety requirements.
- Security requirements.

Local authorities with a point of entry, ERTS or international rail terminals should establish routine local liaison and communication with relevant local organisations for the purpose of general exchange of information on food imports and for the effective handling of incidents. These contacts could include, where appropriate:

- HMRC (Her Majesty's Revenue and Customs) including anti-smuggling and Convention On International Trade in Endangered Species (CITES) teams,
- The State Veterinary Service (SVS),
- The Health Protection Agency in England, or Scottish Centre for Infection and Environmental Health in Scotland or the National Public Health Service for Wales,
- The Horticultural Marketing Inspectorate and Plant Health & Seeds Inspectorate (Defra) in England and Wales or the Horticultural and Marketing Unit (Scottish Executive Environment and Rural Affairs Department) in Scotland,
- Port operator; import agents; Transit Shed \ ERTS operators,
- Maritime and Coastguard Agency (MCA),
- Neighbouring local authorities, particularly for joint boards and ports, which fall under the jurisdiction of more than one local authority, including County Councils for certain Trading Standards responsibilities, and
- The Medicines & Health Care products Regulatory Agency (MHRA).

Contact details and information on the roles and responsibilities of relevant central government departments and other organisations can be found in the Food Standards Agency's Local Authority Resource Pack on Imported Food Control<sup>2</sup>.

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

## **A.14.9: Records**

### **A.14.9.1: Identifying and recording food importers**

All local 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 importers, so far as the EU Hygiene Regulation 852/2004 provides for this.

For the purposes of identifying and recording food businesses and systems falling under the official controls, local authorities / PHAs should refer to the scope of EU Regulation 882/2004 as detailed in Articles 14 and 15. Relevant activities should be identified on the appropriate files together with an indication of the type and origin of foods being imported.



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

#### **A.14.9.2: Records of consignments and examinations**

Local 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 ERTS 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.

#### **A.14.9.3: Arrangements for points of entry without permanent local authority presence**

Where there is no permanent local authority presence at an airport or seaport, and it is not considered by the authority to be a point of entry for food, the local authority should (at least once every three months) contact the port operator, HMRC and/or other commercial operators to confirm the port's status regarding food activities and/or obtain information about the volumes, types, countries of origin and customs status of food entering the port since the last such enquiry. Local authorities should keep a record of these exchanges for a period of three years.

The purpose of these arrangements is to provide local authorities with updated information on food being imported. This will enable risk-based judgements to be made on the targeting of enforcement action and to ensure that emergency controls or restrictions on certain foods are being enforced. This includes at the designated point of entry, and requirements relating to documentary checks and associated statutory sampling (further details on risk-based checks can be found in Section A9.14).

### **A.14.10: Reporting and Notification Arrangements**

#### **A.14.10.1: Nominated officer for imported food controls**

Every local authority with a point of entry should appoint a nominated officer with the necessary competency in imported food control to be a point of contact with the Food Standards Agency on imported food matters. The details of the nominated officer or changes to the nominated officer should be notified to the Agency's Imported Food Division<sup>6</sup>.

#### **A.14.10.2: Monitoring returns**

All local authorities should complete any relevant enforcement monitoring returns required by the Food Standards Agency.

In April 2005 the Food Standards Agency wrote to all local authorities seeking baseline data on imported food law enforcement activity, to be used as a measure for the Government's initiative to achieve a 'step change' in local authority delivery and co-ordination of imported food controls. In order for the Agency to monitor imported food control work, authorities should comply with future requests for such data.

Local authorities should also supply any other information reasonably requested by the Food Standards Agency. This may relate to information about the import of specific food products, or food from certain countries. It may relate to information required by the European Commission in connection with emerging public health issues or for inclusion in the National Control Plan or annual reports that the UK will be required to produce in accordance with the requirements of Articles 42 and 44 of EU Regulation 882/2004. Commission Decisions also require monitoring returns to be made to the Commission through the Food Standards Agency.

#### **A.14.10.3: Notification of food hazards or incidents**

All local authorities should send details of any imports rejected, either at the point of entry or inland, where there is a direct or indirect risk to health to the Agency's Incidents Branch<sup>7</sup> using the Rapid Alert System for Food and Feed (RASFF) notification form. This will include imports rejected for reasons such as chemical, microbiological or foreign body contamination or imports from a country which is not authorised to export that category of products to the EU.

