Food Law

Practice Guidance (Scotland)

FOOD LAW PRACTICE GUIDANCE

TABLE OF SECTIONS AND CHAPTERS

TABLE OF AMENDMENTS ISSUED

Amendment Number	Signed	Date
Amendment No. 1		
Amendment No. 2		
Amendment No. 3		
Amendment No. 4		
Amendment No. 5		
Amendment No. 6		
Amendment No. 7		
Amendment No. 8		
Amendment No. 9		
Amendment No. 10		
Amendment No. 11		
Amendment No. 12		
Amendment No. 13		
Amendment No. 14		
Amendment No. 15		
Amendment No. 16		
Amendment No. 17		
Amendment No. 18		
Amendment No. 19		
Amendment No. 20		

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 in Scotland (FSA) 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 to enforcement or on the law where its intention might be unclear.

Food Authorities should be aware that law relating to food is not necessarily made under the Food Safety Act 1990. Law that applies to food is also contained in and/or made under the Animal Health Act 1981, the European Communities Act 1972, the Consumer Protection Act 1987, the Trades Descriptions Act 1968 and directly under 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 automatically authorised to deal with food law under other legislation. Separate authorisation in respect of other legislation is also required, e.g. legislation made under the European Communities Act 1972, including the Food Hygiene (Scotland) Regulations 2006[1] (as amended) and the Official Feed and Food Controls (Scotland) Regulations 2009[2], (as amended) under which officers may be generally or specially authorised.

This guidance replaces all previous guidance issued with the Code of Practice.

Material in the previous guidance has been reviewed and updated to take account of the Food Hygiene (Scotland) Regulations 2006 (as amended), the Official Feed and Food Controls (Scotland) Regulations 2009 (as amended) and relevant EC Regulations.

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

Food Authorities should be aware that Article 8(5) of Regulation 852/2004[3] stipulates that guides to good practice drawn up pursuant to Directive 93/43/EEC (known in the UK as “Industry Guides to Good Hygiene Practice”) should be given due consideration provided that they are compatible with its objectives.

Attention is drawn to the guidance on the scope and conduct of official checks on establishments subject to approval under Regulation 853/2004[4].

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

[1] SSI 2006 No. 3
[2] SSI 2009 No. 446
[3] Regulation (EC) No. 852/2004 on the hygiene of foodstuffs
[4] Regulation (EC) No. 853/2004 laying down specific hygiene rules for food of animal origin

The guidance contained in this document is given in good faith, and accords with the FSAs 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.

SECTION 1: ADMINISTRATION

CHAPTER 1.1: INTER-AUTHORITY MATTERS

All relevant information on inter-authority matters is contained in the Code of Practice.

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 establishments subject to approval under Regulation 853/2004 and food business establishments that 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.

1.2.3 Service of Hygiene Emergency Prohibition Notices and Emergency Prohibition Notices

Scottish Food Authorities may authorise holders of the Higher Certificate in Food Premises Inspection, issued by the Scottish Food Safety Officers Registration Board, to serve Emergency Prohibition notices and/or Hygiene Emergency Prohibition notices provided that Food Authorities are satisfied that any such officers otherwise meet the experience requirements specified in paragraph 1.2.9.1.7 of the Code of Practice. This trial period will be concluded or modified at the next relevant amendment to the code.

Food Authorities wishing to authorise holders of the Higher Certificate in Food Premises Inspection to serve Emergency Prohibition notices or Hygiene Emergency Prohibition notices should notify the Enforcement Branch, Scotland of their intention in advance of the authorisation. Authorities that have previously notified their intention to authorise such officers to serve Emergency Prohibition notices need not notify their intention to extend that authorisation to Hygiene Emergency Prohibition notices.

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 (Scotland) Act 2002 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 the effective enforcement of food law.

If Food Authorities have any doubts about the release of data or information they should seek legal advice and/or contact the Information Commissioner's Office in relation to data protection (www.informationcommissioner.gov.uk) or the Scottish Information Commissioner in relation to Freedom of Information at (http://www.itspublicknowledge.info)

CHAPTER 1.5: REGISTRATION OF FOOD BUSINESS ESTABLISHMENTS

1.5.1 Registration of Mobile food establishments

A mobile establishment is required to register with the food authority in which it is ordinarily kept. Once the establishment has undertaken this process with its registering authority it should not be asked to register with any further food authorities in whose areas it trades.

This does not however place any limits on the official control activities of the food authorities in which this establishment trades. The food authority can undertake an intervention at any mobile establishment that trades within its area and should undertake any appropriate enforcement action it deems necessary.

Details of the intervention and subsequent enforcement activity undertaken by a food authority should always be passed to the registering authority.

It is the responsibility of the registering authority to determine the establishments risk rating category in accordance with Annex 5 of the Food Law Code of Practice and this should be recorded on the authorities" database of business establishments. When making this determination the registering authority must consider the information supplied to it by other inspecting authorities.

Upon receipt of new information in relation to a mobile establishment, the registering authority should, in a timely manner assess the information provided against the information it holds on file and consider whether it is appropriate to conduct an inspection, partial inspection or audit to investigate the matter.

Food Liaison groups can provide a suitable forum to exchange intelligence to ensure that mobile establishments trading locally are not subject to excessive inspections. An inspecting authority should consider any information held either by the registering authority or details of previous inspection information published on line when deciding whether is appropriate to inspect a mobile establishment which trades in its area

1.5.2 Action on receipt of a completed registration form

In respect of section 1.5.5 of the Food Law Code of Practice, it is acceptable to retain the registration form by scanning and storing digitally a copy of the original form.

CHAPTER 1.6: CROWN AND POLICE PREMISES

1.6.1 Introduction

This Chapter deals with the approach to enforcement in Crown premises and in premises that are occupied by the police (police premises in Scotland are owned by Local Authorities); 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 - Food Safety Act 1990

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

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

1.6.3 Enforcement - Food Safety Act 1990

1.6.3.1: 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, to the Court of Session, for a declaration that any act or omission of the Crown, which amounts to a contravention of food safety legislation, is unlawful.

The identity of the proprietor of the food business concerned should be carefully considered if the question of action under the Food Safety Act 1990 or regulations made under the Act.

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 under Section 54(2) should be addressed to the Scottish Ministers and sent to the Official Solicitors for the Scottish Government.

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

1.6.3.2 : 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.

1.6.3.3 : Statutory Notices

The service of an 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.

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 Sheriff 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 Sheriff 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 Sheriff 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 raise an action for declaration in the Court of Session if a business run by the Crown fails to comply with an emergency prohibition order.

1.6.4 Scope of Application - Food Hygiene (Scotland) Regulations 2006 (as amended)

The scope of the Food Hygiene (Scotland) Regulations 2006 (as amended) extends to police premises, Crown premises, and to people in the public service of the Crown. Authorised officers therefore have power to enter police premises and Crown premises to investigate complaints and to carry out interventions in the same way as they do in any other food business.

As there are no specific exemptions for certain members of the Royal Family or certain Royal residences as afforded by the Food Safety Act 1990, 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 (Scotland) Regulations 2006 (as amended) in respect of Crown premises as they do in respect of the Food Safety Act 1990.

1.6.5 Enforcement - Food Hygiene (Scotland) Regulations 2006 (as amended)

Unlike the Food Safety Act 1990, the Food Hygiene (Scotland) Regulations 2006 (as amended) do not exempt the Crown if it contravenes the Regulations. This means that the Crown can be prosecuted if it contravenes the Regulations. However, as mentioned in Paragraph 1.6.2 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 (Scotland) Regulations 2006 (as amended) in respect of Crown premises as they do in respect of the Food Safety Act 1990.

1.6.6 Conduct and Frequency of Interventions

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

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

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

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 food-borne illness, or from the Consultant in Public Health Medicine (communicable disease / environmental health) (CPHM (CD/EH)), or Health Protection Scotland (HPS)

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 and the Primary Authority Scheme.

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: DISCLOSURE OF INFORMATION

Relevant information on disclosure of information is contained in the Code of Practice. Chapter 1.4 of this Guidance is also relevant.

CHAPTER 2.2: FOOD ALERTS

All relevant information on Food Alerts is contained in the Code of Practice.

CHAPTER 2.3: FSA COMMUNICATIONS AND GUIDANCE

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

CHAPTER 2.4: INFORMATION TO BE SUPPLIED TO THE FSA

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

CHAPTER 2.5: LIAISON WITH OTHER MEMBER STATES

2.5.1 Introduction

This Chapter deals with the administration of and the approach to the single European liaison arrangements that are operated by the FSA. Detailed provisions on administrative assistance and co-operation with other Member States are set out in Articles 34 to 38 of Regulation 882/2004[5].

2.5.2 The role of the FSA

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

In relation to requirements concerning the exchange of information and provision of administrative assistance, the FSA will have a supervisory role. In order to determine whether routine exchanges have any policy implications, the FSA will need to know regularly the number of contacts made between Food Authorities and enforcement bodies in other Member States, when the contacts are taking place, the nature of the assistance provided and the information being exchanged. The FSA will also deal directly with matters falling under categories A and B (see Chapter 2.5 of the Code of Practice).

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

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

2.5.3 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”, “Primary Authority” or “Originating Authority” which terms are defined as follows:

[5] 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

- “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.

- “Primary Authority” means an authority which has entered in to a formal agreement, in relation to specified legislative controls, to be the principal source of advice on compliance with these requirements and to coordinate enforcement actions.

The Local Better Regulation Office (LBRO) co-ordinate the Primary Authority scheme, including approving and registering all Primary Authority partnerships. Where a primary authority is registered, any other Food Authority (known as an „enforcing authority" for the purposes of the scheme) proposing to take enforcement action against a food business within the scheme must contact the primary authority first. The Primary Authority may challenge a proposed enforcement action, if it believes it to be inconsistent with advice or guidance that it has previously provided. LBRO will determine any resulting disputes in consultation with the FSA

A statutory Primary Authority scheme came into force across the UK on 6 April 2009. In Northern Ireland and Scotland the Primary Authority scheme does not extend to the devolved functions of food or feed law enforcement. Although the Primary Authority Scheme does not extend to Northern Ireland on a statutory basis, LAs in NI have agreed to apply the principles of the scheme when discharging their food law functions.

The statutory Primary Authority scheme came into force across the UK on 6 April 2009. The Primary Authority scheme does not replace the existing Home Authority scheme which will continue to operate across the UK, and particularly in Scotland and Northern Ireland where the Primary Authority scheme does not extend to the devolved functions of food or feed law enforcement.

2.5.4 Enquiries from Members States

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

2.5.5 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.

2.5.6 Disclosure of Information

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

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).

2.5.7 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 [6]. 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 Crown Office in Scotland.

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

[6] 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].

The UK Central Authority address is:

Judicial Co-operation Unit
Home Office
5th Floor, Fry Building
2 Marsham Street
London
SW1P 4DF
Tel: 020 7035 1276
Fax: 020 7035 6987

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 above mentioned Act and letters of request must therefore be sought from a sheriff 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 sheriff 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.

2.5.8 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 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 FSA. The FSA will decide whether the Commission should be notified.

2.5.9 Form –Exchange of Information: Routine Food Matters

Food Standards Agency
food.gov.uk
Buidheann Inbhe-Bìdhe

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***		**FA Ref:**	
		Action Requested*		**Agency Ref:**	

* (please tick as appropriate)

Name and Address of Food Authority:

Contact Officer:		**Tel:**	
E-mail:		**Fax:**	

Full product description (to include product name or brand name, health / identification marks):

Nature of complaint/request:
Date of Notification: **Photo:** **Yes** **No**

Name and Address of Manufacturer, Packer, Retailer, Wholesaler (where appropriate):
Details of Investigation by FA: 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 **scottishincidents@foodstandards.gsi.gov.uk or fax it to fax it to 01224 285110** **FSA, St Magnus House, Guild Street, Aberdeen AB11 6NJ.**

SECTION 3: GENERAL ENFORCEMENT

CHAPTER 3.1: APPROACH TO ENFORCEMENT

All relevant material on the approach to enforcement is contained in the Code of Practice.

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 (Scotland) Regulations 2006 (as amended) 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.

3.2.3 Service of Notices

The Food Hygiene (Scotland) Regulations 2006 (as amended) require a hygiene improvement notice to be served on a food business operator. Although unlikely to be used (see Paragraph 3.2.3 of the Code of Practice), 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 in accordance with the statutory requirements.

It is vital to identify the food business operator, however, Regulation 28(2) of the Food Hygiene (Scotland) Regulations 2006 (as amended) gives the capacity for a hygiene improvement notice to be addressed to the “food business operator” and left at the named premises. Similarly, Section 50(2) of the Act allows an improvement notice to be addressed to the “owner” or “occupier” and delivered to the named premises if the proprietor of the food business cannot be identified.

The officer serving a 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.

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.

In respect of Hygiene Improvement Notices or improvement notices requiring structural work to be carried out, the officer should normally discuss the detail of any such work with the food business operator / food business proprietor, or with a person acting on the operators / proprietors 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 (Scotland) Regulations 2006 (as amended) 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 operators / proprietors 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 are to be complied with by the stipulated time limit, Food Authorities should give due regard to any genuine difficulties that may occur in achieving compliance by that deadline.

There 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 food business operator / food business proprietor has a genuine reason for needing more time.

The operator / 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

However, the officer should never issue such a notice automatically. When deliberating a request for an extension of the time limit the officer should always consider whether the facts at that time justify such an extension, taking 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 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 (Scotland) Regulations 2006 (as amended) 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. The visit to check compliance should be witnessed.

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 recipient provided with the name and address of the relevant local Sheriff 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 operator / 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" and or "primary authority" for the business as defined by LBRO/LGG.

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 has been issued by LGG.

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 (Scotland) Regulations 2006 (as amended) 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 (Scotland) Regulations 2006 (as amended)

3.3.2.1: Regulation 7 - Hygiene Prohibition Procedures

A Sheriff may make a hygiene prohibition order under Regulation 7 of the Food Hygiene (Scotland) Regulations 2006 (as amended) to:

- Prohibit the use of a process or treatment for the purposes of the business if the health risk condition is fulfilled;

- Prohibit the use of the premises or equipment for the purposes of the food business or any similar food business if the construction of the premises or use of any equipment fulfils the health risk condition;

- Prohibit the use of the premises or equipment for the purposes of any food business if the state or condition thereof fulfils the health risk condition.

The Food Authority must first successfully prosecute the food business operator for an offence under the Food Hygiene (Scotland) Regulations 2006 (as amended).

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 a hygiene emergency prohibition notice under Regulation 8 of the Food Hygiene (Scotland) Regulations 2006 (as amended) if the health risk condition is fulfilled in respect of a food business and there is an imminent risk of injury to health. The effect of the notice is to immediately close the premises, or prevent the use of equipment, or the use of a process or treatment.

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

The operator must have at least one complete days' notice of the intention to make the application.

3.3.2.3 : Regulation 9 - Remedial Action Notices / Detention Notices

(See Chapter 3.5 of the Code of Practice)

3.3.3 : The Food Safety Act 1990

3.3.3.1 : Section 11 - Prohibition Procedures

A Sheriff 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.

The authorised officer must apply to a Sheriff 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 complete days' 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 (Scotland) Regulations 2006 (as amended) 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 (Scotland) Regulations 2006 (as amended) 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 (Scotland) Regulations 2006 (as amended)

In relation to food hygiene, the health risk condition under the Food Hygiene (Scotland) Regulations 2006 (as amended) may exist if, for example, conditions in premises, or a defective process or treatment, carries a high risk of causing food-borne infection.

Foods containing potentially harmful levels of pathogenic micro-organisms represent an imminent risk and should be seized or detained under Regulation 27 of the Food Hygiene (Scotland) Regulations 2006 (as amended) 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 (Scotland) Regulations 2006 (as amended) where appropriate.

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 the affected child develops or a malignant tumour occur sometime in the future

Foods containing potentially damaging levels of such chemicals represent an imminent risk and should be seized or detained under Section 9 of the Food Safety Act 1990. However, the process or treatment, which exposed the food to this chemical contamination, should be dealt with under Section 12 of the Food Safety Act 1990.

3.3.7 Criteria for Action

3.3.7.1 : Hygiene Prohibition Procedures / Prohibition Procedures

The criteria for action still depend on the conditions in Regulation 7(2) of the Food Hygiene (Scotland) Regulations 2006 (as amended) 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 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 (Scotland) Regulations 2006 (as amended) and Section 12(2) of the Food Safety Act 1990, the application is made by the Food Authority and hence it bears the burden of proof. The necessary evidential requirements are respectively set out in Regulation 7(2) and 7(4) and Regulation 8(1) and 8(4) of the Food Hygiene (Scotland) Regulations 2006 (as amended), and Section 11(2) and 11(4) and Section 12(1) and (4) of the Food Safety Act 1990.

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

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[7].

An authorised officer exercising a right of entry under Regulation 14 of the Food Hygiene (Scotland) Regulations 2006 (as amended) or Section 32 of the Food Safety Act 1990 may be accompanied by anybody else who is necessary, including an expert or experts.

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 might be minimal, as the premises would not be open to the public. The authorised officer would be free to decide on the following morning whether the imminent risk still existed or had been removed.

[7] The Institute of Food Science and Technology maintains a list of experts in particular fields

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 Sheriff 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 is useful to record the time of service, even when the postal service is used.

Immediately the document has been legally served by one of the methods mentioned in Regulation 28 of the Food Hygiene (Scotland) Regulations 2006 (as amended) 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. In Scotland any evidence intended to be placed before a court requires to be corroborated therefore a witness will be necessary.

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.

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 (Scotland) Regulations 2006 (as amended) 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 provisions of Section 11(1) should be brought to the attention of the Procurator Fiscal who may then bring the matter before the Sheriff 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 a relevant offence, the prosecution 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 unsafe food.

In Scotland it is essential for authorised officers to attend court to advise the Procurator Fiscal and to provide any further evidence or opinion the court may require.

3.3.15 : Application to the Court

The Food Authority should discuss a detailed programme of formal action with its litigation solicitor who will contact the Sheriff Clerk to ensure that, if at all possible, applications for hygiene emergency prohibition orders / emergency prohibition orders are expedited.

The food business operator / food business proprietor must be notified that the authorised officer intends to apply for a hygiene emergency 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 of the Food Hygiene (Scotland) Regulations 2006 (as amended) or Section 11 of the Food Safety Act 1990 so that a hygiene prohibition order or prohibition order against a food business operator / food business proprietor is to be considered, it is important that suitable evidence is gathered to produce to the Procurator Fiscal prior to the case being heard.

It is important that the authorised officers brief the Procurator fully on the public health aspect of the case in hand, including the public health basis for the legal

requirements which have been breached, so that they can, in turn, impress upon the Court the seriousness of the charges.

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 the 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.

3.3.18 : Affixing the Notice or Order on the Premises

Regulations 7 and 8 of the Food Hygiene (Scotland) Regulations 2006 (as amended) and Sections 11 and 12 of the Food Safety Act 1990 direct that as soon as practicable after the making of an order or the service of a notice, a copy of the order or notice should be affixed in a conspicuous position on the premises by the Food Authority. In the case of an order, this should be done by Sheriff Officers.

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. The procedure should be witnessed.

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 (Scotland) Regulations 2006 (as amended) nor The Food Safety Act 1990 make any reference to defacing or removing a hygiene prohibition order, a hygiene emergency prohibition order, a hygiene emergency prohibition notice, a prohibition order, an emergency prohibition order, or an emergency prohibition notice.

In this situation, it should be considered as obstruction in terms of Regulation 15 of the Food Hygiene (Scotland) Regulations 2006, as removing or defacing the notice can be considered an act that "intentionally obstructs any person acting in the execution of the Hygiene Regulations".

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, an emergency prohibition notice or order or a prohibition 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. This procedure should be witnessed.

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 (Scotland) Regulations 2006 (as amended), or Section 11(6)(a) 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 (Scotland) Regulations 2006 (as amended), or Section 11(7)(b), 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 a hygiene emergency prohibition notice or emergency prohibition notice may be issued before the application for an emergency prohibition order can be heard, the operator / proprietor may still be prosecuted for the offence(s) against the Food Hygiene (Scotland) Regulations 2006 (as amended) or the Food Safety Act 1990 as appropriate.

The Food Authority should ensure that the Procurator Fiscal 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 (Scotland) Regulations 2006 (as amended) 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 (Scotland) Regulations 2006 (as amended) or Section 12(5) or (6) of the Food Safety Act 1990, respectively.

The authorised officer should submit details of any contravention to the Procurator Fiscal.

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 justifythis 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 so that in the event of the breach of a notice or order, there is no delay in making a report to the Procurator Fiscal.

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 (Scotland) Regulations 2006 (as amended) 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 Summary Application to the Sheriff. 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 Sheriff Court.

3.3.23 : Compensation

Regulation 8(10) of the Food Hygiene (Scotland) Regulations 2005 provides 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 if a hygiene emergency prohibition order is not applied for within five days.

Similarly, 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 an emergency prohibition notice if an emergency prohibition order is not applied for within three days.

Compensation is also payable if the Sheriff 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 spoilt 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 Regulation 27 of the Food Hygiene (Scotland) Regulations 2006 (as amended) and / or Section 9 of the Food Safety Act 1990, as amended.

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 Not Produced, Processed or Distributed In Compliance With the Hygiene Regulations

Under Regulation 27 of the Food Hygiene (Scotland) Regulations 2006 (as amended), 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 the Hygiene Regulations as defined in Regulation 2. A model certificate for this purpose can be found in Annex 7 of the Code of Practice. 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. Food Authorities must continue to use the forms set out in the Detention of Food (Prescribed Forms) Regulations 1990[8] when using powers under Section 9 of the Food Safety Act 1990 following the issue of a certificate as mentioned above.

3.4.3.2 : Food Which Does Not Satisfy Food Safety Requirements - Food Safety Act 1990, Section 9, as amended

If food does not satisfy food safety requirements for other than hygiene reasons, Section 9 of the Food Safety Act 1990 should be used. Section 9 of the Act permits the service of a detention of food notice to prevent the use of the food for human consumption. Food Authorities must continue to use the forms set out in the Detention of Food (Prescribed Forms) Regulations 1990 when using powers under Section 9 of the Food Safety Act 1990.

[8] SI 1990 No. 2614

3.4.4 Specific Powers of Seizure and Detention

The following legislation, as at February 2012 gives powers of seizure and detention to Food Authorities carrying out food standards controls.

Contaminants in Food (Scotland) Regulations 2010

Flavourings in Food (Scotland) Regulations 2010

General Food Contact Materials 2004

Eggs & Chicks (Scotland) Regulations 2010

Food Additives (Scotland) Regulations 2009

Food (Chilli, Chilli Products, Curcuma and Palm Oil) (Emergency Control) (Scotland) Regulations 2005

Food Enzymes (Scotland) Regulations 2009 (as amended)

Food Irradiation (Scotland) Regulations 2009 (as amended)

Genetically Modified Food (Scotland) Regulations 2004

Products of Animal Origin (Third Country Imports) (Scotland) Regulations 2006 (as amended)

Tryptophan in Food (Scotland) Regulations 2005

Scotch Whisky Regulations 2009

Spirit Drinks Regulations 2008

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.