In addition, with regard to testing for residues of veterinary medicines in Annex IV of EU Regulation 2377/90, as amended (such as nitrofurans and chloramphenicol) or those not approved for use, details of ALL positive results should be sent to the Incidents Branch using the RASFF notification form. Where available, copies of the health certificate and the airway bill or bill of lading should also be forwarded to the Incidents Branch at<sup>7</sup>:

[drazenka.tubin-delic@foodstandards.gsi.gov.uk](mailto:drazenka.tubin-delic@foodstandards.gsi.gov.uk) or  
[rajwinder.ubhi@foodstandards.gsi.gov.uk](mailto:rajwinder.ubhi@foodstandards.gsi.gov.uk)

Guidance on completing the RASFF notification form has already been provided to local authorities. Authorities who have access to the European Commission's Circa website, will be able to download copies of the template for the RASFF notification form<sup>8</sup>.

The local authority/ port health authority should also notify local customs of the decision and the final destination of the consignment if it is to be allowed to be re-exported.

All local authorities should notify the Agency 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, using the appropriate contact details and reporting arrangements set out in the Food Law Code of Practice and any subsequent documents.

#### **A.14.10.4: Notification of illegal imports of POAO**

A notification should be made to Defra's Illegal Animal Products Seizures (ILAPS) database whenever illegally imported POAO are seized<sup>14</sup>. Further details are contained in Section A9.18 of this guidance.

#### **A.14.11: Liaison / Referrals**

Whenever inland 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, it is important to ensure that the local authority at the point of entry is informed to help target their future surveillance activities.

In certain circumstances, it may be necessary for local authorities covering points of entry to refer imported food matters to inland authorities (e.g. at ship suppliers or Channelled Goods). This would include situations where inland supervision of consignments is required and also where checks at the point of entry reveal food safety or food standards concerns and it is appropriate to refer the matter to an inland authority.

Examples include:

- Where a consignment of food of non-animal origin, which is subject to emergency controls or other restrictions, has been illegally imported e.g. without being presented to the local authority at the point of entry for the required checks to be carried out.
- Where the local authority at the point of entry is aware that illegal imports of products of animal origin may have been distributed.
- Where checks on imported food reveal labelling issues which cannot be enforced at time of import.
- Where examination under The Official Feed and Food Controls (England) Regulations 2005 has been deferred.
- Where unsatisfactory test results are received for samples taken for routine surveillance and as such the consignment has been released from the port.
- Where analysis indicates that nuts are not suitable for human consumption but are referred for feed use.

Wherever practicable, inland authorities should agree to assist with these referrals and respond as appropriate without undue delay and provide feedback to the local authority at the point of entry on the outcome. To assist this process a suggested pro-forma for this purpose is available on the Agency's website<sup>9</sup>. Records of such referrals and details of any action taken should be maintained by authorities.

It may also be necessary for the Food Standards Agency to refer matters concerning illegally imported POAO to inland authorities. This information will

normally be received from HMRC where they have intercepted illegal imports destined for commercial premises. Local authorities should respond to these referrals without undue delay and where requested provide feedback directly to HMRC. Authorities should maintain records of action taken.

#### **A.14.12: Inland Inspection of Imported Food**

Local authority procedures should ensure food (including imported food) examination forms part of food premises inspections.

During routine inspections and other visits to food business premises (e.g. complaint visits, sampling visits) officers are requested to consider the food in possession or offered for sale, and if imported, ensure it complies with relevant imported food requirements.

The Official Feed and Food Controls (England) Regulations 2005 also cover semi-finished products, materials and articles in contact with food, pesticides, and labelling issues.

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 food from third countries, in particular those premises that are the first destination after import. Such premises are likely to include local food manufacturers and warehouses. Any inspection programme should also be informed by food alerts and the premises compliance history.

In addition to assessing fitness for consumption, reasonable steps should be taken to check the legality of the importation of any POAO and FNAO from a third country. The Food Standard Agency's Local Authority Resource Pack on Imported Food Control provides detailed advice on points to consider when investigating the legitimacy of imports. The Agency's website<sup>10</sup> provides the types of food imports and countries of origin where there are prohibitions and restrictions<sup>11</sup>, as well as links to other relevant sites.