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 paragraphs 3.4.7 and 3.4.9).

3.4.6 Seizure of Food

The officer may be required to prove that the food produced before the Sheriff as 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 Sheriff should be given to the person in charge of the food once the decision to seize food has been taken. This notification is purely administrative and may therefore be signed by any authorised officer.

The officer delivering the notification does not need to hold the same qualifications as the officer who took the decision to detain or seize the food, but 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, as amended, on any person who may be liable to prosecution for selling or producing unsafe food to attend before a Sheriff, 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 food-borne 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, HPS, the CPHM (EH/CD), CCDC, HPA, or the FSA 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[9] defines unsafe food and is relevant to both the Food Hygiene (Scotland) Regulations 2006 (as amended) and the Food Safety Act 1990. The General Food Regulations 2004, deal 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 the food is part of a larger batch, lot or consignment of food of the same class or description. In such circumstances it is presumed, until the contrary is proved, that all of the food in the batch, lot or consignment fails to comply with food safety requirements.

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

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

3.4.10 : Voluntary Procedures

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

The fact that food had been condemned by a Sheriff or 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.

[9] 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: REMEDIAL ACTION NOTICES / DETENTION NOTICES

All relevant information on Remedial Action Notices / Detention Notices is contained in the Code of Practice.

CHAPTER 3.6: TEMPERATURE CONTROL REGULATIONS

3.6.1 Introduction

This Chapter provides guidance on enforcement of Regulation 30 / Schedule 4 of the Food Hygiene (Scotland) Regulations 2006 (as amended). 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 which include Chapter I, Paragraph 2 (d), Chapter III Paragraph 2(g), Chapter IV Paragraph 7, Chapter V Paragraph (2) and Chapter IX Paragraphs (2), (5), (6) and (7), of Regulation 852/2004 would apply, as appropriate or any specific temperature control requirements in Regulation 853/2004.

3.6.2 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 +2.8ºC (0.8ºC as specified for instrument accuracy and 2ºC 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.

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.

3.6.3 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.

3.6.4 Tolerances

“Stage 2” temperature readings may be up to 2ºC 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”.

3.6.5 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 instruments 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 0ºC. The temperature of wet ice from distilled water is 0ºC. Drinking water with a salt content of 0.1% will only depress the melting point to -0.06ºC. 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 0ºC with that of checking the instrument should ensure accuracy at higher temperatures.

3.6.6 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.

3.6.7 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).

3.6.8 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.

3.6.9 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 +/-0.5ºC, or better when the sensor is measuring within the temperature range -20ºC to +30ºC;
- the accuracy must not change by more than +/-0.3ºC when the instrument is operated in temperatures of -20ºC to +30ºC;
- the instrument display should be readable to at least 0.1ºC;
- 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 0ºC and +30ºC.

CHAPTER 3.7: QUICK FROZEN FOODSTUFFS

3.7.1 Introduction

This guidance gives informal, non-statutory advice to Food Authorities on checking temperatures and temperature monitoring systems when enforcing the Quick-Frozen Foodstuffs Amendment (Scotland) Regulations 2007 [10] as amended), (the Regulations) which implement Directives 89/108/EEC[11], and 92/2/EEC[12], and provide for the enforcement and administration of Commission Regulation 37/2005[13] in Scotland (similar, parallel legislation exists in England, Wales and Northern Ireland).

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.

3.7.2 Legislative Changes

Commission Directive 92/1/EEC[14] has been repealed and replaced by the directly applicable Commission Regulation 37/2005[15].

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 new measuring instruments, used in transport, warehousing, or storage of quick-frozen foodstuffs must comply with the relevant CEN standards[16]. Finally, since 1 January 2006, the legislation applies to rail transport for the first time.

In summary, the Regulations:
- provide the administration and enforcement provisions for Commission Regulation 37/2005; and,

[10] , SSI 2007 No. 106
[11] Council Directive 89/108/EEC of 21 December 1988 on the approximation of the laws of the Member States relating to quick-frozen foodstuffs for human consumption
[12] Commission Directive 92/2/EEC of 13 January 1992 laying down the sampling procedure and the community method of analysis for the official control of the temperatures of quick-frozen foods intended for human consumption
[13] 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
[14] Commission Directive 92/1/EEC of 13 January 1992 on the monitoring of temperatures in the means of transport, warehousing and storage of quick-frozen foodstuffs intended for human consumption
[15] 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
[16] European Committee for Standardization, www.cenorm.be (i.e. EN 12830:1999; EN 13485:2001; EN 13486:2002)

- carry forward, and consolidate, the existing requirements on conditions that must be fulfilled by quick-frozen foodstuffs from Council Directive 89/108/EEC and existing requirements on sampling procedures and official methods of analysis of temperatures of quick-frozen foods from Commission Directive 92/2/EEC.

3.7.3 Division of enforcement responsibility between County and District Councils

This section does not apply to Scotland

3.7.4 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 2(2)(b) 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.

3.7.5 aged Approach to Enforcement

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

- checking documents permitting verification that the appropriate measuring instruments conform to the relevant EN standard

- 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 nature of the temperature monitoring equipment and whether it meets any relevant EN standards, 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.

3.7.6 Checking Measuring Instruments meet EN Standards

For temperature monitoring equipment / instruments installed after 1 January 2006, authorised officers should examine all relevant documents that permit verification that the instruments conform to the relevant EN standard. A variety of documents may serve this purpose, including manufacturers" certificates, sales invoices, product brochures, and markings on the instruments themselves.

3.7.7 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 are required by the legislation. Although operators are required to ensure that air temperatures are recorded, except in retail cabinets, cold store facilities of less than $10m^3$ used for storing stock in retail outlets 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 8 (as read with Schedule 1, Article 2.3 of 37/2005) should be commensurate with the maximum shelf-life of the foods to which they relate.

3.7.7.1 : 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.

3.7.7.2 : Air Temperature Checks: Transport

Authorised officers should ascertain whether new temperature measuring instrument(s) used in transport (excluding local distribution vehicles) meet the specified Community provisions of Regulation 37/2005 as set out in Schedule 1 of the Regulations and whether temperature measuring instrument(s) installed before 1 January 2006 meet the specification set out in Schedule 3, Paragraphs 3(e) and 3(f) of the Regulations, and that proper recordings are being made where required (Regulation 8 and Schedule 1, Articles 2.1, 2.2, and 2.3).

Instruments will be deemed to have complied with the appropriate specification in the Regulations, that is Articles 2.1 and 2.2 of Regulation 37/2005 as set out in Schedule 1 for new measuring instruments. Where measuring instruments were installed before 1 January 2006, they will be deemed to be approved if they comply with the appropriate specification in the Regulations, that is Schedule 3, Paragraphs 3(e) and 3(f).

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 an easily visible thermometer (Schedule 1, Article 3.1 – first paragraph and Schedule 3, paragraph 3(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.

3.7.7.3 : 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 retail 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.

3.7.8 : 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.

3.7.9 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 (in accordance with provisions of Regulation 7 and Directive 92/2/EEC).

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.

3.7.10 : 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.

3.7.10.1 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".

3.7.10.2 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.

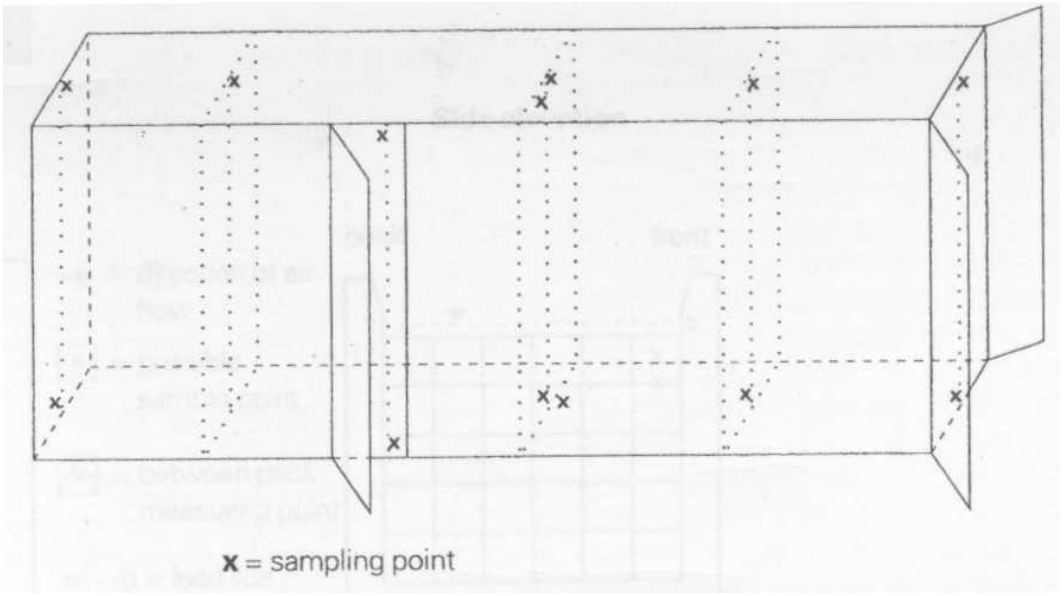


Figure 1. Sampling points for vehicles with more than one set of doors

3.7.10.3 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.

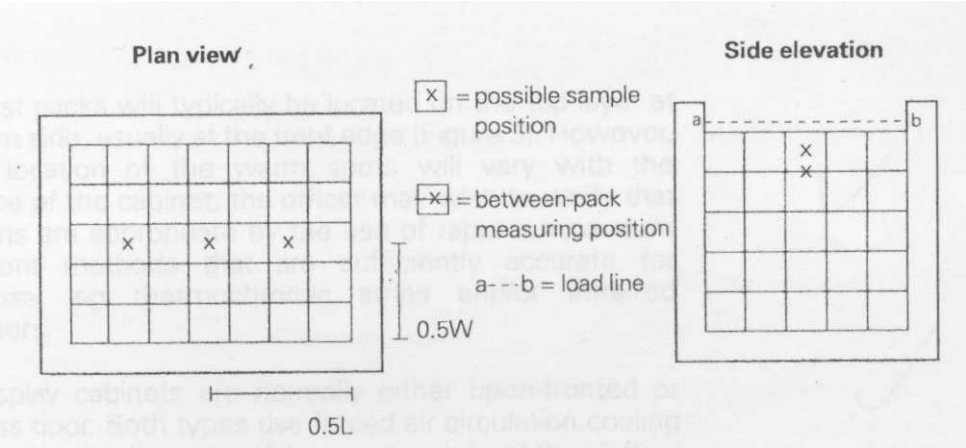


Figure 2. Horizontal cabinet – contact cooling

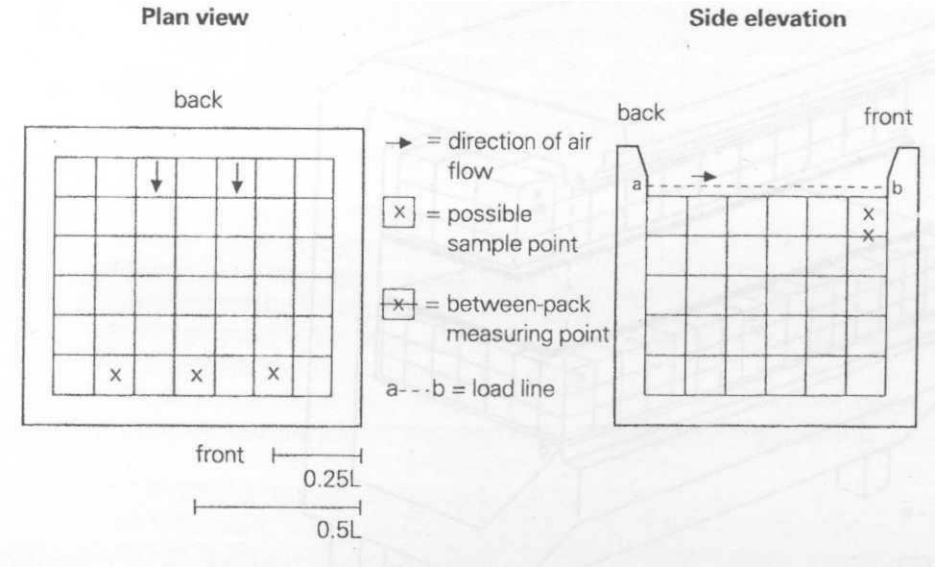


Figure 3. Horizontal cabinet – forced air circulation

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 airflow 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".

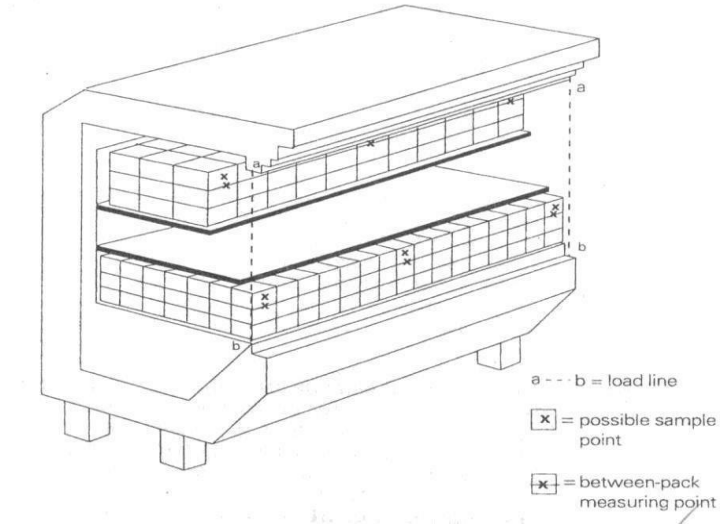


Figure 4. Open vertical cabinet

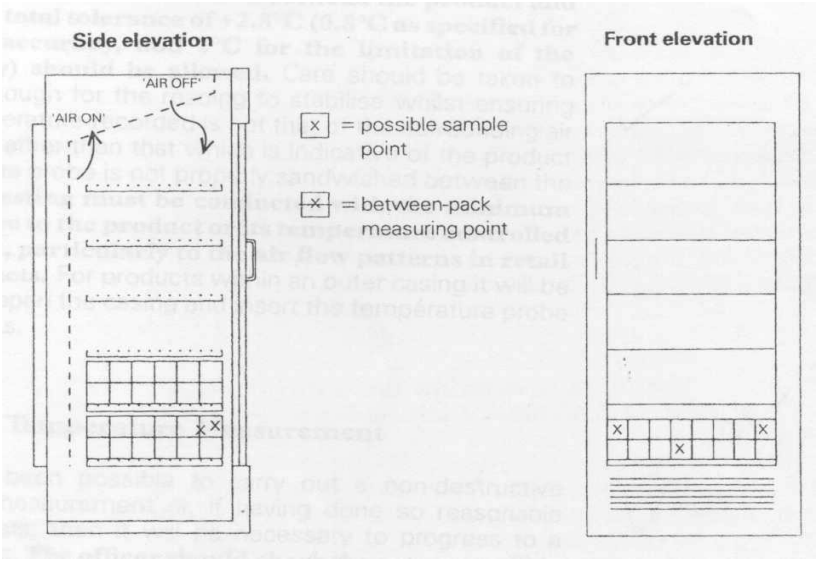


Figure 5. Vertical glass-fronted cabinet

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.

3.7.11 : 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.

3.7.12 : 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.

3.7.13 : 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 3.6.5 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 3.8: FOOD WASTE

3.8.1 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, the Animal Health Act 1981 and (EC) Regulation 852/2004.

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

3.8.2 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.

3.8.3 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 FSA as soon as practicable.

The FSA 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.

3.8.4 : Agency Resources Available to Assist Food Authority Investigations Into Food Fraud

3.8.4.1 : Fighting Fund

Decisions on resourcing for enforcement activity are a matter for local authorities, however, it is acknowledged that some local authorities have to deal with cases with unexpected resource implications.

The Agency has agreed a process developed through its Enforcement Liaison Group which sets out criteria for local authorities who wish to apply for Agency support for their enforcement work and for the Agency to consider such applications.

Decisions on the nature and extent of Agency financial support will be made on a case by case basis and will take account of the limited Agency resources available.

Details of how to apply and the criteria against which applications are considered can be found on the Agency's website at:

http://www.food.gov.uk/multimedia/pdfs/enforcement/fflaguidance10.pdf

3.8.4.2 : Food Fraud Advisory Unit (FFAU)

The Food Fraud Advisory Unit (FFAU) provides an advisory resource for local authorities carrying out investigations into fraud that includes any illegal activity relating to food or animal feed.

FFAU membership consists of local authority enforcement officers working in environmental health, trading standards and port health. All members have extensive experience in carrying out food fraud investigations.

Local authorities can draw on the FFAU's expertise for advice, including the in following example areas:

- the legal framework for an investigation;
- highlighting appropriate use of evidence gathering techniques, such as surveillance;
- coordination of multi-agency investigations;
- following relevant protocols to ensure the integrity of an investigation.

This advice may be given over the telephone, by email or at meetings with an FFAU member or members.

Responsibility for leading the investigation will always remain with the authority requesting support.

Further information on how to be put into contact with a member of the FFAU can be found on the Agency's website at:

http://www.food.gov.uk/enforcement/workwithenforcers/foodfraud/lafoodfraud/ffau

3.8.4.3 : Food Fraud Database (FFDB)

In 2006 the Agency established a national food fraud database. The database is an important resource for local authorities which may be seeking additional information to assist with their investigations into food fraud incidents.

Intelligence is received from a variety of sources, including consumers, industry, Government Departments and other enforcement bodies, but particularly from local authorities. It is important that local authorities share with the Agency, all intelligence they become aware of in relation to known or even suspected food fraud incidents, including historical cases. This intelligence will then be used to populate the database along with data from all other sources.

The Agency also welcomes database search requests from Food Authorities. The Agency may already hold an important piece of information that may be relevant to the requesting Authority.

Further information on the FFDB and how to request a search of the system can be found on the Agency's website at:

http://www.food.gov.uk/enforcement/workwithenforcers/foodfraud/lafoodfraud/foodfrauddatabase

CHAPTER 3.9: DISTANCE SELLING / MAIL ORDER

3.9.1 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.

3.9.2 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 UKs jurisdiction. There are, therefore, important distinctions between UK, EU and non-EU distance selling transactions.

3.9.3 Location of the Buyer

The location of the buyer in a distance selling transaction is important only in so far 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.

3.9.4 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.

3.9.5 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 single liaison role of the FSA (See Chapter 2.5 of both the Code of Practice and of this guidance) to resolve problems relating to the distance selling of food from the EU.

3.9.6 Distance Selling of Food from Third Countries

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

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

3.9.7 Generic Distance Selling Legislation

Generic law regulating distance selling in the UK is set out in the Consumer Protection (Distance Selling) Regulations 2000[17], which implement Council Directive 97/7/EC in the UK.

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

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

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

The central UK Competent Authority with responsibility for these Regulations is the Department for Business, Innovation and Skills (BIS). Enforcement is the responsibility of the Office of Fair Trading (OFT) and Trading Standards Departments.

BIS, OFT, and LGG have each published guidance on the Regulations for businesses, consumers, and enforcement agencies. Copies of the guidance are available either directly from the LGG website at https://knowledgehub.local.gov.uk/ or via links from the LGG website to the relevant BIS or OFT web addresses. If any further advice is required, officers should contact the Contract Regulation Unit at OFT.

[17] SI 2000/2334

3.9.8 Other References

A Guide to Good Hygiene Practice for the mail order food industry, developed in accordance with Article 8 of Regulation 852/2004 was published in 2007.

CHAPTER 3.10: BOTTLED WATERS

3.10.1 : Introduction

This Chapter provides guidance to Food Authorities on enforcement of the Natural Mineral Water, Spring Water and Bottled Drinking Water (Scotland) (No 2) Regulations 2007 [18], (as amended) (the Regulations).

3.10.2 : Legislation

The Regulations transpose into UK legislation the provisions of European Parliament and Council Directive 2009/54, relating to the quality of water for human consumption as it applies to bottled water.

The legislation also implements Commission Directive 2003/40/EC establishing the list, concentration limits and labelling requirements for the constituents of natural mineral waters and the conditions for using ozone –enriched air for the treatment of natural mineral waters and spring waters. The Instrument was amended in 2009 to reflect the recast of the original Directive into 2009/54/EC. It was further amended in 2010 to put in place enforcement powers for by Commission Regulation (EU) 115/2010 laying down conditions for the use of activated alumina for the removal of fluoride from natural mineral water and spring water and to incorporate text from Council Directive 98/83/EC on monitoring by Food Authorities for regulatory purposes.

3.10.3 : 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.

The most recent list of all recognised sources within the EU is available on the EUs website at:

http://europa.eu.int/comm/food/food/labellingnutrition/water/index_en.htm

[18] SI 1999/1540

3.10.4 : 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 FSA 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 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 being tankered for the purposes of exploiting the *spring* before 17 July 1980. Hence transport of water from the spring to the packaging line must be in a closed pipeline made of a suitable material and the filling system must ensure that there is no microbiological contamination of the water before closure of its container.

3.10.5 : 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.

3.10.6 : 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.

However, like natural mineral water, spring water cannot be tankered, unless it was being transported in tankers on or before 13 December 1996. The right to tanker is linked to the *spring*, not the bottler.

3.10.7 : Labelling of Spring and Other Bottled Water

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

Bottled drinking waters are subject to the general labelling requirements of the Food Labelling Regulations 1996[19].

[19] as amended, SI 1996/1499

CHAPTER 3.11: MICROBIOLOGICAL CRITERIA REGULATION

3.11.1 : FSA Guidance for Food Business Operators

The FSA issued revised guidance for food business operators in respect of Regulation (EC) 2073/2005 on Microbiological Criteria for Foodstuffs on 11 January 2006, to coincide with application of the Regulation, of which Food Authorities should be aware. This guidance can be found on the FSAs website at:

http://www.food.gov.uk/multimedia/pdfs/ecregguidmicrobiolcriteria.pdf

3.11.2 : Other Guidance

Food Authorities should be aware that some trade organisations, such as the British Retail Consortium and Chilled Food Association, have produced guidance on complying with the regulation.

CHAPTER 3:12: IMPORT OF FOOD FROM THIRD COUNTRIES

See Annex 12 of this guidance.

Section 4: INTERVENTIONS AND ALTERNATIVE ENFORCEMENT STRATEGIES

CHAPTER 4.1: INTERVENTIONS

4.1.1 Interventions

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

When selecting the type of intervention to use at an establishment, the authorised officer must have regard to the limitations as laid down with section 4.1.5.2 of the Food Law Code of Practice (Scotland) 2009 and the Authority's own enforcement policy. The officer, when selecting from the available intervention types, should choose the intervention that will be most effective in either maintaining or improving business compliance with food law.