##### **A.14.12.1: Deferred examination of FNAO – inland controls**

The Official Feed and Food Controls (England) Regulations 2005 allow for import controls for the examination of consignments of FNAO to be deferred and undertaken by the inland food authority covering the ERTS or international rail terminal or at any other place of destination in the UK. Further guidance on this is given in Section A9.14.

The decision to defer rests with the local authority covering the point of entry and they need to liaise with the receiving authority to ensure that appropriate checks will be carried out and as such the procedure relies on co-operation between authorities. Receiving authorities should wherever possible agree to any reasonable request for a deferred examination. Under The Official Feed and Food Controls (England) Regulations 2005, the enforcement authority at the place of destination would become responsible for enforcement of the

import controls once the point of entry authority had deferred examination to the place of destination.

Inland local authorities should ensure that any available information on imported food, which is sampled, detained, seized or destroyed, wherever practicable is recorded in relevant in-house records or databases.

### **A.14.13: Sampling of Imported Food**

#### **A.14.13.1: Considerations for sampling**

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

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

Commodities sampled under Emergency Control Decisions or Emergency Control Regulations should be detained until the enforcement authority receives the results unless otherwise stated in the implementing rules.

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

Local authorities should take into account any specific central guidance on sampling or other matters set out by the Agency or Defra (Scottish Executive Environment and Rural Affairs Department (SEERAD) in Scotland, National Assembly for Wales Agriculture Department (NAWAD) in Wales), or LACORS.

#### **A.14.13.2: Qualifications / experience / training of officers carrying out sampling**

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

#### **A.14.14: Food of Non-Animal Origin (FNAO)**

This section applies to local authorities with a point of entry, checks undertaken at ERTS or international rail terminals, and deferred examinations under The Official Feed and Food Controls (England) Regulations 2005.

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

##### **A.14.14.1: Identification**

It is important that authorities with a point of entry are aware of the volume and nature of foods entering the port. Local authorities overseeing seaports where enquiries with the port operator indicate that food is imported should check 100% of ships' manifests 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.

Local authorities overseeing airports, ERTS and international rail terminals should set up, implement and maintain documented procedures on the arrangements in place to identify imported food.

This might include:

- Liaison with HMRC regarding food imported directly from third countries or via other Member States or ports under T1 arrangements ( see glossary);
- Liaison with transit shed operators to obtain copies of cargo manifests;
- Random checks of transit sheds/ERTS handling imported food with a view to verifying the information arrangements in place;
- Informal notification systems in co-operation with importers or their agents.

##### **A.14.14.2: Prohibition**

It is an offence under Regulation 27 of The Official Feed and Food Controls (England) Regulations 2005 for any person to import a product that does not comply with the food safety requirements set out in the EU Food Law Regulation (178/2002) or with the requirements of Articles 3 to 6 of EU Hygiene of Foodstuffs Regulation (852/2004). This prohibition applies to products being imported either direct from a third country or from a third country through another EU Member State.

##### **A.14.14.3: Examination**

Imported food should be subjected to risk based checks. EU Regulation 882/2004 requires systematic documentary checks, random identity checks and where appropriate physical checks. A systematic documentary check does not imply 100% checking of commercial documents but there should be risk

based planned arrangements in place. However, documents required to accompany any consignment by food law, such as under Emergency Control Decisions, are likely to require 100% checking. Physical checks might include: checks on the food itself, checks on the means of transport, checks on the packaging, checks on the temperature controls, organoleptic testing, and chemical or microbiological examination, or any other check necessary to verify compliance with EU food safety requirements. Such checks may also take into account any guarantees that the competent authority of the third country has given and which have been assessed by the Commission. The arrangements and follow up actions should be set out in relevant service policies and procedures.

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

Where an authorised officer reasonably requires facilities and assistance to carry out checks on a product, the importer may be asked to provide these. The Official Feed and Food Controls (England) Regulations 2005 also allow an authorised officer to require that physical checks and identity checks take place at a specified place, where necessary for proper examination.

Checks should be informed by:

- Statutory requirements for documentary checks and associated sampling laid down in relevant Emergency Control Decisions and Emergency Control Regulations,
- The risk associated with different types of food safety issues,
- Knowledge of the product e.g. new or unusual,
- Any requirements following a Food Alert or RASFF notification,
- The history of compliance for the product, country of origin and exporter/importer,
- The controls that the food business importing the food has carried out,
- Any guarantees that the competent authority of the third country of origin has given under the third country pre-export checks provisions in EU Regulation 882/2004 (details under Section A9.15 below),
- Any existing co-ordinated programmes e.g. at the request of or under the direction of other food control/advisory bodies,
- Adequacy or sufficiency of documentation e.g. discrepancies which need further investigation, and
- Suspicion of non-compliance.

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

Checks on imported food should also take into account any guidance issued by the Food Standards Agency. Such guidance may cover foods for which specific documentary checking regimes have been laid down or foods with restricted points of entry and/or testing regimes laid down in Commission Decisions or Regulations. Local authorities with points of entry which are not

designated to handle certain FNAO products subject to Emergency Control Decisions may wish to ensure relevant port operators, local HMRC, or agents/importers are aware of any restrictions. Arrangements should also be in place to deal with any such consignments which may arrive at the point of entry.

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.

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

#### **A.14.14.4: Deferred examinations of FNAO**

The Official Feed and Food Controls (England) Regulations 2005 allow for the examination of consignments of FNAO to be deferred and undertaken by the food authority covering the ERTS or international rail terminal or at any other place of destination in the UK. Deferred examinations may be considered where the local authority at the point of entry has a valid reason why an examination needs to be deferred, but it is anticipated this is likely to be in exceptional circumstances only.

Either the local 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 local authority covering the point of entry. In coming to any decision liaison with the receiving authority should be carried out to ensure that appropriate checks will take place and deferral should therefore be based on full co-operation and agreement between authorities.

Where products are subject to Emergency Control Decisions or Emergency Control Regulation measures which require designated points of entry, deferred examination is unlikely to be appropriate but there may be circumstances where there are overriding health and safety considerations. In such cases the Food Standards Agency should be informed. In all cases high 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 (England) Regulations 2005 require that the importer should provide a written undertaking that the consignment has been sealed and will not be opened until it reaches its specified destination and opening has been authorised by the receiving authority. The local authority at the point of entry should notify the receiving authority by the most expeditious means available that the food has not been examined and forward to the authority a copy of any written undertaking given by the importer.

Deferred examinations under The Official Feed and Food Controls (England) Regulations 2005 should be carried out in accordance with Regulation 26 of



the Regulations - only an outline has been provided in paragraphs 14.15 to 14.18.

#### **A.14.15: Third Country Pre-Export Checks**

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

This status can be repealed by the Commission in the light of information or experience. Where such arrangements are in place local authorities at points of entry should check relevant certification and consignments to validate such assurances. Particular consideration should be given to consignments accompanied by certification from non-accredited laboratories. Where authorities have concerns relating to any such arrangements based on checks carried out they should notify the Food Standards Agency.

#### **A.14.16: Charges**

EU Regulation 882/2004 provides that mandatory fees may be introduced for 'high risk' FNAO imports by means of implementing rules when these products are identified at Community level. This is dependent on the Commission putting forward proposals..

Commission Emergency Control Decisions may in some cases provide for charges. Commission Decision 2005/85/EC, on the import of pistachios from Iran, allows for charging for certain provisions relating to Iranian pistachio nuts. Commission Decision 2005/402/EC, on measures regarding chilli, chilli products, curcuma and palm oil, allows for recovery of costs for certain provisions relating to these products.

#### **A.14.17: Enforcement**

Where, for the purpose of examination at points of entry, or deferred examination at ERTS, international rail terminals or other place of destination, an authorised officer considers that a consignment needs to be inspected to confirm compliance, Article 18 of EU Regulation 882/2004 and Regulation 29 of the Official Feed and Food Controls (England) Regulations 2005 allow the product to be detained pending the results of any examination associated with the official controls.

Where an authorised officer has detained a food consignment pending any results of examination, they should notify in writing the person importing the food or any person in possession of the food who is entitled to be in possession of it. The notification should specify that the food should not be removed from the place stated, until the officer's examination of the food has been completed. The person on whom any notification is given should be informed in writing by the authorised officer.

Article 18 of EU Regulation 882/2004 and Regulation 29 of the Official Feed and Food Controls (England) Regulations 2005 do not specify a time limit for examination and investigation of consignments. They give an option of whether to detain or not, if non-compliance is suspected. However, such examinations, and/or detention periods, should be expedited as quickly as practicable such as to avoid unreasonable disruption to the trade.