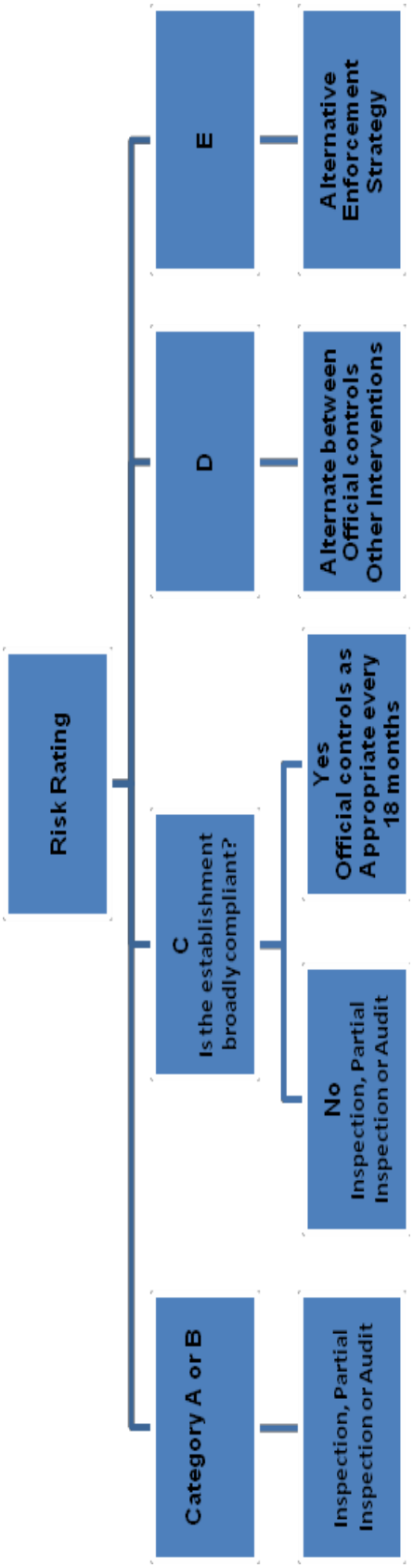
The flow charts on the following pages indicate the types of intervention that can be undertaken to meet the minimum intervention frequency required by Annex 5 of the Code. This guidance does not apply to other controls or interventions carried out in addition to those which meet the minimum frequency.

Broadly compliant is defined (for food hygiene and food standards) as an establishment that has an intervention rating score of not more than ten points under each of the following points of Annex 5 – Part 2 – level of current compliance and Part 3 – confidence in management.

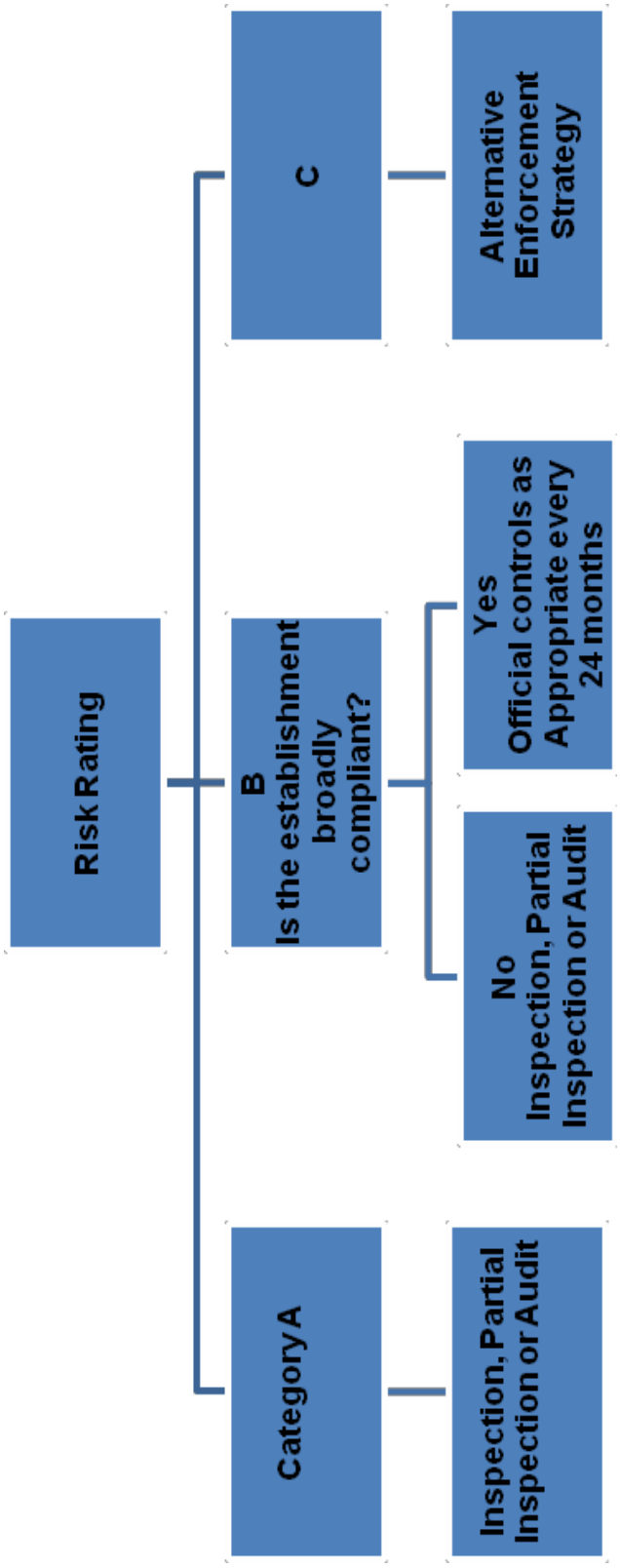
The flexibility in the type of intervention used is intended to allow the LA to adopt the most effective use of resources to achieve compliance. However, it also recognises that there are certain EU restrictions to Official Controls.

The number of Official Controls undertaken by LAs is collected by the FSA through LAEMS returns to satisfy the reporting requirements of EU regulation 882/2004. The UK data, including individual LA returns, are also published on the FSA website and reported to the Food Standards Agency Board.

For Hygiene:

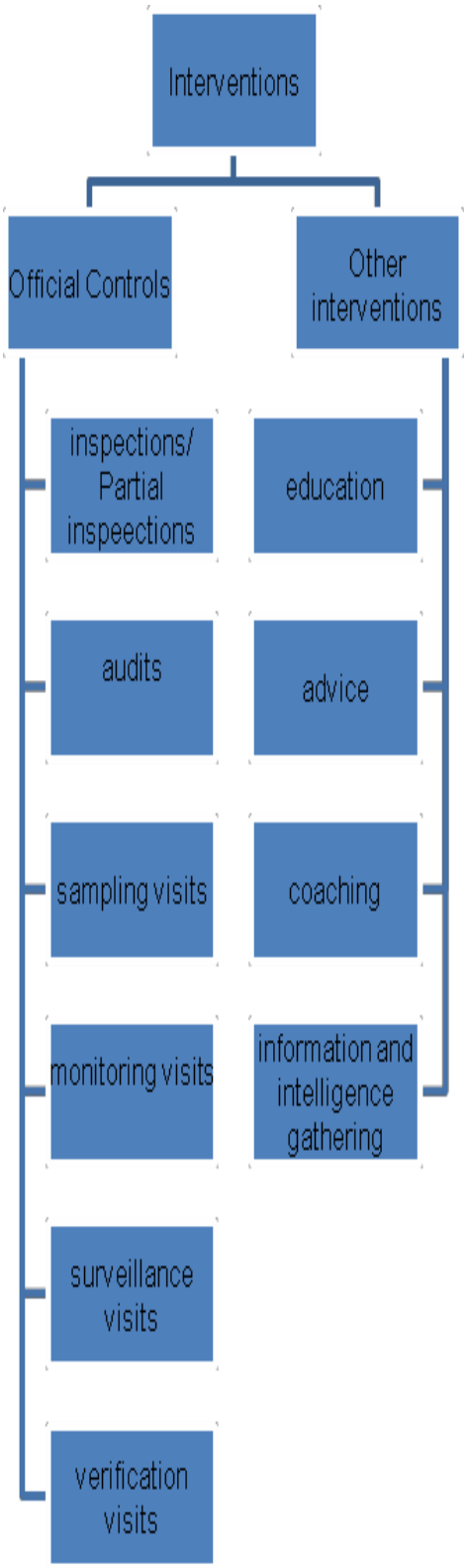

Risk Rating
Category A or B
Inspection, Partial Inspection or Audit
C
Is the establishment broadly compliant?
Yes
Official controls as Appropriate every 18 months
No
Inspection, Partial Inspection or Audit
D
Alternate between Official controls Other Interventions
E
Alternative Enforcement Strategy

For Standards:



4.1.2 Intervention Types

The range of intervention types available are designed to allow the enforcing officer to best select the type of action undertaken at the visit to the establishment.



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

However, at the subsequent visit the type of intervention undertaken should be based on the conditions found at the establishment, and should not be confined to the intervention suggested at the time of the last schedules visit. Should the officer, in the process of undertaking an intervention other than an inspection, partial inspection or audit gather sufficient information in the course of the visit by considering some or all of the elements listed in section 4.2.3 of the Food Law Code of Practice, they should consider revising the risk rating. The intervention would then be considered an inspection, partial inspection or audit and should be recorded as such.

The following intervention types are classed as **official controls**:

- Inspections,
- Partial inspections
- Audits
- Sampling visits
- Monitoring visits
- Surveillance visits
- Verification visits

4.1.2.1 : Inspections, partial inspections and audit

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

- A programmed inspection or audit
- Inspection to risk rate a new food business or establishment which has not previously been rated
- Investigation of complaints about food or a food establishment which require inspection of some aspect of the food business
- Where a scheduled intervention of another type is no longer appropriate due to a change in conditions at the establishment that become apparent when the officer is on site and more intensive action is required

When carrying out inspections local authorities have discretion based on their professional judgement and file history, to cover only certain parts of the establishment's inspection. Circumstances that may warrant a partial inspection of the food establishments may include, (see 4.2 of the Food Law Code of Practice)

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

The authorised officer can only consider revising the risk rating following an Inspection, Partial Inspection or Audit. The other interventions detailed below should not be followed by a change in the risk rating.

4.1.2.2 : Verification

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

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

4.1.2.3 : Monitoring and Surveillance

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

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

4.1.2.4 : Sampling

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

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

- A visit solely to take formal sample/samples to be analysed/examined at an official laboratory. NB if samples are taken during another sort of intervention for instance, an inspection, then the visit should be recorded as an inspection not a sampling visit. Visits to take samples as part of a national,

regional or local sampling programme may be included in this category, as long as the samples are analysed / examined by an official laboratory.

4.1.3 Other Interventions (not Official Controls)

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

- Education
- Advice
- Coaching
- Information and intelligence gathering

4.1.3.1 : Education and advisory work

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

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

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

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

4.1.3.2 : Information and intelligence gathering visits

These are visits to confirm key information relating to the food establishment. They may be carried out under a scheme of information sharing between different regulatory agencies. The information or intelligence gathered must be reviewed by an appropriately qualified officer (see section 1.2.9) who will assess whether further action is appropriate.

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

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

4.1.4 Record(s) keeping

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

4.1.5 Alternative Enforcement Strategies

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

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

An establishment must have been subject to an initial formal inspection, and have been subsequently risk rated in accordance with Annex 5, before it can be determined to be a low risk establishment and therefore appropriate for it to be included in the alternative enforcement strategy.

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

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

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

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

4.1.6 Requirement for first hygiene/standards inspection of newly registered establishments

4.1.6.1 : Introduction

This chapter deals with the requirement for timely inspection of a newly registered food establishment, or when a new establishment comes to the attention of the enforcing authority.

4.1.6.2 : Requirement for an initial inspection.

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

Where Food Standards inspections are handled by a separate authority (such as a county council) the Food Standards authority should be notified as soon as possible after receipt of registration or discovery of an establishment in operation without registration.

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

4.1.6.3 : Determining when to undertake the initial inspection.

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

- Where the new establishment is believed to be undertaking high risk food activities the Authority should undertake an initial inspection within 28 days of commencement of operations.
- Where the establishment is believed to be low-risk from the available information, consideration can be given to postponing the initial inspection in circumstances where it would delay planned interventions to premises involved in, or believed to be involved in, high-risk activities as defined in Annex 5.3 and 5.6 of the Code.
- Where an establishment is registered 28 days before commencement of operations, the inspection may be delayed until operations within the establishment have begun.

4.1.6.4 : Records keeping

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

CHAPTER 4.2: MATTERS RELATING TO UNDERTAKING INTERVENTIONS

4.2.1 Introduction

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

4.2.2 Notice of Inspection

The general principle about pre-notification of interventions 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 the intervention 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 (see also Paragraph 1.6.4 of the Code of Practice on obtaining entry to Crown Premises).

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[20].

[20] The Institute of Food Science and Technology maintains a list of experts in particular fields

CHAPTER 4.3: MATTERS RELATING TO PRIMARY PRODUCTION ASSURANCE SCHEMES

The following assurance schemes have been evaluated against the requirements of the hygiene legislation for primary production and are currently considered to meet those requirements. They are also covered by a Memorandum of Understanding between Assured Food Standards and LGG which enables information exchange:

- Assured British Meat (ABM)
- Assured British Pigs (ABP)
- Assured Chicken Production (ACP)
- Assured Combinable Crops Scheme (ACCS)
- Assured Produce (AP)
- Genesis Quality Assurance (GQA)
- Quality Meat Scotland (QMS)
- Farm Assured Welsh Livestock (FAWL)
- Northern Ireland Beef/Lamb Farm Quality Assured Scheme (NIBLFQAS)
- Scottish Quality Cereals (SQC)

Copies of the evaluations are on the FSA website at

http://www.food.gov.uk/foodindustry/regulation/hygleg/hygleginfo/primprodqanda/

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. An inspection template for aircraft, which may be adapted, where appropriate, provided that the procedures outlined in the Code are not overlooked can be found on the LGG website. (https://knowledgehub.local.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 onboard;
- 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 onboard vessels varies greatly, from large passenger vessels and cargo vessels with large crew and passenger numbers (e.g. some cruise liners with over 3000 passengers and 1200 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 whom 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 Animal By-Products (Enforcement) (Scotland) Regulations 2011[21]. SGRIPD 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 ICTA/IFSA World Food Safety Guidelines, and to develop in-house supplier audits and aircraft audits and to make any reports available to the authorised officer.

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

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

[21] SSI 2011 No. 171

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

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

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

CHAPTER 4.5: ACTION FOLLOWING AN INTERVENTION

4.5.1 Establishment Record Files

The Agency has produced the following guidance document which highlights the recommendation made by the Public Inquiry into the 2005 Outbreak of E. coli 0157 in South Wales and should assist local authorities in effectively managing their establishment records

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

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

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

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

4.5.2 Establishment Record Files retention

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

This does not affect the requirement within section 4.5.4 of the Code to retain records of existing establishments.

CHAPTER 4.6: FOOD ESTABLISHMENT INTERVENTION RATING SCHEMES

4.5.1: Additional advice for risk rating food standards premises to take into account potential risk of chemical contamination of food.

Annex 5 (A5.6) of the Food Law Code of Practice contains the Food establishment intervention rating scheme for Food Standards. Food Authorities that are responsible for enforcing food standards law should determine the food standards intervention frequencies of food businesses within their areas using the risk assessment criteria in this Annex, in order to determine their planned food standards intervention programmes.

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

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

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

SECTION 5: APPROVED ESTABLISHMENTS

CHAPTER 5.1: APPROVAL OF ESTABLISHMENTS UNDER REGULATION 853/2004

5.1.1 Guidance for local authority authorised officers on the approval of establishments

The Agency has revised its guidance for the use of Local Food Authority (LA) Authorised Officers (AOs) in the UK in relation to the approval of food business establishments that handle products of animal origin (POAO). The Guidance can be found at the following link:

http://www.food.gov.uk/enforcement/sectorrules/approvedestabsuk/approvalsguidance

5.1.2 Identification Marks

(See also Code of Practice, Paragraph 5.1.12)

The requirements for the form of the identification mark which establishments subject to approval under Regulation 853/2004 must apply to their products as appropriate are set out in Annex II, Section I B of that Regulation. In accordance with Paragraph 5.1.12 of the Code of Practice the Food Authority should agree an identification mark with each establishment it approves which (a) incorporates the approval code it has allocated and (b) meets the requirements of Annex II, Section I B of Regulation 853/2004.

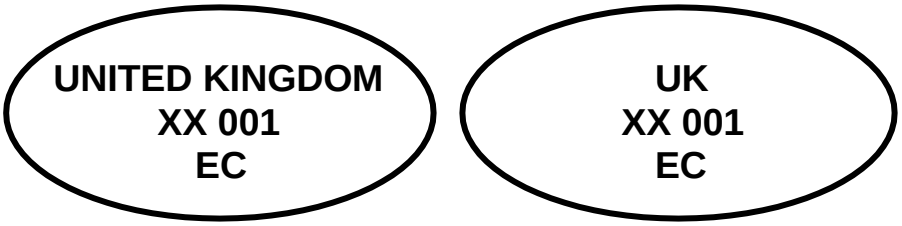
5.1.2.1 : Example Identification Mark Formats

[UK]
[Authority Approval Code] [Authority Unique Number]
[EC]

[UNITED KINGDOM]
[Authority Approval Code] [Authority Unique Number]
[EC]

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

5.1.2.2 : Example Identification Marks



CHAPTER 5.2: ENFORCEMENT OPTIONS IN APPROVED ESTABLISHMENTS

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

CHAPTER 5.3: MATTERS RELATING TO LIVE BIVALVE MOLLUSCS

5.3.1: 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.

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.
All

Additional relevant material on live bivalve molluscs is contained in the Code of Practice, the approvals guidance (see 5.1.1) and at Annex 4 of this Practice Guidance.

CHAPTER 5.4: MATTERS RELATING TO FRESH MEAT

Additional relevant material relating to fresh meat is contained in the Code of Practice, the approvals guidance (see 5.1.1) and at Annex 3 of this Practice Guidance.

.

SECTION 6: SAMPLING AND ANALYSIS

CHAPTER 6.1: SAMPLING AND ANALYSIS[22]

6.1.1 Introduction

This Section concerns the procedures that should be followed when food samples are procured under Regulation 12 of the Food Hygiene (Scotland) Regulations 2006 (as amended) and Section 29 of the Food Safety Act 1990 and the associated requirements of the Food Safety (Sampling and Qualifications) Regulations 1990[23].

6.1.2 Definitions

For both reporting purposes and for use in the Food Surveillance System (FSS) the following definitions should be used.

6.1.2.1 : Formal Microbiological Samples

Microbiological samples taken, including those without a witness, in accordance with the *procedures* outlined in the Code of Practice (and, if applicable, any product specific sampling/examination legislation), and submitted to an accredited laboratory.

Coding microbiological samples for FSS as „formals" refers to the integrity of the sampling and examination, not the intended use of the sample. Similarly, single part samples taken of foods for which multi-part sampling is prescribed are coded as formals on the basis that the sampling is carried out to CoP standards.

6.1.2.2 : Informal Microbiological Samples

Microbiological samples which do not fulfil the criteria for Formal Microbiological samples. These samples should not be logged into FSS nor should they form part of the LAEMS return.

6.1.2.3 Formal Compositional Samples

Chemical samples taken in full compliance with the Code of Practice (and, if applicable, any product specific sampling/analysis legislation), and submitted to an accredited laboratory. In Scotland samples will be witnessed.

[22] 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/
[23] SI 1990 No. 2463

6.1.2.4 : Informal Compositional Samples

Chemical samples which do not fall into the definition of formal samples but which are submitted to an accredited laboratory.

6.1.3 Procurement of Samples

The Food Hygiene (Scotland) Regulations 2006 (as amended) 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.

6.1.4 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.

6.1.5 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).

6.1.6 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 other specimens as evidence, and to ensure the continuity of such evidence.

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

- dates and times of transport;
- identity of custodians;
- date and time of receipt in the laboratory;
- identity of the person receiving sample.

For food samples, the temperature of transport should be monitored, and recorded on receipt at the laboratory. If the sample has been posted, proof of posting or a record of the method of despatch to the Food Examiner or Clinical Microbiologist 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.

6.1.7 Samples for Analysis

6.1.7.1 : 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.

6.1.7.2 : Containers for Samples for Analysis

Samples of non pre-packed 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. Both the sampling officer and their witness should sign the sample label. 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.

6.1.7.3 : Transport and Storage of Samples for Analysis[24]

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 transported 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.

[24] The Campden and Chorleywood Food Research Association publication “Guidelines for the preservation of official samples for analysis” (CCFRA Guideline No. 36) includes further guidance

6.1.7.4 : 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 Food (Sampling and Qualifications) Regulations 1990 allows for the sample to be submitted for analysis complete without division into three parts. There is no final part for the seller/owner, neither is there a final part to be retained. This procedure must therefore be used with caution. Situations where this procedure 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 as soon as reasonably practicable 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.

6.1.8 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.

6.1.8.1 : 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.

6.1.8.2 : 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 LGG “Guidance on Food Sampling for Microbiological Examination”, January 2006. 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.

6.1.8.3 : Handling, Transport and Storage of Faecal Specimens for Examination

On occasions, officers will be required to investigate reported or suspected cases of food-borne 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.

6.1.8.4 : 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.