Where samples are submitted for analysis or examination, and the consignment is detained pending the results, local authorities should inform the analyst or examiner of that fact and also ensure that the consignment is stored appropriately and securely. The importer or the importer's agent should be informed of the analysis/examination results as soon as possible.

If it appears to an authorised officer upon inspection or examination of food, that a batch, lot or consignment of food fails to comply with food safety requirements (Food Safety Act 1990 Section 8 as amended), Regulation 30 of The Official Feed and Food Controls (England) Regulations 2005 allows, after having heard from the importer, for the officer to serve a Notice requiring:

- Destruction of the relevant batch, lot or consignment
- The food be subjected to special treatment
- Re-dispatch of the food outside the European Community
- Another use of the food for purposes other than those for which they were originally intended

In practice, the options specified in the Notice should be drawn up after appropriate consultation with the person importing the food. The person on whom any Notice is served should be informed in writing by the authorised officer of any relevant appeal provisions at the time that the Notice is served. The Notice served should allow 60 days for a decision by the responsible person. Where the official control allows for re-dispatch, if after a 60 day period re-dispatch does not take place, the consignment should be destroyed, unless delay is justified.

Regulation 34 of The Official Feed and Food Controls (England) Regulations 2005 allows for costs associated with such action to be recovered from the person responsible for the consignment.

Special treatment may include such treatment or processing to ensure the food complies with EU requirements, or the requirements of the third country to where it is to be re-dispatched. Special treatment may also include processing for purposes other than human or animal consumption. Where special treatment is permitted liaison should take place with any other relevant enforcement authority or organisation to ensure the necessary processing has been carried out. This process may also be used where a non-conforming product is being imported specifically for the purpose of undergoing treatment to comply with EU law.

A consignment should only be re-dispatched outside the EU where the importer has agreed to the proposed destination and has informed the competent authority for the third country why it has been rejected for import into the EU. Where the consignment is being re-dispatched to a country other

than that of origin, the competent authority for the country of destination should provide notification to the competent authority controlling the product that it is willing to accept the consignment. The consignment should be officially detained pending re-dispatch.

Any decision on the approval of alternative usage of rejected goods should be informed by any relevant guidance issued by the EU or the Food Standards Agency on the appropriateness of alternative use or re-exportation.

Where official controls indicate that a consignment is injurious to health or unsafe, the consignment should be detained until it is either destroyed or undergoes appropriate measures to protect health.

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 may consider Voluntary Surrender as an option for dealing with such consignments. In accordance with Food Law Code of Practice, 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.

Imported food failing food safety requirements may also be subjected to Food Safety Act provisions to ensure appropriate action is taken. Such provisions include detention and seizure powers, applied in accordance with the Code of Practice.

Officers should have regard to The Official Feed and Food Controls (England) Regulations 2005, The Contaminants in Food (England) Regulations 2004 (as amended) and any relevant Emergency Control Regulations, which may provide for specific detention powers and notice provisions in relation to certain foods. Any designated port should have adequate facilities to ensure products can be sampled effectively, hygienically and under appropriate conditions.

Arrangements should be in place to ensure that detained or seized FNAO is stored appropriately, particularly to avoid cross contamination of other goods. Food which is to be destroyed or disposed of should be dealt with so as to ensure that there is no possibility of it re-entering the food chain e.g. deep burial at an approved waste disposal site. Copies of waste disposal notes should be kept on file.

## **A.14.18: Products of Animal Origin - Enforcement**

### **A.14.18.1: Illegally introduced POAO**

POAO should be imported in accordance with the Products of Animal Origin (Third Country Imports) (England) (No 4) Regulations 2004. These require that POAO are imported through a designated Border Inspection Post (BIP) and are subject to veterinary checks. A Common Veterinary Entry Document (CVED)<sup>12</sup> is issued for consignments which pass the veterinary checks and this should accompany the consignment to the first premises after import, where it should be retained for a period of one year. POAO are considered to

be illegally introduced (smuggled) where they have not been presented at the BIP of entry, for clearance.

HMRC became responsible in April 2003 for detecting smuggled POAO in Customs controlled areas including ERTS. However, local authorities still have responsibilities relating to goods presented at Border Inspection Posts and also inland where officers come across illegal POAO in the course of their routine enforcement activities (MHS are responsible for illegal POAO found at premises under their control). Defra have produced guidance clarifying the roles and responsibilities, including relevant contact details, of enforcement agencies involved in the control of illegal imports of POAO<sup>13</sup>. The Food Standards Agency has also produced Enforcement Guidance on Illegal Meat for Enforcement Officers<sup>15</sup>.