SECTION 7: MONITORING OF INTERVENTIONS

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

SECTION 8: ANNEXES

ANNEX 1: GLOSSARY OF TERMS

AHVLA	Animal Health & Veterinary Laboratories Agency
APHA	Association of Port Health Authorities
BIS	Department for Business, Innovation and Skills
BSE	Bovine Spongiform Encephalopathy
CCDC	Consultant in Communicable Disease Control
CDSC	Communicable Disease Surveillance Centre
CEFAS	Centre for Environment, Fisheries and Aqua-culture Science
CIEH	Chartered Institute of Environmental Health
CPHM	(CD/EH)Consultant in Public Health Medicine (communicable disease/environmental health)
DEFRA	Department of the Environment, Food and Rural Affairs
DH	Department of Health
DHI	Dairy Hygiene Inspectorate
DTI	Department of Trade and Industry
EC	European Commission
EEA	European Economic Area
EMIs	Egg Marketing Inspectors
EPU	Egg and Poultry Unit (SGRIPD)
EU	European Union
FLEP	Food Law Enforcement Practitioners
Framework Agreement	Framework Agreement on Local Authority Food Law Enforcement
FSA	The Food Standards Agency
FVO	Food and Veterinary Office (of the European Commission)
HA	Home Authority
HACCP	Hazard Analysis Critical Control Points
HPA	Health Protection Agency
HPS	Health Protection Scotland (formerly SCIEH)
IFST	Institute of Food Science & Technology.
LA	Local Authority
LBRO	Local Better regulation Office
LGG	Local Government Group
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
Seafish	Sea Fish Industry Authority
SFI	Sea Fisheries Inspectorate
SFPA	Scottish Fish Protection Agency
SFSORB	Scottish Food Safety Officers" Registration Board

TSE	Transmissible Spongiform Encephalopathy
UKAS	United Kingdom Accreditation Service
VM	Veterinary Manager

ANNEX 2: LINKS TO LEGISLATION, GUIDANCE AND FORMS (FOOD HYGIENE)

Food Law Code of Practice (Scotland) / Practice Guidance (Scotland)

http://www.food.gov.uk/enforcement/enforcework/foodlawcop/copscotland/

Regulations Relating to Scotland

The Food Hygiene (Scotland) Regulations 2006 (SSI 2006 No. 3):
http://www.legislation.gov.uk/ssi/2006/3/pdfs/ssi_20060003_en.pdf

Official Feed and Food Controls (Scotland) Regulations 2009 (SSI 2009 No. 446):
http://www.legislation.gov.uk/ssi/2009/446/contents/made

EU Regulations

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

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2002R0178:20090807:EN:HTML

Regulation (EC) No. 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules:

http://eur-lex.europa.eu/LexUriServ/site/en/oj/2004/l_191/l_19120040528en00010052.pdf

Regulation (EC) No. 852/2004 on the hygiene of foodstuffs:

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2004R0852:20090420:EN:HTML

Regulation (EC) No. 853/2004 laying down specific hygiene rules for food of animal origin:

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2004R0853:20100715:EN:HTML

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

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2004R0854:20100705:EN:HTML

Regulation (EC) No 1688/2005 implementing Regulation (EC) No 853/2004 of the European Parliament and of the Council as regards special guarantees concerning salmonella for consignments to Finland and Sweden of certain meat and eggs:

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2005:271:0017:0028:EN:PDF

Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs:

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2005R2073:20100519:EN:HTML

Commission Regulation (EC) No 2074/2005 laying down implementing measures for certain products under Regulation (EC) No 853/2004 of the European Parliament and of the Council and for the organisation of official controls under Regulation (EC) No 854/2004 of the European Parliament and of the Council and Regulation (EC) No 882/2004 of the European Parliament and of the Council, derogating from Regulation (EC) No 852/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004:

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2005R2074:20090101:EN:HTML

Commission Regulation (EC) No 2076/2005 laying down transitional arrangements for the implementation of Regulations (EC) No 853/2004, (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004:

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2005R2076:20090224:EN:HTML

European Commission guidance documents

European Commission Guidance Document on Regulation (EC) No. 852/2004 on the hygiene of foodstuffs:

http://ec.europa.eu/food/food/biosafety/hygienelegislation/guidance_doc_852-2004_en.pdf

European Commission Guidance Document on Regulation (EC) No. 853/2004 on the hygiene of food of animal origin:

http://ec.europa.eu/food/food/biosafety/hygienelegislation/guidance_doc_853-2004_en.pdf

European Commission Guidance Documents on the implementation of procedures based on HACCP principles and facilitation of the implementation of the HACCP principles in certain food businesses:

http://ec.europa.eu/food/food/biosafety/hygienelegislation/guidance_doc_haccp_en.pdf

Food Standards Agency Guidance Documents (other than the Code of Practice and Practice Guidance)

FSA guidance on the requirements of food hygiene legislation:
http://www.food.gov.uk/multimedia/pdfs/fsaguidefoodhygleg.pdf

Summary guidance on the new food hygiene regulations for businesses making or handling foods of animal origin:
http://www.food.gov.uk/multimedia/pdfs/summguidpoao060413.pdf

Summary guidance on the new food hygiene regulations for businesses manufacturing food not of animal origin:
http://www.food.gov.uk/multimedia/pdfs/summguidnonpoao060413.pdf

Summary guidance on the new food hygiene regulations for restaurants, caterers and businesses selling food to the final consumer:
http://www.food.gov.uk/multimedia/pdfs/summguidcater060413.pdf

Guidance on Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs:
http://www.food.gov.uk/foodindustry/regulation/europeleg/eufoodhygieneleg/microbiolreg

Guide to Food Hygiene and other Regulations for the Meat Industry:
http://www.food.gov.uk/foodindustry/meat/guidehygienemeat

Model Forms / Template Forms in Microsoft Word Format

Model Forms for use in connection with the Food Hygiene (Scotland) Regulations 2006 (as amended)
http://www.food.gov.uk/multimedia/worddocs/hygieneregsformsscot.doc

Template Forms for use in connection with the Approval of Establishments
http://www.food.gov.uk/multimedia/worddocs/approvalformscot.doc

Model Application Form for the Registration of a Food Business Establishment:
http://www.food.gov.uk/multimedia/worddocs/registrationform.doc

Model Notice of Temporary Closure of Production Area(s) (Live Bivalve Molluscs / Shellfish):
http://www.food.gov.uk/multimedia/worddocs/shellfishformscot.doc

Template Live Bivalve Molluscs / Live Shellfish Registration Document:
http://www.food.gov.uk/multimedia/worddocs/shellfishregscot.doc

Central Register of Letters Sent by the Food Standards Agency to Local Authorities

http://www.food.gov.uk/enforcement/workwithenforcers/centralref/

ANNEX 3: MEAT

A.3.1 : Guidance

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

This Guide can be found on the FSA's website at:
http://www.food.gov.uk/foodindustry/meat/guidehygienemeat

A Food Safety Management Diary for meat producers has been produced for voluntary use and can be found at:

http://www.food.gov.uk/multimedia/pdfs/foodmandiary2008.pdf

A.3.2 : Approval of Establishments

The FSA is responsible for approving establishments subject to veterinary control (i.e. slaughterhouses, cutting plants placing fresh meat on the market and game handling establishments) as well as any cold stores, meat products, minced meat, meat preparations, mechanically separated meat premises and edible co-products plants that are co-located with approved slaughterhouses, cutting plants, or game handling establishments.

Food authorities are responsible for approving all other food business establishments handling products of animal origin (except for co-located premises described above) and for registering establishments that are exempt from approval.

A.3.3 : Enforcement in Meat Establishments

The FSA is responsible for enforcement in meat establishments that require veterinary control (see A.5.2 above).

A.3.3.1 : Co-located Establishments

The FSA is responsible for enforcement in meat products, minced meat, meat preparations, mechanically separated meat plants, cold stores or edible co-products plants that are co-located with an approved slaughterhouse, cutting plant or game handling establishment. When a co-located meat establishment does not require approval e.g. a retail butcher, dual Food Authority/FSA enforcement continues to apply.

A.3.3.2 : Stand-Alone Establishments

Food Authorities are responsible for enforcement in stand-alone establishments that produce meat products, minced meat, meat preparations and mechanically separated meat, and in establishments exempted from approval under Regulation (EC) No.853/2004.

A.3.3.3 : Cold Stores

Cold stores supplying the final consumer exclusively or supplying other establishments (including caterers) on a “marginal, localised and restricted” basis are not subject to approval and must be registered under Regulation (EC) No. 852/2004.

European Commission guidance advises that wholesale meat cold stores require approval on the basis that they are used in relation to activities for which Annex III of Regulation 853/2004 lays down requirements. It has been decided to follow this guidance. There is no requirement for veterinary control of cold stores and Food Authorities are therefore responsible for approving cold stores and for enforcement in cold stores, except where they are co-located with approved slaughterhouses, cutting plants or game handling establishments.

A.3.3.4 : Wild Game

There are exemptions from the scope of Regulation 853/2004 for the supply of wild game by primary producers or by hunters. Such supply can be in-fur or in-feather but must only be supplies of small quantities directly to the final consumer or to retail outlets directly supplying the final consumer – see A.5.4.4. Additionally, hunters can supply small quantities of game meat. However, game supplied under the hunter exemption to a retail outlet cannot be supplied to another retail outlet under the retail to retail exemption. The retail to retail (wholesale) exemption must also be on a marginal, localised and restricted basis.

Primary Producers whose onward supply is limited to small quantities of primary product (i.e. in-fur or in-feather wild game) directly to the final consumer or to retail outlets directly supplying the final consumer are exempt from the scope of both Regulation 853/2004 and Regulation 852/2004 However, they are responsible for supplying safe food under Regulation 178/2002.

Premises used for the supply of small quantities of prepared wild game to the final consumer or to retail outlets directly supplying the final consumer must meet the hygiene requirements of Regulation 852/2004 and are subject to enforcement by food authorities.

Establishments that process wild game and do not qualify under the Wild Game exemptions to supply in-fur/in-feather carcases or small quantities of wild game meat to the final consumer only or to local retail establishments that directly supply meat to the final consumer must be approved by the FSA as an

approved game handling establishment (AGHE). AGHEs are subject to official veterinary controls and they need to comply with both the general hygiene requirements of Regulation (EC) No. 852/2004 and specific provisions for the initial handling of large/small wild game in Regulation (EC) No. 853/2004. They must have in place a food safety management procedure based on HACCP principles and must only accept game that has been examined by a trained person. In certain circumstances, where the trained person is unexpectedly unavailable, certain viscera such as the head (except for antlers and horns) and the heart, lungs, and liver but not the stomach and intestines of the deer, must accompany the body for post mortem inspection.. AGHEs must also ensure that animal by-products are handled and disposed of according to Regulation (EC) No. 1069/2009

A.3.3.5 : Edible Co-products

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

Separate guidance on these products can be found on the FSA's website at:

http://www.food.gov.uk/foodindustry/guidancenotes/meatregsguid/coproductbyproductguide

A.3.4 : Exemptions from Approval

(Also see the approvals guidance at 5.1.1)

A.3.4.1 : Retail Establishments (Regulation 853/2004, Article 1(5)(b)(ii))

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

"*Final consumer*" is 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.

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, 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.3.4.2 : Retail Establishments - “Marginal, Localised and Restricted” Supply to Other Establishments

In respect of fresh or processed meat including meat products, the terms „marginal", „localised" and „restricted" (see A.5.4.1 above) should be interpreted as:

- **„Marginal"**:

Recital 13 of Regulation 853/2004 interprets “marginal” as „a small part of the establishment’s business", but European Commission guidance provides that it may also be interpreted as „a small amount of food of animal origin in absolute terms". Thus:

(i) “a small part of the establishment’s business” means “**up to a quarter of the business in terms of food**”; or.

(ii) “a small amount of food of animal origin” means, in relation to meat (fresh or processed, excluding wild game and wild game meat) **up to two tonnes per week,** (which could be averaged over any 12 month period subject to the establishment having a genuine retail element to its operation supplying the final consumer with part of its production of meat.

(iii) If either (i) or (ii) applies, the establishment is exempt from the requirements of Regulation 853/2004. Provided, in relation to meat, the “localised” criteria below is also met.

and

- **„Local" / „Localised"**

and

- **"Restricted"**

This only applies to the supply of wild game. Supply is subject to the game having been examined by a trained person and carcases of large wild game animals must be accompanied by a trained person’s declaration stating that no abnormalities were observed either before or after shooting. For all other meat, the restrictions relate to the amount of meat supplied.

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.

A.3.4.4 : Wild Game (Primary Producers / Hunters)

The Regulation (EC) No. 853/2004 Article 1(3)(e) exemption repeats the one at Regulation (EC) No.852/2004 Article 1(2)(c) allowing primary producers to supply small quantities of wild game carcases (i.e. in-fur/in-feather) either direct to the final consumer or to local retail establishments directly who can then supply the final consumer only. Primary producers, whether individual hunters or shooting estates, are exempt from both Regulation (EC) No.852/2004 and Regulation (EC) No.853/2004.

The Regulation (EC) No. 853/2004 Article 1(3)(e) exemption applies only to individual hunters who prepare wild game meat from carcases they have shot themselves. Only small quantities of this meat may be sold either direct to the final consumer or to local retailers directly who can then supply the final consumer only. However, because the meat is not a primary product, the hunter is exempt only from Regulation (EC) No. 853/2004, not from Regulation (EC) No. 852/2004.

For these exemptions, the UK is interpreting supply of "small quantities" as self-defining because the demand for in-fur/in-feather carcases from local consumers and local retailers is limited. In the case of the hunter claiming a Regulation (EC) No. 853/2004 Article 1(3)(e) exemption, this is separate from the primary producer exemption as it allows you to supply wild game meat in small quantities. The meat he supplies would have to be part of this amount, rather than in addition to it. Supply direct to a final consumer can be via mail order or internet sales as well as by delivery/collection. The interpretation of “local” is the same as for “localised” (see Paragraph A.5.4.2).

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 FSA website at: http://www.food.gov.uk/foodindustry/meat/.

A.3.4.5 : On-farm slaughter and cutting of small quantities of poultry and lagomorphs

Regulation (EC) No. 853/2004 does not apply to the direct supply, by the producer, of small quantities of meat from poultry 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(3)(d))[25]. Article 1(4) goes on to say that the rules governing the persons and activities benefiting from this exemption (in addition to those in Regulation (EC) No. 852/2004) will be set out in national law. These national rules are set out in Schedule 5 to the Food Hygiene (Scotland) Regulations 2006 (as amended).

[25] As amended by Article 3 of Regulation (EC) 2076/2005 (Transitional and Implementing Measures)

A.3.4.5.1 : 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 allow for some fluctuation in annual throughput around that level provided that it does not habitually exceed a combined limit of 10,000 a year.

Although there is no limit to the number of birds or lagomorphs that producers in the second category may slaughter, the FSA anticipates that the restrictions will limit production to relatively small quantities. In judging whether an assurance scheme is appropriate, regard should be had as to whether the scheme has requirements that go beyond minimum legal requirements in relation to food safety and hygiene and whether it has independent verification arrangements. The FSA can advise in cases of doubt.

A.3.4.5.2 : 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 A.5.4.2 above) and, in addition, anywhere within the UK in the two weeks preceding Christmas and Easter and (for geese) Michaelmas (late September).

A.3.4.5.3 : What rules apply?

Regulation 852/2004 applies to producers who benefit from this exemption. This includes, among other things, the requirement to register the establishment with the local food authority, to maintain procedures based on HACCP principles and to comply with general hygiene and training requirements. The national rules in Schedule 5 to the Food Hygiene (Scotland) Regulations 2006 (as amended) regarding labelling and record keeping also apply.

The labelling rules require that the meat bear a label or other marking clearly indicating the name and address of the farm where the bird or animal was slaughtered. This is in addition to any labelling required by the Food 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 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.3.5 : Meat products, minced meat and meat preparations – Cutting of meat

Paragraph 2 of Section VI of Annex III to Regulation (EC) No. 853/2004 has the effect that premises that cut meat exclusively for the manufacture of meat products, minced meat, meat preparations or mechanically separated meat need to comply with the relevant requirements of Annex III of Regulation (EC) No. 853/2004 for red or white meat cutting plants, but will not need approval as cutting plants.

A.3.6 Meat Preparations and Meat Products Obtained by Mechanical Separation from Bones or Sinew

A new generation of separating machines can separate meat from bones or sinew(e.g. Baader meat, desinewed meat) where the material obtained retains most of its muscle fibre structure. Hence such material may not meet the definition of Mechanically Separated Meat in paragraph 1.14, Annex I of Regulation (EC) No. 853/2004, where the mechanical process results in the loss or modification of the muscle fibre structure. Neither can such material be

considered as minced meat because it is produced under pressure and not by cutting. Such material could fall within the definition of a meat preparation – paragraph 1.15, Annex I of Regulation (EC) No. 853/2004, which includes meat that has been reduced to fragments, or undergone a process insufficient to modify the internal muscle fibre structure and thus to eliminate the characteristics of fresh meat. The FSA has issued guidance on the production of meat preparations obtained by desinewing meat (ENF/S/10/027).

Premises, which produce such material by utilising fresh meat from a cutting plant, and have satisfied themselves that the material they produce meet the requirements of meat preparations above should therefore:

be approved as meat preparations establishments by local authorities when the premises are stand-alone premises;

be approved as meat preparations establishments by the FSA when co-located with a slaughterhouse, cutting plant or game handling establishment;

should comply with the hygiene and microbiological testing rules for meat preparations, not those for minced meat or mechanically separated meat.

A.3.7 Home Slaughter of Livestock: A Guide to the Law in Scotland

Where slaughter of livestock 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, the EU TSE Regulations apply wherever TSE susceptible animal is slaughtered (including home slaughter). This means that after slaughter of cattle, sheep or goats, specified risk material (SRM) must be removed, stained and disposed of in accordance with both the EU TSE Regulation (EC) No. 999/2001 and the EU Animal By-Products Regulation (EC) No 1069/2009. A more detailed guide on home slaughter is available at the web link below:

http://www.food.gov.uk/scotland/regsscotland/regsguidscot/homeslaughterlivestockscot

ANNEX 3, APPENDIX 1: The Wild Game Sector - Which Regulations Apply to Which Activities?

ACTIVITY	Regulation 852/2004	Regulation 853/2004	Regulation 854/2004
1. **Shooting for own consumption**	No Art 1.2a exemption	No Art 1.3a exemption	No
2. **Supply direct to final consumer or to local retailers (directly supplying final consumer) of small quantities of:**			
a) Whole carcasses by primary producer (hunter or estate)	No Art 1.2c exemption National rules apply[1]	No Art 1.3c exemption	No
b) Meat from carcasses (produced by hunter from own shooting)	Yes Premises to be registered as food business[4] and to operate under Annex II	No Art 1.3e exemption National rules apply[1]	No
c) meat from carcasses (produced by estate, shot by others) • **This is a type of approved game handling establishment (AGHE)**	Yes	**Yes[2]** Premises to be approved by CA[3]	**Yes[2]**
5. **Supply of whole carcasses to approved game handling establishments (AGHEs)** ***either direct from shoot or from game larder operated by primary producer***	Yes Premises to be registered as food business[4] and to operate under Annex I	Parts relating to primary producer ("trained person[5]" requirements and hygiene practices e.g. initial handling, temperature controls and transport)	Parts relating to primary producer"s documentation and hygiene practices, including OV[6] examination of "trained person[5]" information
6. **Supply of whole carcasses to approved game handling establishments (AGHEs)** ***not by the primary producer***	Yes Premises to be registered as food business[4] and to operate under Annex II (including any game larders and vehicles)	Parts relevant to documentation originally supplied by "trained person[5]", plus temperature controls, hygienic handling and transport	Parts relevant to supplier"s hygiene practices, plus OV[6] to check supply of documentation from "trained person[5]"
7. **All other (non-retail) establishments preparing wild game meat for placing on the UK domestic or export market** • **These are approved game handling establishments (AGHEs)**	Yes	Yes Premises to be approved by CA[3]	Yes

[1] Food Safety Act 1990 (as amended by General Food Regulations 2004). "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)

[2] Details of proposed variation in official veterinary controls and precise criteria for inclusion in UK Pilot Project to be advised

[3] Competent Authority (i.e. the Food Standards Agency)

[4] By the Local Authority

[5] Either the gamekeeper or game manager on the hunting party/in the immediate vicinity or a hunter who has completed training provided to the satisfaction of the Competent Authority (see Regulation 853/2004, Annex III, Section IV, Chapter I)

[6] Official Veterinarian

ANNEX 3A:: GUIDANCE FOR FOOD LAW ENFORCEMENT OFFICERS ON HALAL FOOD ISSUES

Halal is an Arabic word which means „permissible", a related word in the Qur"an is *Tayyab* which means wholesome and fit for human consumption. With regard to food described as *Halal,* it means food that Muslims are permitted to consume under Islamic law. The opposite of *Halal* is *Haram*, which means „prohibited by God, unwholesome, foul". It follows, for example, that any meat that has not been rendered *Halal* by Islamic slaughter or that is liable to cause ill health, e.g. meat that is contaminated and unfit for consumption, cannot be considered *Halal*. Meat also cannot be considered *Halal* if it is past its "minimum durability marking". If a Muslim is sold *Haram* food, it is viewed very seriously, as it causes them to eat food prohibited in Islam and, in addition, it may be a form of fraud or deception.

Muslims regard Al Qur"an as the very words of God as revealed to the last prophet Muhammed, and is the primary source of Islamic law. In the Al Qur"an there are prohibitions on the consumption of pork, blood, carrion and alcohol, among other things. For a product to be *Halal* (lawful) for Muslim consumption, and described as such, all the ingredients should be *Halal*. The Muslim requirement for food to be *Halal* applies whether the food business operator is preparing, handling, processing, manufacturing, packaging, storing, importing, distributing, supplying, transporting or selling food, whether for profit or not, from a factory, warehouse, shop, restaurant, van, village hall, community centre or vending machine.

Examples of where the requirements of food law relate to *Halal* requirements

There are many similarities between aspects of *Halal* requirements and aspects of food law. A *Halal* food business operator must not only comply with food law but with the **Islamic Shariah (Law)** related to food. The requirements of the **Islamic** dietary laws are that:

- Meat, and other foods, including food ingredients, whether home-produced or imported, must be *Halal*.
- Meat must be obtained from *Halal* sources; e.g. an abattoir must have the facilities and personnel to undertake *Halal* slaughter. See Annex 1 for further information on Islamic Shariah (Law) relating to *Halal* slaughter, provided by the FSA"s Muslim Organisations Working Group.
- Meat must be wholesome and meet food safety requirements - if meat is unfit for human consumption it cannot be considered *Halal*, even if slaughtered in the prescribed manner.

To be *Halal*:

- The animal should be alive or deemed to be alive at the actual time of slaughter and slaughter must be carried out in compliance with Islamic Shariah and the Welfare of Animals (Slaughter or Killing) Regulations 1995

(as amended)[26]. Animals/birds must be slaughtered by severance of neck arteries and jugular veins.

- No pork or pork ingredients must be present in the food.
- No alcohol or other intoxicants must be used.
- Any animal product, such as gelatine, must be produced from animals slaughtered in accordance with the Islamic Shariah.
- Any animal fat or meat must come from animals slaughtered in accordance with the Islamic Shariah.
- Any preparation area and the equipment used should be kept in such a manner as to prevent cross contact, contamination or mixing *Halal* food with non-*Halal* food.

Displaying *Halal* and non-*Halal* meat on the same premises does not in itself render *Halal* meat non-*Halal*. If open, unpackaged *Haram* food is stored and displayed alongside *Halal* meat, there would have to be clear separation and suitable labelling. However it should be noted that, as any direct or indirect contact between *Halal* and *Haram* food (e.g. use of the same knives or chopping boards etc.) would render *Halal* meat and poultry as *Haram,* this could be difficult to achieve in practice.

There is no legal requirement to label food as being non-*Halal*. If a description "HALAL" is made, then it must be clear which product the description refers to, if the business is not to run the risk of committing offences of mis-describing the foods on sale.

At present there are few recognised systems of certifying that a particular food is *Halal.* However, certain Muslim organisations are collaborating to develop an umbrella certification board for *Halal* foods.

Officers carrying out routine inspections or following up complaints should whenever possible consider, apart from hygiene issues, checking whether food claiming to be *Halal* is actually *Halal*. This may be done, for example, in any informal food sampling programme, of canned meat, where the presence of pork in what is purported to be *Halal* meat would obviously be *Haram* to a Muslim and may well contravene food law in terms of composition and labelling.

Where officers suspect misdescription of fresh meat they should liaise with the Official Veterinarian– through FSA Scotland

In summary, officers are asked to consider action, where appropriate, against food business operators who sell and mis-describe *Halal* foods, in the same way as they would for any contravention of food law in food premises generally.

[26] Under Regulation 22 "Schedule 5 (which relates to the stunning and killing of animals) shall not apply to any animal which is slaughtered in accordance with Schedule 12 (which relates to s la ught er b y a r e li gi ous m ethod) " .

Islamic Shariah (law) relating to slaughter of animals or poultry

Animal and birds should have preferably been raised in a natural environment.

- Their feed should not contain animal-based products.
- Animals and poultry at farms or lairages must be cared for properly. They must be fed and watered before slaughter.
- They must receive ante-mortem inspection so that only healthy animals are brought in for slaughter.
- In the slaughterhouse animals must not be able to see other animals being slaughtered, nor must they have sight of blood. This requires cleaning the area before the next slaughter.
- There must be no cruelty to animals or poultry at any time.
- The slaughterman must be a Muslim, who has been properly trained and licensed.
- All slaughtering must be carried out in a licensed slaughterhouse.
- Places where pigs are slaughtered should be avoided.
- The slaughterman must use a sharp knife (which must not be sharpened in front of the animal). He must sever the jugular veins and carotid arteries as well as the oesophagus and trachea, but not the spinal cord as this restricts convulsion, which in turn restricts the pumping out of blood.
- At the time of slaughter he must pronounce *Bismillah Allahu Akbar* (In the name of God, God is the Greatest) on each animal or bird.
- At all times the meat and general hygiene regulations must be complied with.
- Any carcasses found unfit on post mortem inspection must not be used for food for human consumption.

NB: This is included for information

Acknowledgement: The FSA is grateful for the help and advice received from members of the FSA"s Muslim Organisations Working Group.

ANNEX 4: LIVE BIVALVE MOLLUSCS

A.4.1 : Introduction

This Annex provides specific guidance to Food Authorities on the application and enforcement of the Live Bivalve Mollusc (LBMs) aspects of Regulations 852/2004, 853/2004 and 854/2004. In line with Annex III, Section VII(1) of Regulation 853/2004 (as amended), 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 **marine gastropods which are not filter feeders**

A.4.2 : 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.4.3 : Allowances for small quantities of live bivalve molluscs

(a)	**(b)**
Species	**Maximum amount**
Cockles	25.0 tonnes
Oysters	5.0 tonnes
King Scallops	5.0 tonnes
Queen Scallops	10.0 tonnes
Mussels	20.0 tonnes
Other Live Bivalve Molluscs	10.0 tonnes
Marine Gastropods	20.0 tonnes

While Regulation 853/2004 does not apply to small quantities, it is still the responsibility of the harvester to ensure that LBMs they are placing on the market meet the end product standards set down for placing on the market. Any amount of the catch must have originated from an „A" class area, which means it can be placed on the market with no further treatment.

A.4.4 : Pectinidae (scallops) and non filter feeding gastropods harvested from outside classified production areas

Food authorities will wish to note the specific exemption for scallops („pectinidae") and non filter feeding gastropods, which may be harvested from outside classified areas providing the requirements in Annex III, Chapter VII, Section IX are met.

A.4.5 Heat Treatment

LBMs which are to undergo an approved heat treatment process or other processing, e.g. freezing, are subject to the requirements of Regulation 853/2004 that relate to live bivalve molluscs 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 (5) of Regulation 853/2004 and if appropriate Annex II, Chapter XI of Regulation 852/2004.

A.4.6 Shellfish Liaison Arrangements

The Food Authority's shellfish liaison officer will be the FSA"s first point of contact in relation to non-routine matters concerning the enforcement of the Regulations.

It is essential for the effective enforcement of the Regulations that adjoining Food Authorities maintain effective liaison arrangements. In Scotland the Fish Hygiene Working Group assists in ensuring continued dialogue between Food Authorities. This group should be attended by Food authorities where there are commercial bivalve mollusc harvesting activities.

Each local shellfish liaison group should also include representatives of other relevant local and national organisations as appropriate. These may include representatives from the Scottish Environmental Protection Agency, Marine Scotland, Seafish and relevant representatives from the nominated Official Control Laboratories and National Reference Laboratories.

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 LBM relaying areas (if any) (working with the industry);
- Joint sampling plans to monitor the quality of LBMs from classified areas;
- Arrangements for the issue of registration documents;
- Arrangements for the making of Temporary Closure Notices covering waters from more than one Food Authority area;
- Arrangements for the detention/recall of bivalve molluscs affected by any Temporary Closure Notices;

- 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.

- Identification of relevant training needs in this area

A.4.7 Notification of Classified Live Bivalve Mollusc (LBM) Production Areas and Relaying Areas

The FSA will supply a list of classified 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 classified LBM production and 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 classification of bivalve mollusc production areas and relaying areas.

It may be necessary from time to time for the FSA to re-classify a bivalve mollusc production area. Relevant Food Authorities will be informed by the FSA 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.4.8 Monitoring of Registration Documents

Under Regulation 853/2004, food businesses placing live bivalve molluscs on the market are required to complete a registration document (unless issued with a permanent transport authorisation) to identify each batch harvested from production and relaying areas and each batch leaving purification centres and processing establishments. 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 establishment or area. Operators are required to retain registration documents for at least 12 months. Gatherers are also obliged to keep a copy of completed registration documents for the same period.
The same requirements apply to batches of scallops („pectinidae") and non filter feeding gastropods harvested from outside classified production areas. Although the classification status of the production area (i.e. Class A, B or C) is not appropriate, the location of the production area should be described in as precise detail as is practicable or by a code number (e.g. ICES coordinates, OS grid references etc.).

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 Annex III, Section VII, 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.

It is not possible for Food Authorities to monitor every landing in their area, or to detect abuses in the use of registration documents by concentrating resources on sampling only. However, authorities should familiarise themselves with the commercial activities within ports in their local area and implement some degree of monitoring of landings of LBMs and other shellfish (e.g. pectinidae). This can be achieved through effective and periodic liaison with other statutory inspectorates e.g. Marine Scotland. It is within the remit of IFCAs to track the movement of fishing vessels in their local waters and provide other vital information to help verify the information contained in registration documents and the activities of harvesters e.g. the seasonality of the harvesting season, minimum landings size, checks on whether shellfish were harvested under the appropriate permissions/IFCA licences.

Food authorities responsible for establishments receiving batches of LBMs from outside their local area are encouraged to contact the issuing food authority when inspecting registration documents. In order to ensure efficiency in this verification process, food authorities are advised to keep a log of all registration documents that have been issued by them for at least one year, including details of the harvesters to whom they have been issued and the production areas which the harvester requires the registration documents for.

In addition to local liaison, food Authorities are also encouraged to have in place procedures to assist tracking and verifying the authenticity of registration documents they have issued. For example, the use of one or a combination of coloured carbon tear offs, embossed local authority stamps in conjunction with unique reference numbers on documents may be used when trying to ensure registration documents may not be easily falsified.

Food Authorities should be aware that registration documents may be completed on behalf of the gatherer, for example, by an “agent” providing all required information relating to the batch is appropriately completed. The supplying harvester(s) must be able to support the declaration made on the

registration document by the “agent”. Food authorities may wish to consider amending their forms to reflect this activity.

A.4.9 Sampling by Operators

Operators of approved processing establishments, auction halls and purification / dispatch centres should also have adequate laboratory arrangements to ensure that the LBMs comply with the microbiological end product standard set for LBMs in Regulation 2073/2005 and the health standards referred to in Annex III, Section VII, Chapter V of Regulation 853/2004.

Officers should be aware that the Regulations do not prescribe a frequency for these tests (to detect microbiological and marine biotoxin contamination) but they should be in line with the businesses‟ food safety management system. As part of the system of own checks, operators should be encouraged to use commercial kits for the detection of marine biotoxins

In determining what level of sampling is appropriate, Food Authorities should have regard to HACCP principles, any advice issued by the FSA or LGG or contained in voluntary guidelines produced by relevant trade associations.

A.4.10 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 under Annex III, Section VII, 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 an Official Control Laboratory, or any other appropriate laboratory.

However, recognition by the Food Authority will depend on the laboratory using methods that are acceptable to the FSA. The current recognised method for microbiological testing 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 Regulations is a five tube, three dilution, Most Probable Number (MPN) test. The Impedance method is also an accepted and validated alternative to the MPN method for detecting *E.coli* in live bivalve molluscs.

The regulatory limits and current recognised methods for the detection of marine biotoxins are included in the table below:

Toxin group & Regulatory Limit (Reg. 853/2004)	EU Reference method (Reg. 2074/2005)	Method of analysis in Scotland
ASP 20 mg of domoic acid/kg shellfish flesh	HPLC	HPLC – all species
PSP 800 µg of saxitoxin/kg shellfish flesh	Biological method *HPLC – validated alternative*	HPLC - all species
Lipophilic toxins (LT) • 160 µg okadaic acid eq/kg • 1 mg yessotoxin eq/kg • 160 µg azaspiracids eq/kg	LCMS	LCMS – oysters, cockles, hard/razor clams, mussels and scallops Biological method to continue for remaining species

A.4.11 Sampling of Live Bivalve Molluscs by Food Authorities

Sampling by Food Authorities should be aimed at verifying food business operators" compliance with the requirements for end product at all stages of production, processing and distribution. est results that are inconsistent with the food business operators" own records should be followed up by further investigations and tests.

A.4.12 Information on Standards to be applied in purification centres

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 Hygiene Regulations.. In some instances the guidance makes recommendations for good industry practice, which go beyond the requirements of legislation. These documents are available on the Seafish Website **www.seafish.org**.

Food Authorities may refer to the guidance document 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.4.13 Molluscs and Other Shellfish Which Fail to Satisfy Requirements

In accordance with Regulation 27 of the Food Hygiene (Scotland) Regulations 2006 (as amended), 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 Sheriff 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.4.14 Transfer of Seed Molluscs to Classified Production Areas

Live bivalve molluscs may be transferred from areas that are not classified as production areas for "growing on" within a production area of any Class. Such molluscs must be genuine "seed shellfish". In fisheries regulated for conservation purposes under the Sea Fish (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 classified production area for a period of not less than six months before they are harvested for human consumption. This does not permit the movement of adult or partially developed bivalve molluscan shellfish from an unclassified area for further short-term growth before marketing. It is restricted to the seeding of new areas or the re-seeding of existing classified production areas. If new areas are seeded they must be classified before harvesting can take place. Harvesters should inform the relevant Food Authority if any such movements are contemplated.

A.4.15 Temporary Closure Notices

(See also Chapter 5.3 of the Code of Practice)

It is recommended that the Food Authority should issue a Closure Notice as the appropriate means to notify interested parties where it is satisfied that the consumption of species covered by the Regulation taken from the area is likely to cause a risk to public health. A Closure Notice might be considered appropriate where, for example, the classified mollusc production area was subject to sudden or accidental pollution which affected the quality of the production area. The use of a Closure Notice may also be appropriate where there is a local problem with environmental pollution caused by microbiological or chemical contamination, or due to the presence of marine biotoxins above the regulatory limit 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 or the relevant biotoxin or microbiology experts at the National Reference Laboratories.

A model Closure Notice can be found at Annex 9 to the Code of Practice.

A.4.16 Reporting of illegal harvesting activity

It is an offence to place on the market LBMs that have been harvested from areas that are not classified, or which are unsuitable for health reasons. Similarly, it is also illegal for food businesses to place on the market scallops and non filter feeding gastropods from outside classified areas that do not meet the microbiological end product standard or which contain harmful level of marine biotoxins.

Food authorities should routinely monitor areas within their remit, including areas affected by temporary Closure Notices (as described above) to ensure this practice does not occur. Where authorities become aware of these instances, they will need to consider appropriate surveillance and follow up enforcement. Authorities are encouraged to establish close working relationships with other local inspectorates, such as IFCAs who may be able to assist in combating this practice e.g. through surveillance, notification of fishing activity in waters under restrictions, assistance in the verification of information in registration documents etc.

All cases of illegal harvesting should be reported on the Food Standards Agency's Food Fraud database, which can be accessed using the following link:

http://www.food.gov.uk/enforcement/workwithenforcers/foodfraud/lafoodfraud/foodfrauddatabase

Food Authorities should contact the Food Fraud team for further advice on surveillance and enforcement foodfraud@foodstandards.gsi.gov.uk

ANNEX 4, APPENDIX 1: Guidance Note for Food Authorities in Scotland – Live Bivalve Molluscs / Shellfish

INDEX

Approval of Establishments

1. When does a harvester or handler of live bivalve molluscs need to consider becoming an approved dispatch centre?

Annex I(2) of Regulation 853/2004, defines a dispatch centre as „any on-shore or off-shore establishment for the reception, conditioning, washing, cleaning, grading, wrapping and packaging of live bivalve molluscs fit for human consumption." All dispatch centres must be approved. As fishing vessels are considered primary production, fishing vessels do not need approval for washing and grading live bivalve molluscs at sea. Though fishing vessels will need to be registered and subject to the Food Authorities Food Hygiene Interventions programme.

Annex III, Section VII, Chapter I of Regulation 853/2004 requires all live bivalve molluscs destined to be placed on the market for retail sale to enter the market via a dispatch centre. At the dispatch centre they are sampled, wrapped and identification marked. The dispatch centre 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 bivalve molluscs 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. The suffixes “DC, PC” may be used to identify the activities for which the establishment is approved.

4. What locations are considered suitable for dispatch centres and purification centres?

Regulation 853/2004, Annex III, Section VII, Chapter III requires dispatch and purification centres to be located on land that is not subject to flooding by ordinary high tides or run-off from surrounding areas.

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 bivalve molluscs 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 live bivalve molluscs 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 Marks

7. If a dispatch centre is selling live bivalve molluscs 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 bivalve molluscs prior to retail sale. After live bivalve molluscs 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 bivalve molluscs through the retail outlet may suffice. The position is similar for live bivalve molluscs sold by mail order.

Seed Shellfish

8. What is the minimum period for growing on 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 4, APPENDIX 2: Model Registration Document

LIVE BIVALVE MOLLUSCS / LIVE SHELLFISH^
REGISTRATION DOCUMENT

(Regulation (EC) No. 853/2004 – Article 7 / Annex III, Section VII, Chapter I)
^including pectinidae and non filter feeding gastropods harvested from unclassified areas (Regulation (EC) No. 853/2004 – Annex III, Section VII, Chapter IX)

Registration Document
No……..

Issued by: …….

Date of Issue: ……..

Name of gatherer — Signature of gatherer

……

Food Authority where shellfish landed — Address of gatherer

……

LBMs harvested within classified production areas
Location of production area (Name, Code or Grid ref) — Class of production area. (A, B* or C*)

.....

Pectinidae and non filter feeding gastropods harvested from outside classified production areas
Location of production area (ICES area):

.....

Date of gathering

……

Name of LBM species being moved (common and scientific name) and quantity of shellfish being moved — Destination (country, establishment and approval number

……

*When shellfish originate from a production area classified as B or C:

Relaying area ..……

Duration of relaying ……
or
Address of Purification Centre

……

Duration of purification.....

Date batch entered Purification Centre — Date batch left Purification Centre

.....

☐ Checks to verify health standards have not been carried out and have been deferred to the approved establishment stated above.

Date of Receipt ……

Place of Receipt ……..

[Date of Signature] …….

REMINDER – This document is to be kept by the person receiving the shellfish for a period of not less than 12 months and the gatherer is to keep a copy for the same period.

ANNEX 5: FISHERY PRODUCTS

A.5.1 : Introduction

This Annex provides specific guidance to Food Authorities on the application and enforcement of the fishery products aspects of Council Regulations 852/2004, 853/2004 and 854/2004.

A.5.2 : Competent Authority

The FSA 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.5.3 : 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.

Factory and freezer vessels, 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 Chapters I and II respectively.

A.5.4 : Direct supply of small quantity of Fish.

The Regulations do not apply to the direct supply of small quantities of fishery products (i.e. primary products) to the final consumer or to local retail establishments directly supplying the final consumer. For the purposes of fishery products (not including live bivalve molluscs) a small amount is a total amount of not more than 25 tonnes of fishery products in a calendar year. While the Regulations do not apply to this allowance it is still the responsibility of the harvester to ensure that these products meet the end product standards set down for placing these fishery products on the market.

A.5.5 : 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. Marine Scotland to ensure that any enforcement action taken is appropriate.

A.5.6 : 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 5, APPENDIX 1: Guidance Note for Food Authorities in Scotland - Fishery Products

INDEX

Conditions of approval

17. Do all the requirements of Regulation 853/2004 in relation to fishery products apply to all fishery products establishments?

18. Could such facilities as wash basins and lavatories be communal to a number of establishments?

19. When the Regulations refer to temperature recording devices, does this mean that readings can be taken and logged manually?

20. Are communal filleting premises permissible?

21. The Regulations require that operations such as filleting and slicing must be carried out in a place other than that used for heading and gutting operations. How should this be interpreted?

22. Is there a list of approved detergents and similar substances for maintaining general conditions of hygiene in establishments and on equipment?

Fish farms

23. Are fish farms covered by the Regulations?

Identification marks

24. Where should the identification mark appear in the case of fresh fish sold by an auction or wholesale market to a person who is not a retail customer?

Landings of fishery products

25. Do EHOs have to carry out histamine checks on other compounds listed in Regulation 854/2004 on all consignments of fish?

26. Do quaysides where fish are landed need to comply with the Regulations?

Approval of establishments

1. Which establishments handling fishery products are subject to approval under Regulation 853/2004?

Under Article 4 of Regulation 853/2004, establishments handling products of animal origin for which Annex III of that Regulation lays down requirements (including fishery products) require approval. There are however a number of exemptions from this requirement.

Article 1(2) of Regulation 853/2004 has the effect of exempting establishments engaged only in the production of food containing both products of plant origin and processed fishery products (e.g. sandwich makers) from approval, provided that the fishery products used enter the establishment as processed products. In such cases compliance with the relevant requirements of Regulation 852/2004 is required and the processed fishery products must be obtained and handled in accordance with the requirements of Regulation 853/2004.

Certain establishments such as those carrying out „primary production" and „retail" (as defined in Article 3(7) of Regulation 178/2002) establishments carrying out certain activities are also exempt from the requirement to be approved, although some provisions of Regulation 853/2004 are nonetheless applicable. Primary production establishments exempt from approval, including fishing vessels, are required to comply with Section VIII (Fishery Products) of Regulation 853/2004 as appropriate. Retailers exempt from approval are required to comply with Chapter III, Parts A, C and D, and Chapter IV and V of Section VIII (Fishery Products), of Regulation 853/2004. Section VIII Paragraphs 2 and 3 of Regulation 853/2004 refer respectively. Factory and freezer vessels are required to be approved and comply, as appropriate, with Chapters I – III of Regulation 853/2004, Annex III, Section VIII. Food authorities may wish to use the checklists included in Appendix B, C and D of this section when carrying out official controls.

In order to decide whether a retail activity is or is not exempt from approval, Article 1(5) of Regulation 853/2004 must be considered. If a retail operation consists of transport and storage only then it will not require approval. Although the regulation generally applies to retail when food operations are conducted with the purpose of supplying another establishment, a retail establishment without approval may supply products of animal origin which would normally trigger the need for approval, but only to other retail establishments on a marginal, localised and restricted.

Food businesses claiming exemptions from the requirement to be approved must be considered on a case by case basis.

2. What is retail?

The definition of „retail", which is given in Article 3(7) of Regulation 178/2002, is as follows:

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

3. Who is the Final Consumer?

The definition of „final consumer", which is given in Article 3(18) of Regulation 178/2002, is as follows:

„final consumer" means the ultimate consumer of a foodstuff who will not use the food as part of any food business operation or activity

4. In what circumstances would auction halls or wholesale markets need to be approved?

Under Article 2(1)(c) of Regulation 852/2004 an „establishment" is defined as „any unit of a food business". Regulation 853/2002 defines „wholesale market" as „a food business that includes several separate units which share common installations and sections where foodstuffs are sold to food business operators".

It is the case that wholesale outlets are included under the definition of „retail" in Regulation 178/2002 (see Q&A 2, above). However, for such establishments to fall within this definition, an element of their sale or delivery of food must be to the final consumer. Auction halls and wholesale markets may fall under this definition.

Auction halls and any units within wholesale markets considered to be „retail" under the definition would not require approval and would be subject to Regulation 852/2004 only. They would be permitted to supply the final consumer and other retail establishments on a marginal, localised and restricted basis. Auction halls and units within wholesale markets that do not sell, or deliver, to the „final consumer" cannot be considered to be „retail" as defined and as such would need to be approved and would be subject to the relevant requirements of both Regulation 852/2004 and Regulation 853/2004.

5. Should individual stalls / units within auction halls and wholesale markets be approved establishments?

Individual stalls / units within auction halls and wholesale markets are classed as establishments. If the stall / unit can be considered to be „retail" as defined (see Q&A 2 and 4, above) and is supplying only the final consumer and other retail establishments on a marginal, localised and restricted basis approval would not be required and Regulation 852/2004 only would be applicable.

Otherwise, the stall / unit would require approval and would be subject to the relevant requirements of both Regulation 852/2004 and Regulation 853/2004.

6. Should retailers who also sell fishery products on a wholesale basis be approved?

Establishments falling under the definition of „retail" as defined (see Q&A 2 and 4, above) which also sell wholesale other than to the final consumer and/or other retail establishments on a marginal, localised and restricted basis would require approval. Such establishments would be subject to the relevant requirements of both Regulation 852/2004 and Regulation 853/2004.

7. Are retail establishments engaged in processing of fish covered by Regulation 853/2004?

Unless they are only selling processed fish to the final consumer and to other retail establishments on a marginal, localised and restricted basis, retail establishments would require approval and would be subject to the relevant requirements of both Regulation 852/2004 and Regulation 853/2004.

8. Do cold stores need to be approved?

European Commission guidance advises that wholesale meat cold stores require approval on the basis that they are used in relation to activities for which Annex III of Regulation 853/2004 lays down requirements. It has been decided to apply this guidance across all products of animal origin. There is no requirement for veterinary control of cold stores and Food Authorities are therefore responsible for approving fish cold stores and for enforcement in such establishments.

Stand-alone Cold stores supplying the final consumer exclusively or supplying retail establishments (including caterers) on a marginal, localised and restricted basis are not subject to approval and must therefore be registered under Regulation 852/2004.

9. Do cash and carrys need to be approved?

The definition of „retail" in Article 3(7) of Regulation 178/2002 (see Q&A 2, above) includes „wholesale outlets". Cash and carrys may therefore fall into this category and could, depending on their specific activities, be exempt from the requirements of Regulation 853/2004. Although a wholesale outlet may be considered to be „retail" as defined, if it is not supplying final consumers exclusively and/or other retail establishments on a marginal, localised and restricted basis approval would be required.

10. Are sandwich makers covered by the Regulations and do they need to be approved establishments?

Owing to the exemption provided by Article 1(2) of Regulation 853/2004, sandwich makers will not be subject to approval under that Regulation if the fishery products they use to make the sandwiches enter their establishment as processed products. However, the processed fishery products used in the

production of the sandwiches must be obtained and handled in accordance with the requirements of Regulation 853/2004. Such sandwich makers will still need to comply with the relevant requirements of Regulation 852/2004.

11. Do retail fishmongers who also process fish (including smoking) and, if applicable, supply retail fish vans, need to be approved establishments?