All local 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 should 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 ERTS, which they have reason to believe has been illegally introduced, they should notify HMRC and if needed for adequate interim control of the consignment, issue a detention notice under Regulation 16(4) of the POAO (Third Country Imports)(England) (No 4) Regulations 2004.

Where illegal imports of POAO are found inland in an area/premises outside customs control, the local authority has responsibility for the enforcement action. Where an authorised officer is satisfied that a POAO has been illegally introduced, they should serve a notice under Regulation 24 of the POAO (Third Country Imports) (England) (No 4) Regulations 2004 on the person having charge of any consignment or product. An authorised officer should by such notice, take charge of the consignment or product and either:

- Have it re-dispatched, by the mode of transport by which it was first introduced into the EU, to a destination in a third country within sixty days; or
- Have it re-dispatched for rendering or incineration in accordance with relevant animal by-products legislation.

Although the final decision rests with the enforcing authority, in most circumstances it is unlikely to be appropriate or practical to re-dispatch the products. If re-dispatch was appropriate this would need to be carried out through the relevant importer and subject to appropriate control.

#### **A.14.18.2: POAO Presenting a risk to public or animal health**

Where an authorised officer, either at a port of entry or inland, considers that a consignment or product from a third country presents a risk to animal or public health, they should serve a notice under Regulation 25 of the POAO (Third Country Imports) (England) (No 4) Regulations 2004 on the person having charge of the consignment or product. The product should then be destroyed without undue delay in accordance with relevant animal by-products legislation.

#### **A.14.18.3: Detention of POAO inland**

Where an officer wishes to detain any POAO inland in order to investigate further to establish its safety or compliance, voluntary co-operation could be sought in the first instance. In situations where this is not possible or is inappropriate due to risk, there is a provision under Regulation 8 of the POAO (Third Country Imports) (England) (No 4) Regulations 2004 for an authorised officer to serve a notice on the person having charge of the consignment to detain the product until such a time any further notice allows the product to be removed. In order to use this provision a sample should be taken, however the sample does not have to be submitted to a Public Analyst/Food Examiner.

Where Third Country POAO has been imported correctly through a BIP in another Member State, but are found to be non-conforming, for example, they are not marked with the approval number of the establishment of origin, as opposed to being deliberately smuggled, provisions under the Products of Animal Origin (Import and Export) Regulations 1996 as amended may be used. Part III of these Regulations applies to intra-community trade and includes goods, which originate in a third country but have received full clearance in a Member State i.e. they are in free circulation. Regulation 16 covers consignments posing a risk to health or illegal consignments. Under 16(3), where an authorised officer has reasonable grounds for believing that any POAO does not comply with animal or public health conditions relating to import into Great Britain or the European Community, a Notice may be served to prohibit the movement of the consignment. Regulation 16(4) provides that a notice should then be served ordering the destruction of the goods, or public and animal health considerations permitting, use of the goods for other purposes as may be specified in the notice, including returning them (with the authorisation of the competent authority of the country of origin) to their country of origin. If the consignment fails to comply with legislation due to an irregularity in documentation only, the notice shall grant the consignor a period of seven days to produce the correct documentation before action is taken (Regulation 16(5)).

#### **A.14.18.4: Reporting**

A notification to Defra's Illegal Animal Products Seizures (ILAPS) database should be made by local authorities when illegally imported POAO is seized<sup>14</sup>. In particular, this will include any instances where a Notice is served under Regulation 24 of the Products of Animal Origin (Third Country Imports) (England) (No 4) Regulations 2004.