Retail fishmongers that sell their own processed products, but only to the final consumer would not be subject to approval under Regulation 853/2004. They would, however, need to comply with Regulation 852/2004. If a retail fishmonger sells their own processed products to other establishments (including those in the same ownership) it will be subject to approval under Regulation 853/2004, unless the other establishments are retail establishments and the supply is marginal, localised and restricted.

12. Are retail fishmongers who keep fish live covered by the Regulation 853/2004?

Regulation 853/2004 does not apply if they sell only to their final consumers. However, such establishments will still need to comply with the relevant requirements of Regulation 852/2004, as appropriate.

13. If a retail establishment only has upright or chest freezer cabinets, does it need to be approved?

There is no need for a retail establishment to be approved where the only storage activity in respect of fishery products is their display, in upright or chest freezer cabinets, for retail sale to the final consumer. However, they will need to comply with Regulation 852/2004 as appropriate.

14. Do establishments storing only cans and jars of fishery products need to be approved?

No.

15. Are airport caterers which supply fishery products to companies, which supply airlines, covered by Regulation 853/2004 and do they need approval?

As they are not retail and are not supplying the final consumer exclusively, approval would be required for such industrial catering establishments unless all the products they make contain both products of plant origin and processed fishery products and the fishery products used enter the establishment as processed products (see Article 1(2) of Regulation 853/2004). In this case, the processed fishery products used must be obtained and handled in accordance with the requirements of Regulation 853/2004, and compliance with the relevant requirements of Regulation 852/2004 would be required.

16. If a non-retail establishment supplies a company or a contractor, who then supplies the final consumer would it be covered by the Regulation 853/2004?

Yes. The establishment is not a retailer and is supplying other establishments.

Conditions of Approval

17. Do all the requirements of Regulation 853/2004 in relation to fishery products apply to all fishery products establishments?

No. In Regulation 852/2004 there are general requirements applicable to both businesses involved in primary production and manufacturing food businesses and indicates where separate conditions apply. Similarly, in Regulation 853/2004 there are specific requirements for establishments such as purification centres, fishing vessels, factory vessels and fishery product processing establishments.

18. Could such facilities as wash basins and lavatories be communal to a number of establishments?

Regulation 852/2004 sets out the general hygiene requirements for food business establishments. As regards to wash basins and lavatories in wholesale markets (see Q&A 4), it is for the Food Authority to decide whether separate facilities, for different units within the market (see Q&A 5) are necessary in the interests of public health or whether the communal facilities are sufficient for compliance with the Regulation.

19. When the Regulations refer to temperature recording devices, does this mean that readings can be taken and logged manually?

Annex II, Chapter I(2)(d) of Regulation 852/2004 stipulates that, where necessary, it should be possible to monitor and record temperatures at which foodstuffs are maintained. The Regulation does not stipulate that the recording of temperatures should be done automatically, which implies that manual recording is allowed. However, for freezer vessels or establishments on land where the freezing of fishery products is undertaken, there is a requirement that a temperature recording-device is installed (see Regulation 853/2004 Annex III, Section VIII, Chapter I(C) (Requirements for Freezer Vessels) and Chapter III(B) (Requirements for Frozen Products (on land)).

20. Are communal filleting premises permissible?

The Regulations do not specify whether or not communal filleting premises are permissible. Provided that control arrangements are adequate, ensuring that filleting is carried out to avoid contamination or spoilage then communal filleting premises would not be precluded. However, a separate establishment for communal filleting is likely to require approval and compliance with the relevant requirements of Regulation 852/2004 would be required.

21. The Regulations require that operations such as filleting and slicing must be carried out in a place other than that used for heading and gutting operations. How should this be interpreted?

The main requirement under Regulation 853/2004 is to avoid contamination of fillets. There may be a number of ways in which this can be achieved, one of which is to separate operations by time rather than place. As long as the 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.

22. Is there a list of approved detergents and similar substances for maintaining general conditions of hygiene in establishments and in respect of equipment?

No. Chemicals suitable for use in the food industry are governed by other legislation.

Fish Farms

23. Are fish farms covered by the Regulations?

Yes, farmed fish are classified as primary production, which is covered by Regulation 852/2004. Although fish farms are covered by other animal health legislation Annex 1 of that Regulation lays down hygiene provisions, which stipulate that primary products must be protected against contamination with respect to further processing. Various hygiene requirements to achieve this are laid down.

Identification marks

24. Where should the identification mark appear in the case of fresh fish sold by an approved auction hall or wholesale market?

Annex II(C) of Regulation 853/2004 allows for the identification mark to be applied in either of these ways; directly on the product, the wrapping or packaging, a label affixed to the product, its wrapping or packaging and be an irremovable tag of resistant material. Under these provisions approval number of the market (and the individual trader if applicable) can appear on the crate or whatever other container is being used as well as the accompanying documentation. The documentation may be in the form of a receipt or other proof of purchase e.g. some wholesale markets use a docket system to ensure that sold fish goes to the right buyer.

Landings of fishery products

25. Do Food Authorities have to carry out histamine checks on other compounds listed in Regulation 854/2004 on all consignments of fish?

According to Regulation 854/2004, random checks for histamine are to be carried out to verify compliance with permitted levels. Food Authorities will decide when these checks are necessary, but these are likely to take place should the freshness of the product be in doubt.

Other checks are required under Annex III, Chapter II of Regulation 854/2004 and corresponding checks must also be carried out by food business operators.

26. Do quaysides where fish are landed need to comply with the Regulations?

There are no structural requirements for quays laid down in the regulations, However Annex II of Regulation 852/2004 does lay down general hygiene requirements for establishments which will be applicable to auction and wholesale markets. Additionally, handling practices for the unloading and landing of fish and some requirements relating to equipment are specified in Annex III, Section VII, Chapter II of Regulation 853/2004.

Seafish Guidelines for Facilities and Equipment during Landing, Storage, Auction, and Dispatch from the Landing Area contain recommendations for quaysides and suggests that the following should be in place:

- Laboratory arrangements for the purpose of carrying out sampling in accordance with the Regulations;
- Documented cleaning schedules with details of any checks, including sampling, carried out by the occupier to establish the efficacy of proposed cleaning and disinfection methods;
- Documented maintenance schedules. These should specify the checks to be carried out and any reporting arrangements;
- Documented pest control arrangements, including copies of any contracts with external pest control companies;
- Details for calibrating and monitoring automatic temperature control equipment, where required by the Regulations;
- Staff hygiene training programme, including records of training undertaken to date;
- Written company policy on staff illness and exclusion from work;
- Medical certificates for all staff;
- Details of traceability system, including checks on incoming raw materials, arrangements for controlling application of the health mark and correct use of commercial documentation. Details should include arrangements for documenting these procedures. It may also be appropriate to request examples of identification marked labels;
- Emergency withdrawal procedure;

- Up to date list of suppliers;
- Up to date list of customers (National, EU, 3rd Country).

Annexe 5 – Appendix B: Fishing vessel check list

Vessel name:_____ Inspecting officer: _____
Registration number: Person Inspection date: _____
seen: _____

A. Vessel and Fish Handling Equipment		yes	no	n/a*
1.	Is the vessel designed to avoid contamination of the catch with bilge water, fuel, oil, grease or other objectionable substances?			
2.	Are surfaces and equipment that fish come into contact with corrosion resistant, smooth and easy to clean? Are surface coatings durable?			
3.	Are the engine room and any crew quarters separated from fish handling and fish storage areas?			
4.	If you pump seawater for use on your catch, is the water intake positioned to avoid contamination of the water from exhaust etc.?			
5.	If ice is used, is it made from potable water or clean seawater?			

B. Fish Handling		yes	no	n/a
1.	Once the catch is brought on board, is it protected from contamination?			
2.	Is the catch protected from the sun and any source of heat?			
3.	When handling the catch, whether manually or mechanically, is your system designed to minimise bruising?			
4.	Is the catch gutted and washed quickly and efficiently?			
5.	Is the catch chilled quickly?			
6.	Is fish stored at a temperature approaching that of melting ice?			
7.	Can melt water drain away from the stored fish?			

C. General Hygiene Requirements		yes	no	n/a
1.	Are the crew aware of the health risks associated with fish handling?			
2.	Is the vessel and equipment kept clean and, where necessary, disinfected?			
3.	Is the fish storage area and fish storage containers kept clean, in a good state of repair and free of contaminants?			
4.	Is the vessel kept free of pests? *valid ships sanitation certificate seen/issued?Any issues noted from certificate?			
5.	Following the last vessel check, if there was a request for remedial action, has the appropriate action been taken?			
6.	Applicable only to some vessels: Do you keep records relating to the control of hazards?			

* n/a: not applicable. Further explanation required in the comments box below.
* Ships Sanitation Certificate- where issued/valid port/ in date?

Comments

Annexe 5 – Appendix D: Factory vessel check list

Vessel name: _____ Inspecting officer: _____
Registration number: _____ Inspection date: _____
Person seen: _____

A. Vessel and Fish Handling Equipment	yes	no	n/a*
1. Is the vessel designed and constructed to prevent contamination from bilge-water, smoke, fuel, sewage, oil, grease or other objectionable substances, and to permit pest control?			
2. Are storage containers and holds kept clean and in good repair?			
3. Are all fish handling contact surfaces made of a material that is corrosion-resistant, smooth, easy to clean, durable and non-toxic?			
4. Is all equipment and material used for handling fishery products corrosion-resistant and easy to clean and disinfect?			
5. Are water intakes situated in a position to avoid contamination of the water supply used for fish handling/processing?			
6. Do you have an area reserved for taking the catch on board?			
7. Can each successive catch be separated?			
8. Is the receiving area easy to clean?			
9. Is it protected from the sun and any potential source of contamination?			
10. Do you have a system to transport the catch from the receiving area to any processing areas in a hygienic way?			
11. Are work areas of sufficient size and design to allow work to be carried out hygienically and for cleaning to be easy and efficient?			
12. Are areas for finished product large enough and easy to clean?			
13. Is waste stored separately to fishery products for human consumption?			
13 (a) If a waste processing unit operates on board is there a separate hold for its storage?			
14. Do you have special equipment for disposing of processing waste directly into the sea or into a watertight tank for that purpose?			
15. Is the vessel designed to prevent pests from causing contamination?			

B. **Fish Handling**	yes	no	n/a
1. Are fish protected from sun or other sources of heat soon after being taken on board?			
2. Is clean water used for washing the fish?			
3. Are fishery products handled and stored to minimise bruising or damage to the flesh?			
4. Are fishery products kept chilled?			
5. Is any ice that is used to chill fishery products made from clean water?			
6. Are fish headed or gutted on board?			
7. Is this carried out as soon as possible after capture?			
8. Are the fishery products washed with clean water?			
9. Are any viscera not intended for human consumption kept apart from products for human consumption?			
10. Are any livers and roes for human consumption kept chilled or frozen?			

C. **General Hygiene Requirements**	yes	no	n/a
1. Does the vessel have an adequate number of flush lavatories for the number of crew?			
2. Do all the lavatories open directly into non-food/non-fish rooms?			
3. Is there adequate ventilation to the lavatories?			
4. Are there an adequate number of washbasins for hand washing?			
5. Are basins located to facilitate hand washing during fish handling?			
6. Are washbasins provided with hot and cold water and materials for cleaning hands and hygienic drying?			
7. Are any fish washing facilities separate from the hand washing facilities (or in use at different times, with effective cleaning between any changes of use)?			
8. Is there adequate ventilation to the fish preparation areas and sanitary conveniences?			
9. Do fish preparation rooms have adequate lighting?			
10. Are drainage facilities in the fish preparation areas adequate?			
11. If open drains are used (such as gullies) do they flow from the cleaner areas to the more contaminated area?			
12. Are adequate changing facilities provided for staff where needed?			
13. Are cleaning materials stored away from areas where fish is handled or stored?			

D. Fish Preparation Areas	yes	no	n/a
1. Are floor surfaces made of a non-toxic material that is easy to clean?			
2. Do floors in wet rooms allow adequate drainage of water?			
3. Are walls made of a non-toxic material that is easy to clean?			
4. Are the walls, ceilings, windows etc. constructed so that dirt cannot accumulate and fall onto the product?			
5. Are the fittings on walls and ceiling securely attached so they cannot fall into the product?			
6. Are all doors made of a smooth material that is easy to clean and disinfect?			
7. Are all food contact surfaces made of smooth, non-corrosive material that is non-toxic?			
8. Are all food contact surfaces maintained so that surface material cannot come loose and contaminate the food?			
9. Are adequate facilities provided for washing equipment?			
10. Is hot and cold water supplied to equipment washing facilities?			
11. Are there adequate facilities for any fish washing?			
12. Is clean water supplied to these facilities?			
13. Have all staff received training in food hygiene to enable them to carry out their duties?			
14. Do they have suitable work wear to prevent contamination of the food?			
15. Do you have a reporting and exclusion policy for staff sickness?			
16. Are wrapping and packaging materials stored to protect them from contamination?			
17. Are wrapping and packing carried out in a way that prevents contamination of the product?			
18. Are there members of staff responsible for HACCP and have they been adequately trained in HACCP application?			
19. Is any packaging stored separately from food processing and preparation areas?			
20. Are hand-washing facilities in the work rooms designed to prevent the spread of contamination?			
21. Pest control- is there a valid Ships sanitation certificate? Where and when issued?			

*n/a: not applicable. Further explanation required in the comments box below.

Comment

ANNEX 6: RAW MILK AND DAIRY PRODUCTS

A6.1: Introduction

This Annex provides specific guidance to Food Authorities with regard to Raw Milk and Dairy Products.

A.6.2: Enforcement

Food Authorities approve dairy establishments, and otherwise enforce the Regulations except for the carrying out official tests for tuberculosis and brucellosis where appropriate, which is the responsibility of the Scottish Government.

A6.3: Prohibition of sale of Raw Milk and Cream

Schedule 6 of The Food Hygiene (Scotland) Regulations 2006 (as amended) prohibits the sale of raw milk and cream in Scotland which is intended for direct human consumption.

A6.4: Hygiene Rules for Production Holdings

The operation of a production holding comes within the definition of primary production. As such, it is regulated by the provisions of Annex I of EC Regulation 852/2004. This class of food business does not therefore require approval. However, specific requirements of section IX of Annex III of EC Regulation 853/2004 apply. Food Authorities should monitor production holdings on a risk-basis in accordance with the minimum frequencies set out in Chapter 4.3 of the Code in order to ensure that the requirements of these Regulations are met.

A.6.4.1 : General requirements to protect milk from contamination.

Annex I of EC Regulation 852/2004 requires primary producers to protect primary products from contamination as far as possible having regard to any subsequent processes that the product will undergo. Authorised officers should be mindful that Schedule 6 of the Food Hygiene (Scotland) Regulations 2005 prohibits raw milk or cream from being placed on the market for direct consumption when considering the extent of measures required where milk is supplied for heat treatment. It is however, fundamentally important to establish whether the milk from a production holding is liable to be used for production of cheese or milk products without prior treatment that would control microbiological hazards.

The control measures to be considered include, where applicable:

- The cleaning and, where necessary, disinfection, of any facilities used in connection with primary production and associated operations, including facilities used to store and handle feed;
- The cleaning and, where necessary, disinfection of equipment, containers, crates, vehicles and vessels;
- The measures taken to ensure the cleanliness of production animals;
- The requirement to use potable water, or clean water, whenever necessary to prevent contamination;
- Measures in place to prevent, as far as possible, animals and pests from causing contamination;
- Measures in place to store and handle waste and hazardous substances so as to prevent contamination;
- Measures in place to prevent the introduction and spread of contagious diseases transmissible to humans through milk;
- Measures to respond to the results of any relevant analyses carried out on samples taken from animals or other samples that have importance to human health;
- Measures to ensure that feed additives and veterinary medicinal products are used correctly, as required by the relevant legislation.

A.6.4.2 : Record Keeping.

Food business operators are required to keep and retain records relating to measures put in place to control hazards in an appropriate manner and for an appropriate period, commensurate with the nature and size of the food business. Annex I of Regulation 852/2004 requires records to be kept in relation to the following:

- The nature and origin of feed fed to the animals;
- Veterinary medicinal products or other treatments administered to the animals, dates of administration and withdrawal periods;
- The occurrence of diseases that may affect the safety of the milk;
- The results of any analyses carried out on samples taken from animals or other samples taken for diagnostic purposes, that have importance for human health;
- Any relevant reports on checks carried out on animals or milk.

Inspections at production holdings should include checks on the foregoing records.

A.6.4.3 : Premises and Equipment.

Premises for the storage of milk must be protected against vermin, have adequate separation from premises where animals are housed and, where necessary to meet the requirements laid down in paragraph A.8.4.5 below, have suitable refrigeration equipment.

Milking equipment, and premises where milk is stored, handled or cooled must be located and constructed so as to limit the risk of contamination of milk.

Surfaces of equipment that are intended to come into contact with milk must be of suitable construction, maintained in a sound condition, easy to clean and, where necessary, easy to disinfect.

Suitable facilities must be available near the place of milking to enable persons performing milking and handling raw milk to wash their hands and arms.

Clean or potable water should be used for cleaning purposes associated with milking equipment, milking operations, hand/arm washing facilities for food handlers and in any other circumstance where there might otherwise be a risk of contamination to the milk.

A.6.4.4 : Hygiene during milking, collection and transport

Milking animals should be inspected to ensure that there are no obvious signs of ill health such as discharge from the genital tract, diarrhoea and fever, or a recognisable inflammation of the udder.

Teats, udder and adjacent parts are clean prior to milking. Heavily soiled animals, which are incapable of being adequately cleaned prior to milking, should be kept separate and milked last. The milk from those animals should not be sold for human consumption, as there is potentially a high risk of contamination.

Authorised officers should ensure that the food business operator is aware that milk from individual animals showing positive reaction to tests for tuberculosis or brucellosis is not to be used and that such animals require to be effectively isolated. Further checks should be made on isolation arrangements where appropriate, in liaison with Animal Health if animals in the herd have tested positive.

Authorised Officers should check that all veterinary products are being administered and controlled in accordance with veterinary advice and, where appropriate, under veterinary supervision. Records should be examined to determine that appropriate withdrawal periods are being observed and that animals undergoing treatment can be readily identified.

Milk from each animal requires to checked for organoleptic or physico-chemical abnormalities by the milker or a method achieving similar results and that milk presenting such abnormalities is not used for human consumption. Automated milking systems should be capable of meeting this requirement.

Surfaces of equipment that are intended to come into contact with milk must be cleaned and, where necessary, disinfected after use. Containers and tanks used for the transport of raw milk may be cleaned and disinfected less frequently than after every journey if the period of time between unloading and the following loading is very short, but in all cases the frequency must be at least once a day.

A.6.4.5 : Temperature Control

Immediately after milking, milk must be held in a clean place designed and equipped to avoid contamination. Unless processed within two hours milk must be cooled immediately to not more than 8°C in the case of daily collection, or not more than 6°C if collection is not daily. Food Authorities may authorise relaxation of these requirements where a higher temperature is necessary for technological reasons related to the manufacture of certain dairy products. In such cases, the authorisation should be in writing, stating the reasons for granting and a copy should be kept on file.

A.6.4.6 : Staff hygiene

Food handlers handling milk require to be in good health and undergo training on relevant health risks. Persons performing milking and/or handling raw milk must wear suitable clean clothes. Persons performing milking must maintain a high degree of personal cleanliness.

A.6.4.7 : End product standards

The totality of hygiene practices should be capable of ensuring that the rolling geometric averages for plate and somatic cell counts are within the limits set out in Annex III of EC Regulation 853/2004. Annex IV of Regulation 854/2004 provides Food Authorities with the power to suspend the supply of milk or make requirements as to its treatment and use sufficient to protect public health where the producer fails to meet that standard within 3 months of first notifying such a failure. Heat treatment in accordance with Annex III, Section IX, Chapter II (II) of Regulation 853/2004 should be sufficient to protect public health. In normal circumstances, it should therefore only be necessary to consider requiring additional measures if the raw milk is intended for supply for use in milk products without undergoing sufficient treatment during production to ensure protection of public health.

A.6.4.8 : Animal 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 I 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 AHVLA or private veterinary. 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 producer direct, and advise them to take appropriate advice e.g. from their private veterinary surgeon.

A.6.5 : 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.6.6 : Criteria and Standards for Raw Milk

In the case of the standards laid down in Regulation 853/2004, Annex III, Section IX, Chapter I, Part III, Part 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. Arrangements relating to milk for heat-treatment are set out in Annex III, Section IX, Chapter II of Regulation 853/2004, as amended by Article 8 / Annex VII(2)(d) of Regulation 2074/2005.[27]

[27] Commission Regulation (EC) No 2074/2005 of 5 December 2005 laying down implementing measures for certain products under Regulation (EC) No 853/2004 of the European Parliament and of the Council and for the organisation of official controls under Regulation (EC) No 854/2004 of the European Parliament and of the Council and Regulation (EC) No 882/2004 of the European Parliament and of the Council, derogating from Regulation (EC) No 852/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004

A.6.7 : Temperature Requirements for Milk Used for the Manufacture of Dairy Products

Regulation 853/2004, Annex III, Section IX, Chapter II Part I Paragraph 1 stipulates that the acceptability of raw milk applies from the arrival of the milk at a processing establishment. Paragraph 2 allows temperatures and times specified for treatment of raw milk to be exceeded for "technological reasons". These reasons will include cases where higher temperatures may be essential to the manufacture of certain products e.g. cheeses and also instances over a weekend for example when establishments are unable to process milk within the specified period. Authorisation by the Food Authority is required whenever it is anticipated that these times will be exceeded.

A.6.8 : Heat Treatment of Raw Milk or Dairy Products

Requirements for pasteurisation and ultra heat treatment are set out in Annex III, Section IX, Chapter II of Regulation 853/2004, as amended by Article 8 / Annex VII(2)(d) of Regulation 2074/2005.

A.6.9 : Phosphatase Testing

Commission Regulation (EC) No 1664/2006, which amended Regulation (EC) 2074/2005, implemented new requirements for the alkaline phosphatase (ALP) testing method for heat-treated milk:

- All FBOs should have implemented the new reference method for ALP activity ISO 11816-1.
- An ALP test is considered to give a negative result if the measured activity in cow's milk is not higher than 350 mU/L

An alternative analytical method can be used as long as it is validated against the reference method.

A.6.10 Labelling of cheeses made from raw milk

Cheeses made from raw milk which are sold pre-packaged are required to be labelled on the packaging as being 'made with raw milk' at point of sale. The legislation provides that 'labelling' includes any packaging, document, notice, label, ring or collar accompanying or referring to such products.

Blocks of cheese on display at a delicatessen counter which it is intended will be cut into smaller portions for sale to the consumer are required to be labelled as 'made with raw milk' either by a label on the cheese or by a notice referring to it. However, such cheese once it is cut and wrapped and given to the consumer for purchase does not require to be labelled with the prescribed wording.

ANNEX 6, APPENDIX 1: Guidance to Food Authorities in Scotland on Officially Tuberculosis Free Status and Dairy Hygiene Legislation

Scope

1. This guidance has been produced by the Food Standards Agency in consultation with Food Authorities, Scottish Government, 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 Scotland who have dairy establishments in their area producing unpasteurised dairy products. The guidance will be of assistance to those involved with investigations following notification from the Scottish Government Rural and Environment Directorate (SGRED) of the loss[2] of "Officially Tuberculosis Free" (OTF) status of dairy herds.

3. The Scottish ban on sales of raw cows" milk was introduced in 1983 following a number of milk-related illnesses and 12 associated deaths. In 2004, Scottish Ministers reconfirmed their wish to maintain and extend the ban so that all raw drinking milk and cream sales in Scotland would be prohibited. This was introduced by regulation 32 and Schedule 6 of The Food Hygiene (Scotland) Regulations 2005 which came into effect on 1 January 2006.

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 raw cows" or buffaloes" milk must come from animals belonging to a herd which is OTF (Annex III, Section IX, Chapter I(1)(2)(b)(i)). Raw milk from other species susceptible to TB must come from herds regularly checked for the disease under a control plan that SGRED has approved (Annex III, Section IX, Chapter 1,1,2(b)(ii)). Milk which does not satisfy these conditions may only be used for the manufacture of dairy products after it has been heat-treated (Annex III,

[2] 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.

Section IX, Chapter I, 3). Animal Health will notify Food Authorities of conditions in a herd that result in the loss of OTF status.

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.

8. 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 the milk is being offered as part of an on-farm B&B business, or in a farm shop, or at a market stall; and

   e) establish whether the milk is being used to make unpasteurised milk-based products either on the particular farm or elsewhere.

9. Where the affected farm has heat treatment facilities installed, the Food 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 Public Health Medicine (CPHM) and the DVM, for products made prior to the herd losing its OTF status. Advice should also be obtained where appropriate from Health Protection Scotland (HPS). 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. 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).

12. 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.

13. Types of cattle reacting to the test. For example, heifers or bullocks being non-milk-producing animals would be of less significance.

14. 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*.

15. 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.

16. The baseline testing frequency for the civil parish. This provides an indication of whether the herd is in a high TB prevalence area. The Animal Health case veterinary officer will provide expert opinion and judgement of the TB incidence in the locality.

17. General herd health and herd bio-security. Consideration should also be given to:

    f) milk somatic cell counts - higher cell counts may indicate a higher likelihood of TB organisms being present in the milk; and
    g) 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).

18. 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.

19. 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.

20. 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.

21. 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.

22. The Regulations do not prohibit the marketing of products made before the removal of OTF status. If a voluntary solution cannot be concluded with the producer any action taken will need to be under the Food Safety Act 1990 (as amended) and the General Food Regulations 2004. Enforcement Officers 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 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.

Action to take before OTF problems arise

23. Food Authorities should liase with DVMs to ensure that herds supplying establishments or processors manufacturing unpasteurised dairy products are tuberculin tested annually. For example, Food Authorities should notify DVMs when they become aware of the production of unpasteurised dairy products in their area. Food Authorities should advise manufacturers producing unpasteurised dairy products from raw cows" or buffaloes" milk 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.

24. Food Authorities may find it helpful to liase with Local Authority Animal Health and Welfare Inspectors as their responsibilities include checking farm records under animal health legislation.

Contacts

25. 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.

26. 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.

27. If more information is required on SGRED procedures concerning TB controls in Scotland, you should contact the duty Veterinary Officer at the local Animal Health Divisional Office of Animal Health.

28. Additional details may be found on the following web sites:

    http://www.scotland.gov.uk/Topics/Agriculture/animal-welfare

    http://www.defra.gov.uk/food-farm/animals/diseases/tb/

    http://www.hps.scot.nhs.uk/resp/tuberculosis.aspx

    https://knowledgehub.local.gov.uk/

ANNEX 1

Legislative Background and Human Health

Raw Milk Ban and unpasteurised dairy products

1. As outlined in paragraph 4, the Scottish ban on sales of raw cows" milk was extended on 1 January 2006 to prohibit sales of raw drinking milk and cream from all farmed animals. This was introduced by Regulation 32 and Schedule 6 of The Food Hygiene (Scotland) Regulations 2005.

2. As outlined in paragraph 7, EC Regulation 853/2004 requires that raw cows" or buffaloes" milk must come from animals belonging to a herd which is OTF (Annex III, Section IX, Chapter I,1,2(b)(i)). Raw milk from other species susceptible to TB must come from herds regularly checked for the disease under a control plan that SGRED has approved (Annex III, Section IX, Chapter I,1,2(b)(ii)). Therefore milk which does not satisfy these conditions may only be used for the manufacture of dairy products after it has been heat-treated (Annex III, Section IX, chapter 1, 3).

3. While the law requires that unpasteurised dairy products made from raw cows" or buffaloes" milk 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

4. In the event of a CPHM being notified that a person(s) has confirmed bovine TB, and the infection is thought to be recently acquired, the CPHM 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 Animal Health (AH)

M. bovis infection in cattle

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, milk pasteurisation, and the introduction of the raw milk ban in Scotland, 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. 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.

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

4. Most TB testing in Great Britain is carried out by Local Veterinary Inspectors (LVIs). These are veterinarians in private practice appointed by Scottish Government to carry out specific statutory duties. Veterinary Officers of AH undertake some of the follow-up tests in herds under TB restrictions and the re-testing of inconclusive reactors. AH 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 DVM that they wish to pay for private testing outside of the routine testing, the farmer must notify the DVM of the results accordingly.

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 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.

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.

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 Scottish Government 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 and, where this information is available to the DVM, suppliers of milk for the manufacture of unpasteurised dairy products.

Finding a TB reactor

8. Disclosure of tuberculin test reactors at a routine herd test is the most common reason for the service of TB restrictions by the ANIMAL HEALTH, but other situations may also lead to the suspension of the OTF status of a herd. These include detection by the FSA of suspect lesions of TB at routine meat inspection in the abattoir; disclosure of inconclusive reactors within three years of the resolution of a confirmed TB incident; or 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.

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

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.

11. As indicated 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. AH 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.

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[4]. The DVM will notify the CPHM 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 CPHM will be notified by the DVM.

[4] EC Regulations 852/2004 and 853/2004

Inconclusive Reactors

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.

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 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.

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.

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

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 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 (Scotland) Regulations 2006 (as amended). 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(1)(3) 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 7: EGG PRODUCTS AND LIQUID EGG

A.7.1 : 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.7.2 : 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.

A.7.3 : 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^{o}C and the storage period before processing must not exceed 48 hours. Any establishment approved for category ii) only, must comply with the same requirements for approval as egg product manufacturers in category i). When notifying the FSA of approvals, the Authority should specify whether the approval is for i) or ii) and if the premise is also a packing centre.

A.7.4 : 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.7.5 : 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.7.6 : 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.7.7 : 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.7.8 : 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.7.9 : 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.7.10 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.

Regulation 853/2004 does 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.7.11 Egg Marketing

(See also Annex 10)

Egg packing centres, whether or not approved to produce liquid egg under the Regulations, are the responsibility of SGRED in respect of egg quality and marketing regulations and are inspected by Egg Marketing Officers of the Egg and Poultry Unit (EPU).

It is recommended that authorised officers should liaise with EPU prior to inspecting egg product facilities at egg-packing centres.

ANNEX 8: EGG PACKING CENTRES

A.8.1 : Introduction

This annex provides specific guidance to Food Authorities for the enforcement of Annex III, Section X, Chapter I 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.8.2 : Scope of the Regulations

The Regulations apply to food establishments engaged in the following activities:

- Egg Packing Centres – the grading, packing, handling, and storage of eggs;
- Wholesalers and Retailers – the handling and storage of eggs.

The production and collection of eggs at the producer"s establishment are activities that take place at the primary production level. 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. However, if an egg packing centre sells eggs on a wholesale basis, then approval is required for the area of the establishments involved in packing eggs.

A.8.3 : Specific Hygiene Requirements for Shell Eggs

The specific requirements set out in the Regulations are:

- At the producer"s establishment, and until sale to the consumer, eggs must be kept clean, dry, free of extraneous odour, effectively protected from shocks and out of direct sunshine;

- Eggs must be stored and transported at a temperature, preferably constant, that is best suited to assure optimal conservation of their hygiene properties;

- Eggs must be delivered to the consumer within a maximum time limit of 21 days of laying.

These specific requirements are self-explanatory" save for the requirement to deliver eggs to the final consumer within 21 days from laying. It is not possible to determine the age of an egg directly and any legal requirement to provide the date of lay or the age of an egg is covered in egg marketing legislation. Eggs 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 SGRIPD"s Egg & Poultry Unit for further guidance and help in taking the appropriate action). From a hygiene perspective, eggs need to be used within 28 days of lay. Retailers need to sell fresh eggs to the public within 21 days so that consumers have 7 days in which to use the eggs.

A.8.4 : Egg & Poultry Unit

Class A hens" eggs for human consumption are also subject to egg marketing standards regulations. These regulations are enforced by SGRIPD at egg producers, packing centres and wholesalers. SGRIPD employs a small dedicated team of Egg Marketing Officers within the Egg & Poultry Unit (EPU) to enforce the egg marketing regulations at these premises.

Food Authorities enforce the egg marketing regulations at retail and catering establishments.

From 1 January 2006 all egg packing centres are required to register with the EPU under egg marketing regulations and obtain approval when appropriate from their Food Authority under food hygiene regulations before trading.

Packing centres seeking registration/approval for the first time may approach either the EPU or their Food Authority in the first instance. It is recommended that enforcement officers should liaise appropriately with the EPU prior to inspecting egg packing centres and until the application has been processed.

The EPU and Food Authority may wish to consider a joint visit to assist in the registration/approval process.

A separate approval number is not required for egg packing centres as they will receive a packing centre code upon registering with the EPU under egg marketing regulations. However, packing centres will not be permitted to operate until both the EPU and Food Authority are satisfied that the relevant statutory requirements have been met by the applicant.

Contact details for the EPU are shown below:

Charles Russell (Senior Marketing Officer)

Scottish Government Rural Inspections and Payments Directorate
Egg & Poultry Unit
Room 303
Pentland House
47 Robb"s Loan
Edinburgh
EH14 1TY

Tel: 0131 244 6271
Email: charles.russell@scotland.gsi.gov.uk

A.8.5 : Non-UK eggs

Wholesalers or packing centres 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 I of Regulation 853/2004.

A.8.6 : 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 and Poultry Unit (EPU) of SGRIPD inspections. Enforcement officers may wish to take into account these assurance schemes in developing a risk-based approach to inspections.

~~ANNEX 9: APPROVAL OF ESTABLISHMENTS UNDER REGULATION 853/2004 - TEMPLATE FORMS~~

Please note – the Annex 9 forms have been updated and have therefore been removed from this publication and can now be accessed from the FSS website here[1].

~~Template forms which may be used by authorised officers in connection with the approval of establishments are provided from A.11.1 to A.11.6, as detailed the following table:~~

~~Practice Guidance Reference~~	~~Template Form~~
~~A.9.1~~	~~Application for Approval~~
~~A.9.2~~	~~Notification of Grant of Full Approval / Conditional Approval~~
~~A.9.3~~	~~Notice of Decision Not to Grant Approval~~
~~A.9.4~~	~~Notice of Decision to Withdraw Approval / Conditional Approval~~
~~A.9.5~~	~~Notice of Decision to Suspend Approval / Conditional Approval~~
~~A.9.6~~	~~Notification of Refusal to Grant Full Approval to an Establishment which is Conditionally Approved~~

~~As stated in Paragraph 5.1.5 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.~~

[1] https://www.foodstandards.gov.scot/publications-and-research/publications/food-law-code-of-practice-scotland-2019

A.9.1 : Model Application for Approval

Application for Approval of a Food Business Establishment Subject to Approval under Regulation (EC) No. 853/2004

To be completed by the food business operator

Print a copy of this form and fill it in with a black pen in BLOCK CAPITALS, or complete it on screen. Complete Parts 1 to 8 inclusive, and the specific sections of Part 9 that relate to the products of animal origin in respect of which you are applying for the approval of your establishment, then sign and date Part 10.

PART 1 - Establishment for which approval is sought

Trading name	
Full postal Address Postcode:	

PART 2 – Type(s) of product(s) of animal origin for which approval is sought

Indicate the product(s) of animal origin in respect of which you are applying for approval to use the establishment (tick all that apply)?

☐	Minced Meat
☐	Meat Preparations
☐	Mechanically Separated Meat
☐	Meat Products
☐	Live Bivalve Molluscs (Shellfish)
☐	Fishery Products
☐	Dairy Products
☐	Eggs (not Primary Production) / Egg Products
☐	Frogs" Legs / Snails
☐	Rendered Animal Fats and Greaves
☐	Treated Stomachs, Bladders and Intestines
☐	Gelatine
☐	Collagen

PART 3 – Food business operator and management of the establishment

Name and full Address of Food Business Operator	Postcode:

Tel (Incl. Dialling code)	
Fax (incl. Dialling code)	
E-mail	

Full names of managers of the establishment	1.	2.	3.
Job titles	1.	2.	3.

Full Names of others In control of the business	1.	2.	3.
Job titles	1.	2.	3.

PART 4 – Use of the establishment

Which of the following activities will be conducted in / from the establishment (tick all that apply)?

- ☐ Stand-alone cold store
- ☐ Wholesale market
- ☐ Manufacture
- ☐ Other processing (please specify)
- ☐ Packing
- ☐ Storage
- ☐ Distribution
- ☐ Cash and carry / wholesale
- ☐ Catering (preparation of food for consumption in the establishment)
- ☐ Retail (direct sale to consumers or other customers)
- ☐ Market stall or mobile vendor
- ☐ Other (please specify)

PART 5 – Transport of products from the establishment

How will products be transported from the establishment (tick all that apply)?

- ☐ Your own vehicle(s)
- ☐ Contract / Private Haulier
- ☐ Purchaser"s own vehicle(s)
- ☐ 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)?

- ☐ Other businesses that manufacture or process food
- ☐ Wholesale packers
- ☐ Cold stores that are not part of the establishment to which this application relates
- ☐ Warehouses that are not part of the establishment to which this application relates
- ☐ Restaurants, hotels, canteens or similar catering businesses
- ☐ 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.:	☐	☐	
Cutting fresh (including chilled and frozen) meat, poultry meat or game:	☐	☐	
Storage of fresh (including chilled and frozen) meat, poultry or game:	☐	☐	

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) food safety management system based on HACCP principles
☐	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 - Products to be handled in the establishment / activities

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 and specific products handled

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 Live Bivalve Molluscs (Shellfish) / Fishery Products 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 will be handled in the establishment per week on average?	

How many litres / tonnes of Dairy Products 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 will be packed in the establishment per week on average?	

How many litres of Egg Products will 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~~

	~~Rendered Animal Fats~~
	~~Greaves~~

~~Full details of activities and specific products handled~~

How many tonnes of rendered animal fats will be handled in the establishment per week on average?	

How many tonnes of greaves will be handled in the establishment per week on average?	

~~PART 9(9) – Treated Stomachs, Bladders and Intestines~~

	~~Treated Stomachs~~
	~~Treated Bladders~~
	~~Treated Intestines~~

~~Full details of activities and specific products handled~~

~~How many tonnes of treated stomachs in total will be handled in the establishment per week on average?~~	
~~How many tonnes of treated bladders in total will be handled in the establishment per week on average?~~	

How many tonnes of treated intestines 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) – 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?	

PART 10 – APPLICATION

I hereby apply, as food business operator of the establishment detailed in Part 1, for approval to use that establishment for the purposes of handling products of animal origin for which Regulation (EC) No. 853/2004 lays down requirements, as set out in the relevant Parts of this document.

Signature of Food Business Operator		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 Regulation relates, or the circumstances in which approval under the Regulation 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, in writing to the Food Authority at the address shown.

A.9.2 : Model Notification of Grant of Full Approval / Conditional Approval

Notification of Grant of Full 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 food business operator

PART 1 – Name and address of food business operator

TO:	**IMPORTANT** 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]

PART 2 – Introduction

Further to your application dated for approval of your establishment in accordance with Regulation (EC) No. 853/2004, approval / conditional approval* is GRANTED in respect 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 format stipulated by, and when required by, Regulation (EC) No. 853/2004.

In accordance with Regulation 13 of the Official Feed and Food Controls (Scotland) Regulations 2009, any person who is aggrieved by a decision of a Food Authority not to grant a full approval may appeal against that decision to a Sheriff 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 Sheriff Court at which you should lodge your appeal is

PART 3 – Trading name and address

Trading name of establishment	
Full postal address	Postcode:

☐ The establishment has been APPROVED in accordance with Article 31(2)(c) of Regulation (EC) No. 882/2004.

☐ The establishment has been CONDITIONALLY APPROVED in accordance with Article 31(2)(d) of Regulation (EC) No. 882/2004.

~~PART 3(1) – Conditional Approval (To be completed when conditional approval has been granted)~~

~~The requirements of the Regulations with which you have failed to comply are:~~

~~Regulation / Article No.~~	~~Requirement~~

~~The reasons you have failed to comply with the requirements of the Regulations are:~~

~~Regulation / Article No.~~	~~Details of non-compliance~~

~~The measures you need to take in order to comply with the requirements of the Regulations are:~~

~~Regulation / Article No.~~	~~Measures needed to secure compliance~~

~~In accordance with Article 31(2)(d) of Regulation (EC) No. 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~~

~~Name and full address of Food Business Operator~~	~~Postcode:~~

PART 5 – Scope of approval / conditional approval*

This approval/conditional 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:

☐	Minced Meat
☐	Meat Preparations
☐	Mechanically Separated Meat
☐	Meat Products
☐	Live Bivalve Molluscs (Shellfish)
☐	Fishery Products
☐	Dairy Products
☐	Eggs (not Primary Production) / Egg Products
☐	Frogs' Legs / Snails
☐	Rendered Animal Fats and Greaves
☐	Treated Stomachs, Bladders and Intestines
☐	Gelatine
☐	Collagen
☐	Stand-alone cold store

Full Details of Activities and Specific Products Handled:

FSA Category	**FSA Associated Activity**	**FSA Species**	**FSA Remarks**

(see Codes key table at end of document)

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:

Telephone:

Fax:

E-mail:

IMPORTANT

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 to delete as appropriate

Codes Key

Category/Associated Activity		**Species**		**Remarks**	
AH =	Auction Hall	A =	Poultry	bl =	Blood Products
CC =	Collection Centre	B =	Bovine (eg cattle)	mp =	Meat Products
CP =	Cutting Plant	C =	**Caprine (eg goat)**	pap =	Meat extracts and any powdered products derived from meat
CS =	Cold Store	L =	Lagomorphs (eg hares)	st =	Treated stomachs, bladders and intestine
DC =	Dispatch Centre	O =	Ovine (eg sheep)	fl =	frogs' legs
EPC =	Packing Centre	P =	Porcine (eg pigs)	Sn =	Snails
FFPP =	Fresh Fishery Products Plant	S =	Solipeds (eg horses)	c =	Collagen
FV =	Factory Vessel	fg =	Farmed Land Mammals other than Domestic Ungulates	g =	Gelatine
GHE =	Game Handling Establishment	R =	Ratite (eg ostriches)	Raf =	Rendered Animal Fats and Greaves
LEP =	Liquid Egg Plant	wA =	Wild Birds		
MM =	Mince Meat Establishment	wL =	Wild Lagomorphs		
MP =	Meat Preparation Establishment	wU =	Wild Ungulates		
MSM =	Mechanically Separated Meat Establishment	wG =	Wild Land mammals other than Wild Ungulates and Wild Lagomorphs		
PC =	Purification Centre				
PP =	Processing Plant				
RW =	Re-Wrapping Establishment				
SH =	Slaughterhouse				
WM =	Wholesale Market				
ZV =	Freezer Vessel				

A.9.3 : Model Notice of Decision Not To Grant Approval

Notice of Decision to REFUSE 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 food business operator

PART 1 – Name and address of food business operator

TO:	**IMPORTANT** **You must not use the establishment detailed in Part3 for ANY purpose which would render the establishment subject to approval under Regulation (EC) No. 853/2004 unless this Food Authority has granted approval or conditional approval.**	[Food Authority Logo]

PART 2 – Notification of decision

Further to your application dated for approval of your establishment in accordance with Regulation (EC) No. 853/2004, approval is REFUSED in respect 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 decision to refuse your application was made for the reason(s) set out in Part 4 of this document.

The establishment 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 GRANTS APPROVAL OR CONDITIONAL APPROVAL.

In accordance with Regulation 13 of the Official Feed and Food Controls (Scotland) Regulations 2009 (as amended), 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 Sheriff 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 Sheriff Court at which you should lodge your appeal is .

PART 3 – Trading name and address of the establishment

Trading name of establishment	
Full postal address	Postcode:

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 the establishment detailed in Part 3 for ANY purpose which would render the establishment subject to approval under Regulation (EC) No. 853/2004 unless this Food Authority has granted approval or conditional approval.

A.9.4 : Model Notice of Decision to WITHDRAW the Approval / Conditional Approval

Notice of Decision to WITHDRAW 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 food business operator

PART 1 – Name and address of food business operator

TO:	**IMPORTANT** With immediate effect, you must not use the establishment detailed in Part 3 for ANY purpose which would render the establishment subject to approval under Regulation (EC) No. 853/2004 or use the associated approval code on any product unless this Food Authority has granted approval or conditional approval.	[Food Authority Logo]

PART 2 – Notification of decision to withdraw 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 3 of this document, which is subject to approval under Regulation (EC) No. 853/2004, to handle the products of animal origin indicated in Part 4 of this document, has been WITHDRAWN in accordance with Article 31(2)(e) of Regulation (EC) No. 882/2004. The decision to withdraw the approval / conditional approval* was made for the reason(s) set out in Part 5 of this document.

With immediate effect you must cease the use of the establishment detailed in Part 3 for ANY purpose which would render the establishment subject to approval under Regulation (EC) No. 853/2004, or use the associated approval code on any product, UNLESS THIS FOOD AUTHORITY GRANTS APPROVAL OR CONDITIONAL APPROVAL.

In accordance with Regulation 13 of the Official Feed and Food Controls (Scotland) Regulations 2009 (as amended), 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 Sheriff 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 Sheriff Court at which you should lodge your appeal is .

PART 3 – Trading name and address of the establishment

Trading name of establishment	
Full postal address	Postcode:

PART 4 – Product(s) of animal origin for which approval / conditional approval* had been granted

☐	Minced Meat
☐	Meat Preparations
☐	Mechanically Separated Meat
☐	Meat Products
☐	Live Bivalve Molluscs (Shellfish)
☐	Fishery Products
☐	Dairy Products
☐	Eggs (not Primary Production) / Egg Products
☐	Frogs' Legs / Snails
☐	Rendered Animal Fats and Greaves
☐	Treated Stomachs, Bladders and Intestines
☐	Gelatine
☐	Collagen
☐	Stand-alone cold store

PART 5 – Reasons for withdrawal

The approval / conditional approval* has been withdrawn because 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

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 to delete as appropriate.