## A.14.19: References

[imported.food@foodstandards.gsi.gov.uk](mailto:imported.food@foodstandards.gsi.gov.uk)

Tel: 020 7276 8018

This guidance can be found on the Agency's website [www.food.gov.uk](http://www.food.gov.uk)

<sup>1</sup> For information and guidance on international trade in animal products see Defra's website [www.defra.gov.uk/animalh/int-trde/prod-im/vet-chks](http://www.defra.gov.uk/animalh/int-trde/prod-im/vet-chks)

<sup>2</sup> Food Standards Agency Imported Food Control Resource Pack (available on the Agency's website at:  
[http://www.food.gov.uk/enforcement/imports/enforce\\_authorities/resourcepack](http://www.food.gov.uk/enforcement/imports/enforce_authorities/resourcepack)

<sup>3</sup> Benchmarking the Port Health Function, The Syniad Benchmarking Centre ([martin.goodman@wlga.gov.uk](mailto:martin.goodman@wlga.gov.uk))  
[http://www.food.gov.uk/enforcement/imports/enforce\\_authorities/benchmarking](http://www.food.gov.uk/enforcement/imports/enforce_authorities/benchmarking)

<sup>4</sup> [www.food.gov.uk/enforcement/frameagree](http://www.food.gov.uk/enforcement/frameagree)

<sup>5</sup> Local Authority Delegated Powers, Authorisation of Officers and Use of Credentials, LACORS.

<sup>6</sup> Imported Food Division – Tel. 020 7276 8018 , fax 020 7276 8024, email [imported.food@foodstandards.gsi.gov.uk](mailto:imported.food@foodstandards.gsi.gov.uk)

<sup>7</sup> Incidents Branch – Tel. 020 7276 8448, fax 020 7276 8446, email

[drazenka.tubin-delic@foodstandards.gsi.gov.uk](mailto:drazenka.tubin-delic@foodstandards.gsi.gov.uk) or  
[rajwinder.ubhi@foodstandards.gsi.gov.uk](mailto:rajwinder.ubhi@foodstandards.gsi.gov.uk)

<sup>8</sup> [www.forum.europa.eu.int/Public/irc/sanco/Home/main](http://www.forum.europa.eu.int/Public/irc/sanco/Home/main)

<sup>9</sup> [www.food.gov.uk/multimedia/worddocs/referralsproforma.doc](http://www.food.gov.uk/multimedia/worddocs/referralsproforma.doc)

<sup>10</sup> [www.food.gov.uk/imports](http://www.food.gov.uk/imports)

<sup>11</sup> [www.food.gov.uk/multimedia/pdfs/foodstuff\\_controls.pdf](http://www.food.gov.uk/multimedia/pdfs/foodstuff_controls.pdf)

<sup>12</sup> This document was introduced on 1 March 2004 and is standardised throughout EU Member States. The predecessor of the CVED was the Certificate of Veterinary Checks (CVC).

<sup>13</sup> Enforcement guidance for anti-smuggling activity against illegal imports of meat and other products of animal origin. For further information, contact [andy.green@defra.gsi.gov.uk](mailto:andy.green@defra.gsi.gov.uk), or phone 020 7904 8233.

<sup>14</sup> <http://ilaps.defra.gov.uk>. Food authorities without user names and passwords should contact [Andy.Green@defra.gsi.gov.uk](mailto:Andy.Green@defra.gsi.gov.uk) to be allocated these.

<sup>15</sup> Food Standards Agency Illegal Meat. Enforcement Guidance for Local Authority officers in England July 2004. This can be found at:

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

<sup>16</sup>. The BIP Manual. Published by DEFRA. Available at:  
<http://www.defra.gov.uk/animalh/int-trde/prod-im/bipmanual.pdf>

## Appendix 1 : Glossary of Terms

BIP	EU Border Inspection Post situated at a seaport or airport or international rail or road link – designated point of entry for products of animal origin from third countries.
CITES	Convention on International trade in Endangered Species, enforced by HM Revenue & Customs.
Consignment	Consignments can consist of one type of product, or a number of different types of products, which is covered by the same health certificate and/or airway bill or bill of lading. See also legal definition in POAO Regs.
ERTS	Enhanced Remote Transit Shed. Customs approved warehouse facilities where 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 or airport, so may therefore fall under the jurisdiction of another local authority. May be referred to as “temporary storage facilities”.
High risk FNAO	Products subject to special import conditions / emergency controls. These are laid down in specific Community and domestic legislation concerning individual products/groups of products and/or countries of origin.
Manifest	Document/computer file describing all cargo carried on a ship, cargo train or aircraft.
PHA	Port Health Authority. These are specially constituted local authorities with a remit of administering a range of environmental health functions in docks/seaports.
T1 arrangements	A transit declaration made to HM Revenue & Customs. T1 signifies that the goods are not in Free Circulation i.e. they are still subject to Customs control.



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