A.9.5 : Model Notice of Decision to Suspend Approval / Conditional Approval

Notice of Decision to SUSPEND 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 food business operator

PART 1 – Name and address of food business operator

TO:	**IMPORTANT** **With immediate effect, you must not use the establishment detailed in Part 3 for any purpose which would render the establishment subject to approval under Regulation (EC) No. 853/2004 or use the associated approval code on any product until such time as the Food Authority lifts this suspension.**	[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 3 of this document, which is subject to approval under Regulation (EC) No. 853/2004, to handle the products of animal origin indicated in Part 4 of this document, has been SUSPENDED in accordance with Article 31(2)(e) of Regulation (EC) No. 882/2004. The decision to suspend the approval / conditional approval* was made for the reason(s) set out in Part 5 of this document.

With immediate effect you must cease the use of the establishment detailed in Part 3 for ANY purpose which would render the establishment subject to approval under Regulation (EC) No. 853/2004, or use the associated approval code on any product, UNTIL SUCH TIME AS THIS FOOD AUTHORITY LIFTS THE SUSPENSION.

In accordance with Regulation 13 of the Official Feed and Food Controls (Scotland) Regulations 2009 (as amended), any person who is aggrieved by a decision of a Food Authority to suspend an approval or conditional approval may appeal against that decision to a Sheriff 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 Sheriff Court at which you should lodge your appeal is .

PART 3 – Trading name and address of the establishment

Trading name of establishment	
Full postal address	Postcode:

PART 4 – Product(s) of animal origin for which approval / conditional approval* had been granted

☐	Minced Meat
☐	Meat Preparations
☐	Mechanically Separated Meat
☐	Meat Products
☐	Live Bivalve Molluscs (Shellfish)
☐	Fishery Products
☐	Dairy Products
☐	Eggs (not Primary Production) / Egg Products
☐	Frogs' Legs / Snails
☐	Rendered Animal Fats and Greaves
☐	Treated Stomachs, Bladders and Intestines
☐	Gelatine
☐	Collagen
☐	Stand-alone-cold-store

PART 5 – Reasons for suspension

The approval has been suspended because 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:

* Food Authority to delete as appropriate

IMPORTANT

With immediate effect, you must not use the establishment detailed in Part 4 for any purpose which would render the establishment subject to approval under Regulation (EC) No. 853/2004 or use the associated approval code on any product until such time as the Food Authority lifts this suspension.

A.9.6 : Model Notification of Decision to REFUSE to Grant Full Approval to an Establishment which is Conditionally Approved

Notice of Decision to REFUSE to Grant Full Approval to an Establishment subject to Approval under Regulation (EC) No. 853/2004, which was Conditionally Approved under Regulation (EC) No. 882/2004

To be completed by the Food Authority and sent to the food business operator

PART 1 – Name and address of food business operator

TO:

IMPORTANT

With immediate effect, you must not use the establishment detailed in Part 3 for any purpose which would render the establishment subject to approval under Regulation (EC) No. 853/2004 or use the associated approval code on any product unless this Food Authority has granted approval or conditional approval.

[Food Authority Logo]

PART 2 – Notification of decision

Your establishment, as detailed in Part 3, which is subject to approval under Regulation (EC) No. 853/2004 and was conditionally approved in accordance with Article 31(2)(d) of Regulation (EC) No. 882/2004 to handle the products of animal origin indicated in Part 4 of this document has been REFUSED full approval.

The decision to refuse to grant full approval was made for the reason(s) set out in Part 5 of this document.

With immediate effect you must cease the use of the establishment detailed in Part 3 for ANY purpose which would render the establishment subject to approval under Regulation (EC) No. 853/2004, or use the associated approval code on any product, UNLESS THIS FOOD AUTHORITY GRANTS APPROVAL OR CONDITIONAL APPROVAL.

In accordance with Regulation 13 of the Official Feed and Food Controls (Scotland) Regulations 2009 (as amended), 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 Sheriff 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 Sheriff Court at which you should lodge your appeal is .

PART 3 – Trading name and address of the establishment

Trading name of establishment	
Full postal address	Postcode:

PART 4 – Product(s) of animal origin for which conditional approval had been granted

☐	Minced Meat
☐	Meat Preparations
☐	Mechanically Separated Meat
☐	Meat Products
☐	Live Bivalve Molluscs (Shellfish)
☐	Fishery Products
☐	Dairy Products
☐	Eggs (not Primary Production) / Egg Products
☐	Frogs' Legs / Snails
☐	Rendered Animal Fats and Greaves
☐	Treated Stomachs, Bladders and Intestines
☐	Gelatine
☐	Collagen
☐	Stand-alone-cold-store

PART 5 – Reasons for refusal

Full 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 Regulations are:

Regulation / Article No.	Details of non-compliance

Signed:	
Name:	
Designation:	
Date:	

Name and address of Food Authority:	Contact Name:	**IMPORTANT** **With immediate effect, you must not use the establishment detailed in Part 3 for any purpose which would render the establishment subject to approval under Regulation (EC) No. 853/2004 or use the associated approval code on any product unless this Food Authority has granted approval or conditional approval.**

ANNEX 10: APPROVAL OF ESTABLISHMENTS 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:

    - The layout of the establishment;
    - The location of equipment;
    - Work flows for each product line;
    - Water distribution system within the establishment including all outlets and sampling points;
    - Drainage layout;
    - Pest control - baiting and/or trapping points within the establishment and external areas;

- A synopsis of the establishment, 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:

    - Details of activities to which the approval relates;
    - Approval number;
    - Classification;
    - Special hygiene direction(s);
    - Any derogations that have been granted;
    - Any other conditions or limitations specified by the Food Authority;
    - 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:

    - HACCP documentation;
    - supplier information;
    - product list;
    - raw material, product & water test results;
    - process records;
    - management and key contact names and contact details;
    - photographs & digital images;
    - product recall procedures;
    - results of all samples taken by the Food Authority;
    - location of any off-site facilities.

ANNEX 11: APPROACH TO ENFORCEMENT - REQUIREMENT FOR FOOD SAFETY MANAGEMENT PROCEDURES BASED ON HACCP PRINCIPLES

A.11.1 : 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.11.2 : Enforcement Approach

Enforcement should continue to be graduated and educative.

A.11.3 : Regulation 852/2004

Regulation 852/2004 requires food businesses to put in place and maintain food safety management procedures (based on HACCP principles). The FSA has produced guidance materials to help businesses to comply with this legislation, which will be available through local authorities and through the FSA‟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.

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.11.4 : 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.

The guidance document “Implementation of procedures based on the HACCP principles, and facilitation of the implementation of the HACCP principles in certain food businesses” produced by the Commission provides further advice on flexibilities.
http://europa.eu.int/comm/food/food/biosafety/hygienelegislation/guidance_doc_haccp_en.pdf

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 Commission guidance on flexibility. Similarly, the terminology or „jargon" of HACCP need not be used, and may be confusing to some businesses.

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

1.	**Identify any hazards that must be prevented eliminated or reduced;** 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. 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.

	For enforcement, in practice, this means: • *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 FSA, industry guides, advice from trade bodies etc.*

2. 3.	**Identify the critical control points (CCPs) at the steps at which control is essential;** **and establish critical limits at CCPs;** 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. 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 FSA, trade bodies or others. **For enforcement, in practice, this means:** • *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.*
4.	**Establish procedures to monitor the CCPs;** Management of food safety through the procedures detailed above will need to be demonstrated. This can be shown in many ways. In some larger businesses this may be achieved by monitoring protocols and record keeping. In other businesses – particularly where the person responsible spends significant time in the food preparation areas, this 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. 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.

	For enforcement, in practice, this means: • *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.*

5.	**Establish corrective actions to be taken if a CCP is not under control;** It is also important that the business knows what to do when things go wrong – the corrective action that needs to be taken. **For enforcement, in practice, this means:** • *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 also questioning staff working in the area where the CCP exists, to provide assurance that HACCP based controls are understood, implemented and that when things go wrong appropriate action is taken.*
6.	**Establish procedures to verify whether the above procedures are working effectively;** The business will need to demonstrate that its procedures are verified and reviewed and kept up to date, and that changes to menus, types of foods and cooking methods, and new equipment are reflected. In larger businesses, verification 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. **For enforcement, in practice, this means:** • *Seeing evidence that the procedures in a business are reviewed to ensure they continue to be appropriate and reflect changes in the business.*
7.	**Establish documents and records to demonstrate the effective application of the above measures;** Documentation and record keeping are particularly onerous for smaller businesses and the 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. **For enforcement, in practice, this means:** • *Seeing documentation that is up to date and describes the main*

	procedures or methods used in the business to control the most important hazards; • *Seeing 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.* • *For simple small businesses following good hygienic practice guides, documentation and record keeping may not be necessary.*

A.11.5 : Role of Food Authorities

The legislation requires 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 FSA, Cook**Safe** 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 Cook**Safe** will allow a food business to demonstrate compliance.

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. 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 12: GUIDANCE FOR FOOD AUTHORITIES ON IMPORT OF FOOD FROM THIRD COUNTRIES

A.12.1 : Introduction

All local authorities have responsibilities for 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). FNAO import controls were 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. The provisions of this Regulation are directly applicable but are given effect at national level by the Official Feed and Food Controls (Scotland) Regulations 2009 (as amended) (and parallel legislation in England, Wales, and Northern Ireland).

A.12.1.1 : Scope

The scope of this guidance extends to imported foods not of animal origin (FNAO) and imported products of animal origin (POAO). The guidance does not cover control activities for POAO at Border Inspection Posts (BIPs), where central guidance produced by Defra is available at http://ww2.defra.gov.uk/food-farm/import-export/.

The guidance does, however, provide enforcement guidance for local authorities relating to illegally introduced POAO. The guidance covers imported food control only.

Except where a specific distinction is made this guidance applies to all 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 and the European Economic Area (“third countries”); and “point of entry” means a seaport, airport or international rail link at which imported food is introduced into the UK.

Local authorities (including Port Local 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 FSA"s Local Authority Resource Pack on Imported Food and Feed Control which can be accessed using the link

http://www.food.gov.uk/foodindustry/imports/enforce_authorities/resourcepack

A.12.2 : Status of this Guidance

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

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

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

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

A.12.3 : Imported Food Legislation (FNAO)

A.12.3.1: EU Regulation 882/2004

This provides EU-wide harmonised rules for import controls for FNAO from 3rd Countries. 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.12.3.2 : The Official Feed and Food Controls (Scotland) Regulations 2009 (as amended)

The Official Feed and Food Controls (Scotland) Regulations 2009 (as amended), gives effect to Articles 15 to 25 of Regulation (EC) 882/2004 in Scotland only. Parallel legislation is in place in England, Wales, and Northern Ireland.

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

A.12.3.3 : 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 (Scotland) Regulations 2009 (as amended). Separate and detailed European Commission guidance on the contaminants legislation is available at:

http://ec.europa.eu/food/food/chemicalsafety/contaminants/index_en.htm

A.12.3.4 :'High risk' FNAO

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

http://www.food.gov.uk/foodindustry/imports/banned_restricted/restricted_foodstuffs

The frequency and nature of such checks are specified by the Commission when the products from particular Third Countries are identified. The enhanced controls provided for by this Regulation include; prior notification, import through designated points of entry (DPEs), that must have particular facilities available and be approved by the FSA, and specified documentary, identity and physical checks are undertaken at these points of entry.

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

http://www.food.gov.uk/multimedia/pdfs/ec6692009enforcers1003.pdf (advice for enforcement officers)

http://www.food.gov.uk/multimedia/pdfs/fbohighriskguidance1003.pdf (advice for FBOs)

In addition, Regulation (EC) No 1152/2009 imposes special conditions governing the import of certain FNAO from particular Third Countries due to contamination risk by aflatoxins. These special conditions include that specified products can only enter the UK through specific ports or airports approved as designated points of import (DPIs). Consignments must be accompanied by a health certificate and results of sampling and analysis.

Further information on this regulation can be found on the FSA‟s website at: http://www.food.gov.uk/foodindustry/imports/banned_restricted/aflatoxinreg11522009

A.12.4 : Service Planning

The Framework Agreement on Official Feed and Food Controls by Local Authorities includes service planning guidance. Section 2.3 (“Scope of the feed and food service”) and Section 2.4 (“Demands on the feed and food service”) provide for 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. 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.12.5 : 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 (Scotland) Regulations 2009 (as amended) should cover both food safety and food standard issues where applicable.

Such procedures may be audited by the FSA and should be suitable and sufficient for these purposes. They should make public, information on their control activities and their effectiveness.

A.12.6 : 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 legislation such as The Official Feed and Food Controls (Scotland) Regulations 2009 (as amended)..

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 specific enforcement powers, as its primary function is to provide a mechanism by which Regulations can be enacted. Powers of enforcement for Regulations made under the Act are usually contained in the Regulations themselves. Therefore, the FSA"s view is that all Regulations relevant to imported food control should specifically be referred to in authorisation documents, including officers" credentials. As such these should, for example, include:

The Products of Animal Origin (Third Country Imports) (Scotland) Regulations 2006 (as amended).
Emergency Control Regulations
The Official Feed and Food Controls (Scotland) Regulations 2009 (as amended).

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

General advice on the authorisation of officers has been developed by LGG. Local Authorities may also wish to consult their own legal advisers on this matter.

A.12.7 : 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:

(a) Attendance at Food Standards Agency enforcement training on imported food control; and
(b) Familiarisation with the FSA"s Local Authority Resource Pack on Imported Feed and Food Control; or
(c) Other relevant training of an equivalent content e.g. in-house training or cascade training relating to points above and appropriate e-learning.

A.12.8 : 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 in their BIP Manual which can be found at:

http://www.defra.gov.uk/foodfarm/animaltrade/imports/ovsnotes/10/1052.htm

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 (in particular relation to the time-scale of analysis/examination and issuing of the results).
- Health and safety requirements.
- Security requirements.

Local authorities with a point of entry or ERTS 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:

- Neighbouring local authorities,
- Her Majesty"s Revenue and Customs (HMRC), United Kingdom Border Agency (UKBA) and Convention on International Trade in Endangered Species (CITES) teams
- Animal Health (AH)
- The Health Protection Scotland (HPS)
- Food and Environment Research Agency (Fera)
- Port operator; import agents; Transit Shed \ ERTS operators,
- Maritime and Coastguard Agency (MCA),
- The Medicines & Healthcare 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[2]

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.12.9 : Records

A.12.9.1 : 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
For the purpose 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. Records can be refined further after visits to food premises and/or communications with food business operators and other local government departments as part of outline programmed activities.

A.12.9.2 : 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 recorded about food examinations (including examinations undertaken at ERTS) 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.12.9.3 : 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.

A.12.10 rting and Notification Arrangements A.12.10.1:

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 FSA Scotland.

A.12.10.2 : Monitoring Returns

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

Local authorities should also supply any other information reasonably requested by the FSA. This may relate to information about the imports of specific food products, or food from certain countries. It may relate to information required by the European Commission in connection with emerging animal/public health issues or for inclusion in the National Control Plan or annual reports that the UK produces in accordance with the requirements of Articles 42 and 44 of EU Regulation 882/2004. Commission Decisions also require monitoring returns to be made to the Commission through the Food Standards Agency as does 669/2009 and 1152/2009.

A.12.10.3 : 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 FSA 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. The FSA can be contacted on scottishincidents@scotland.gsi.gov.uk or 01224 285138.

In addition, with regard to testing for residues of veterinary medicines in Annex IV of EC 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 Incident Branch using the RASFF notification form. Where available, copies of the health certificate and the airway bill or bill of landing should also be forwarded to the FSA at:

scottishincidents@scotland.gsi.gov.uk

Authorities may access the FSA"s website, and download copies of the template for the RASFF notification form at:

http://www.food.gov.uk/foodindustry/incidents/report/

The local authority/ port local authority should also notify local customs of the rejection decision and the final destination of the consignment if it is to be allowed to be re-exported.

All local authorities should notify the FSA of a serious localised incident or a wider problem under the Food Alert System as soon as a decision has been taken that one has occurred. This should be done using the appropriate contact details and reporting arrangements set out in the Food Law Code of Practice and any subsequent documents.

A.12.10.4 : Notification of illegal imports of POAO

A notification should be made to Defra whenever illegally imported POAO are seized. You should report the seizures to Defra using the IIT1 form. The reporting of seizures by LAs/PHAs requires the completion (preferably electronically) of a common form (IIT 1 (4/08)), which is then sent by e-mail for Defra to record the appropriate information required. However, the option remains for the form to be completed manually, if that method is preferred, and sent to Defra by fax/post. Details of where to e-mail/fax/post the form is included on the form. The form is located on the secure parts of the following websites which cannot be accessed without password permission:

APHA: http://www.apha.org.uk
CIEH: http://www.ehcnet4.net/govt/defra/iit/iitrept.php
LGG https://knowledgehub.local.gov.uk/:

The information provided in this form is also shared with the Food Standard Agency's Food Fraud team.

A.12.11 ison / 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 (Scotland) Regulations 2009 (as amended) 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, for example, 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 FSA"s website. Records of such referrals and details of any action taken should be maintained by authorities.

It may also be necessary for the FSA to refer matters concerning illegally imported POAO to inland authorities. This information will normally be received from UKBA 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 UKBA. Authorities should maintain records of action taken.

A.12.12 and Inspection of Imported Food

Local authority procedures should ensure imported food 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 (Scotland) Regulations 2009 (as amended) also cover semi-finished products, materials and articles in contact with food, pesticides, and labelling issues.

When considering specific imported food inspection programmes local 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 Feed and Food Control (see A.14.1.1) provides detailed advice on points to consider when investigating the legitimacy of food imports.
For further information about imported food controls and the types of food imports and countries of origin where there are prohibitions and restrictions see: www.food.gov.uk/imports.

A.12.12.1 : Deferred Examination of FNAO – inland controls

The Official Feed and Food Controls (Scotland) Regulations 2009 (as amended) allows for import controls for the examination of consignments of FNAO to be deferred and undertaken by the inland food authority covering the ERTS or at any other place of destination in the UK.
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 (Scotland) Regulations 2009 (as amended), theenforcement 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.

Deferred examination does not apply to high-risk food covered by Regulation (EC) No 669/2009.

A.12.13 : Sampling of Imported Food

A.12.13.1: 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 LGG/Food Standards Agency sampling programmes,
- any sampling required following a Food Alert or RASFF notification,

- information from any EU, LGG, 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 FSA or LGG

A.12.13.2: 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.12.14 od of Non-Animal Origin (FNAO)

This section applies to local authorities with a point of entry, checks undertaken at ERTS, and deferred examinations under The Official Feed and Food Controls (Scotland) Regulations 2009 (as amended).

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

A.12.14.1 : 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 and ERTS 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.12.14.2 : Prohibition

It is an offence under Regulation 28 of The Official Feed and Food Controls (Scotland) Regulations 2009 (as amended) for any person to import a product that does not comply with the food safety requirements set out in the Regulation (178/2002) or with the requirements of Articles 3 to 6 of 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.12.14.3 : 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 (Scotland) Regulations 2009 (as amended) also allow an authorised officer to require that physical checks and identity

checks take place at a specified place, where necessary for proper examination 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,
- Statutory requirements for documentary checks and associated sampling laid down in,
- The risk associated with different types of food safety issues,
- Knowledge of the product e.g. new or unusual,
- Any requirements following a Food Alert or RASFF notification,
- The history of compliance for the product, country of origin and exporter/importer,
- The controls that the food business operator importing the food has carried out,
- Any guarantees that the competent authority of the third country of origin has given under the third country pre-export checks provisions in EU Regulation 882/2004 (details under Section A.14.15 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 should 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 or ERTS 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.12.14.4 : Deferred Examinations of FNAO

The Official Feed and Food Controls (Scotland) Regulations 2009 (as amended) allow for the examination of consignments of FNAO to be deferred and undertaken by the food authority covering the ERTS or at any other place of destination in the UK. Deferred examinations may be appropriate 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 (Scotland) Regulations 2009 (as amended) 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 (Scotland) Regulations 2009 (as amended) should be carried out in accordance with Regulation 27 of the Regulations - only an outline has been provided in paragraphs 14.15 to 14.18.

A.12.15 d 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.12.16 harges

Regulation 669/2009 provides that mandatory fees for „high risk" FNAO imports are collected in accordance with the criteria laid down in Annex VI of Regulation 882/2004.
Commission Emergency Control Decisions may in some cases provide for charges.

A.12.17 orcement

Where, for the purpose of examination at points of entry, or deferred examination at ERTS 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 Food and Feed Controls (Scotland) Regulations 2009 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 to 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 (Scotland) Regulations 2009 (as amended) 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, and /or detention periods 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. The importer or his agent is entitled on request to a copy of the certificate of analysis/examination.

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 32 of The Official

Feed and Food Controls (Scotland) Regulations 2009 (as amended) 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 one month from the date of service 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 36 of The Official Feed and Food Controls (Scotland) Regulations 2009 (as amended) 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 (Scotland) Regulations 2009 (as amended), The Contaminants in Food (Scotland) Regulations 2009 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.12.18 ucts of Animal Origin - Enforcement

A.12.18.1: Illegally introduced POAO

POAO should be imported in accordance with the Products of Animal Origin (Third Country Imports) (Scotland) Regulations 2006, as amended. 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)[12] 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.

UKBA are responsible for detecting smuggled POAO in Customs controlled areas including ERTS. However, local authorities still have responsibilities relating to goods presented at BIPs and also inland where officers come across illegal POAO in the course of their routine enforcement activities. The FSA"s Operations Group are responsible for illegal POAO found at premises under their control. Where FSA Operations staff find meat in approved cutting plants that they suspect is illegally imported, they have the primary responsibility and powers to deal with it. 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. The FSA has also produced

Enforcement Guidance on Illegal Meat for Enforcement Officers, which can be found at:

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

All 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 UKBA (in the absence of any local reporting arrangements, contact UKBA National Co-ordination Unit on 0870 785 3600) and if needed for adequate interim control of the consignment, issue a detention notice under Regulation 16(4) of the POAO (Third Country Imports)(Scotland) Regulations 2006,.

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) (Scotland) Regulations 2006 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.12.18.2 : 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) (Scotland) Regulations 2006, as amended 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.12.18.3 : 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) (Scotland) Regulations 2006, 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 except as specified in the notice. 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.12.18.4 : Reporting

A notification to Defra‟s database should be made by local authorities when illegally imported POAO is seized. In particular, this will include any instances where a notice is served under Regulation 24 of the Products of Animal Origin (Third Country Imports) (Scotland) Regulations 2006.
The reporting of seizures requires the electronic completion of IIT 1 (04/08) form, which is located on the secure parts of APHA, CIEH and LG Regulation websites. See section A.14.10.4 above.

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	A consignment is a quantity of food or feed of the same type, class or description covered by the same document(s), conveyed by the same means of transport and coming from the same third country. In some cases a definition is given in legislation, in particular for POAO see the definition in the POAO(TCI) Regulations 2006 (as amended) and for products listed in Annex I of Regulation (EC) 669/2009 (as amended) see the definition in that Regulation.
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 subject to Customs control

Index